03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Not Yet Assigned
JATIN PATEL ET AL.	)	
	:	Group Art Unit: Not Yet Assigned
Application No.: N.Y.A.	)	
	:	Confirmation No.: Not Yet Assigned
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	August 17, 2012

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Sir:

Prior to calculating the filing fee and conducting the examination on the merits, please amend the above-captioned application as follows.

SPECIFICATION

Below the title, and before the FIELD OF THE INVENTION section, please add the following paragraph:

--This application is the National Stage of International Application No. PCT/US2011/025994, filed February 24, 2011, which claims the benefit of U.S. Provisional Application No. 61/308,056, filed February 25, 2010.--

CLAIMS

A complete listing of all the claims appears below; this listing replaces all earlier amendments and listings of the claims.

1. (Original) A composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 89 μm and a pharmaceutically acceptable diluent or carrier.

2. (Original) A composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 85 μm and a pharmaceutically acceptable diluent or carrier.

3. (Currently Amended) A composition as defined in claim 1 ~~or claim 2~~, wherein said composition comprises Form N-1 of apixaban.

4. (Original) A composition as defined in claim 1, wherein particles with a D_{90} equal to or less than 89 μm.

5. (Original) A composition as defined in claim 2, wherein particles with a D_{90} equal to or less than 85 μm.

6. (Currently Amended) A composition as defined in ~~any one of claims 1-5~~claim 1, wherein particles with a D_{90} equal to or less than 50 μm.

7. (Currently Amended) A composition as defined in ~~any one of claims 1-5~~claim 1, wherein particles with a D_{90} equal to or less than 30 μm.

8. (Currently Amended) A composition as defined in ~~any one of claims 1-5~~claim 1, wherein particles with a D_{90} equal to or less than 25 μm.

9. (Original) A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the apixaban mean particle size is 89 μm.

10. (Original) A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the apixaban mean particle size is 85 μm.

11. (Currently Amended) A composition as defined in ~~any one of claims 1-10~~claim 1, further comprising:

from 1% to 2 % by weight of a surfactant.

12. (Original) A composition as defined in claim 11, wherein the surfactant is sodium lauryl sulfate.

13. (Currently Amended) A ~~composition as defined in any one of claims 1-12 for use in treating~~ method for the treatment or prophylaxis of a thromboembolic disorder, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition as defined in claim 1.

14-15. (Cancelled)

16. (Currently Amended) A process of manufacturing apixaban tablets having a composition as defined in ~~any one of claims 1-12~~claim 1, comprising the steps of:

(1) blending raw materials prior to granulation;

(2) granulating the raw materials from the step (1) using a wet or dry granulation process;

(3) blending the granules obtained in the step (2) with extragranular raw materials;

(4) compressing the blend from the step (3) into tablets; and

(5) film coating the tablets from the step (4).

17. (Currently Amended) A process of manufacturing apixaban tablets having a composition as defined in ~~any one of claims 1-12~~claim 1, comprising the steps of:

(1) blending raw materials with apixaban of controlled particle size to form a mix;

(2) adding intragranular portions of a binder, a disintegrant and at least one filler to the mix from the step (1) to form a blend;

(3) granulating the materials from the step (2) using a dry granulation process or a wet granulation process,

wherein the dry granulation process comprises:

delumping an intragranular lubricant using a screen or mill;

adding the intragranular lubricant to the blend from the step (2) and blending to form a lubricated blend;

compacting the lubricated blend to ribbons of density in a range of 1.1 to 1.2 g/cc and sizing the compacted ribbons using a roller compactor, and

wherein the wet granulation process comprises:

wet granulating the blend from the step (2) using water to a target end point and, optionally, sizing the wet-granules by passing through a screen or mill;

removing the water from the granulation by drying in a convection oven or a fluid-bed dryer; and

sizing the dried granules by passing through a screen or mill;

(4) blending the granules obtained in the step (3) and an extragranular disintegrant in a blender;

(5) delumping an extragranular lubricant using a screen or mill and blending with granules from the step (4);

(6) compressing the blend from the step (5) into tablets; and

(7) film coating the tablets from the step (6).

18. (Original) A process of manufacturing apixaban tablets according to claim 17, wherein the dry granulation process is used.

19. (New) A composition as defined in claim 2, wherein said composition comprises Form N-1 of apixaban.

20. (New) A composition as defined in claim 2, wherein particles with a D90 equal to or less than 50 μm.

21. (New) A composition as defined in claim 2, wherein particles with a D90 equal to or less than 30 μm.

22. (New) A composition as defined in claim 2, wherein particles with a D90 equal to or less than 25 μm.

23. (New) A composition as defined in claim 2, further comprising:

from 1% to 2 % by weight of a surfactant.

24. (New) A composition as defined in claim 23, wherein the surfactant is sodium lauryl sulfate.

25. (New) A method for the treatment or prophylaxis of a thromboembolic disorder, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition as defined in claim 2.

REMARKS

The claims are 1-13 and 16-25, with claims 1 and 2 being independent. Claims 14 and 15 have been cancelled without prejudice or disclaimer. Claims 3, 6-8, 11, 13, 16, and 17 have been amended to remove multiple dependencies without prejudice or disclaimer as to any excised subject matter. Claim 13 has also been revised to better comply with formal requirements. Support for the changes in claim 13 may be found, for example, in the specification at paragraph [0009]. New claims 19-25 have been added based on original claims 3, 6-8, and 11-13. The specification has been amended to recite the benefit claims to a prior provisional application.

No new matter has been added. Favorable consideration of the claims is respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun
Attorney Docket Number:	03822.000060.

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
National Stage Fee	1631	1	380	380
Natl Stage Search Fee - Report provided	1642	1	490	490
National Stage Exam - all other cases	1633	1	250	250
Pages:				
Claims:				
Claims in excess of 20	1615	3	60	180
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1300**

Electronic Acknowledgement Receipt

EFS ID:	13522764
Application Number:	13579796
International Application Number:	PCT/US11/25994
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	17-AUG-2012
Filing Date:	
Time Stamp:	16:15:35
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1300
RAM confirmation Number	2889
Deposit Account	503939
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	ADS03822000060.PDF	1089053 fce0139ec96ad459309032fa7ec4af940aee68f7	no	6
Warnings:					
Information:					
2	Drawings-only black and white line drawings	DWGS03822000060.pdf	233871 6acddb55eccd87d07f9e798a383fa975583fe343	no	4
Warnings:					
Information:					
3		SPEC03822000060.PDF	701532 b49b4144cd8ca7b9757c7b90a40e196535f6356b	yes	17

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	13
Claims	14	16
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Warnings:					
Information:					
4	Documents submitted with 371 Applications	371Doc103822000060.PDF	458621 f793dc452869afe8a266767c2bbd4a43029a0a86	no	6
Warnings:					
Information:					
5	Documents submitted with 371 Applications	371Doc203822000060.pdf	2588372 1cb21e5dfeda1391271c0f39eab551a5431a72c6	no	19
Warnings:					
Information:					
6	Documents submitted with 371 Applications	371Doc303822000060.pdf	52797 42159587db7d875d09423894111e4b6a22aec306	no	1
Warnings:					

Information:					
7	Documents submitted with 371 Applications	371Doc403822000060.pdf	68525 1a169b5bf87bd051971be0534be760a4160c7914	no	1
Warnings:					
Information:					
8	Documents submitted with 371 Applications	371Doc503822000060.PDF	60111 3e553f56e497524f08708688613bf023d0b4f2f1	no	1
Warnings:					
Information:					
9	Documents submitted with 371 Applications	371Doc603822000060.PDF	63327 9a279c42ad2a3cee4cb0e11cecd67f8d9623f76e	no	1
Warnings:					
Information:					
10	Documents submitted with 371 Applications	371Doc703822000060.PDF	828582 efacd41daee55cc355f0ff257da15fbbee14fc7d	no	22
Warnings:					
Information:					
11	Documents submitted with 371 Applications	371Doc903822000060.pdf	345262 07a85dc2de9ac429b453fc103237d02055e6abe4	no	5
Warnings:					
Information:					
12		PRELAMD03822000060.pdf	100062 e7f7c962221fbe4b6c57a6596a547bb8d78214f1	yes	8

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	2
Claims	3	7
Applicant Arguments/Remarks Made in an Amendment	8	8

Warnings:					
Information:					
13	Fee Worksheet (SB06)	fee-info.pdf	36521 54849fbc3cb7931da33a29fa7f8fcacb35c60ade	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	6626636

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/14 (11-08)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jatin		Patel	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	West Windsor	State/Province	NJ	Country of Residence[i]	US

Citizenship under 37 CFR 1.41(b)[i] US

Mailing Address of Applicant:

Address 1	c/o Bristol-Myers Squibb Company
Address 2	Route 206 and Province Line Road

City	Princeton	State/Province	NJ
Postal Code	08543	Country[i]	US

Applicant 2 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Charles		Frost	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Yardley	State/Province	PA	Country of Residence[i]	US

Citizenship under 37 CFR 1.41(b)[i] US

Mailing Address of Applicant:

Address 1	c/o Bristol-Myers Squibb Company
Address 2	Route 206 and Province Line Road

City	Princeton	State/Province	NJ
Postal Code	08543	Country[i]	US

Applicant 3 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jingpin		Jia	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Belle Mead	State/Province	NJ	Country of Residence[i]	US

PTO/SB/14 (11-08)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

Citizenship under 37 CFR 1.41(b) i	US				
Mailing Address of Applicant:					
Address 1	c/o Bristol-Myers Squibb Company				
Address 2	Route 206 and Province Line Road				
City	Princeton	**State/Province**	NJ		
Postal Code	08543	**Country**i	US		

Applicant 4 Remove

Applicant Authority (•) Inventor ( ) Legal Representative under 35 U.S.C. 117 ( ) Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Chandra		Vema-Varapu	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Hillsborough	**State/Province**	NJ	**Country of Residence** i	US
Citizenship under 37 CFR 1.41(b) i	IN				
Mailing Address of Applicant:					
Address 1	c/o Bristol-Myers Squibb Company				
Address 2	Route 206 and Province Line Road				
City	Princeton	**State/Province**	NJ		
Postal Code	08543	**Country**i	US		

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	05514		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	APIXABAN FORMULATIONS		
Attorney Docket Number	03822.000060.	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	4	**Suggested Figure for Publication (if any)**	

PTO/SB/14 (11-08)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	05514		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	a 371 of international	PCT/US2011/025994	2011-02-24
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/US2011/025994	non provisional of	61308056	2010-02-25

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			◉ Yes ○ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

PTO/SB/14 (11-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1 Remove

If the Assignee is an Organization check here. ☒			
Organization Name	Bristol-Myers Squibb Company		
Mailing Address Information:			
Address 1	Route 206 and Province Line Road		
Address 2			
City	Princeton	**State/Province**	NJ
Country [i]	US	Postal Code	08543
Phone Number		Fax Number	
Email Address			

Assignee 2 Remove

If the Assignee is an Organization check here. ☒			
Organization Name	Pfizer, Inc.		
Mailing Address Information:			
Address 1	235 East 42nd Street		
Address 2			
City	New York	**State/Province**	NY
Country [i]	US	Postal Code	10017
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the **Add** button. Add

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/			Date (YYYY-MM-DD)	2012-08-17
First Name	Jason	Last Name	Okun	Registration Number	48512

PTO/SB/14 (11-08)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

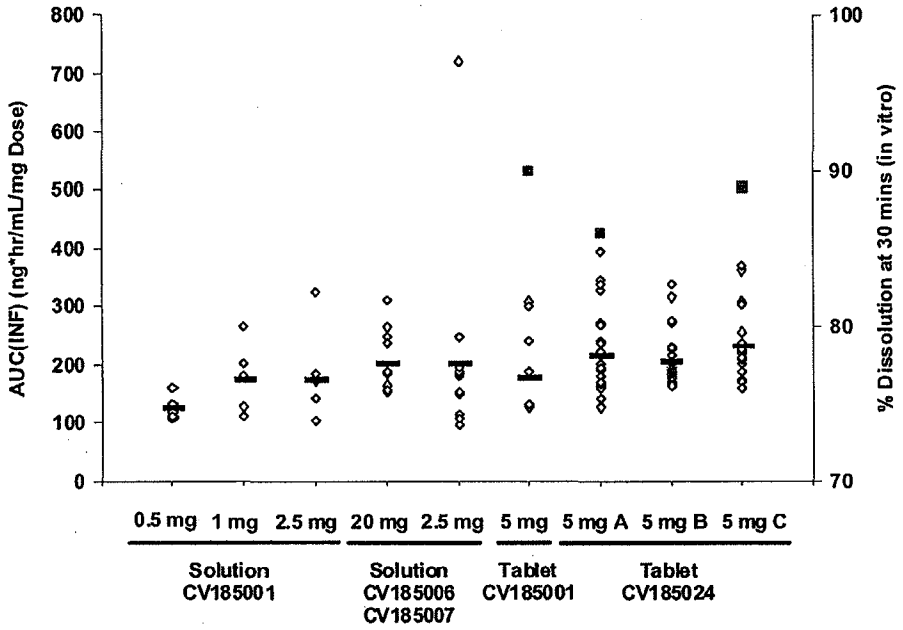
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Figure 1: Scatter Plot of Individual Dose-Normalized AUC(INF) Values for Solutions (CV185001, CV185006, and CV185007) and Tablets (CV185001 and CV185024)

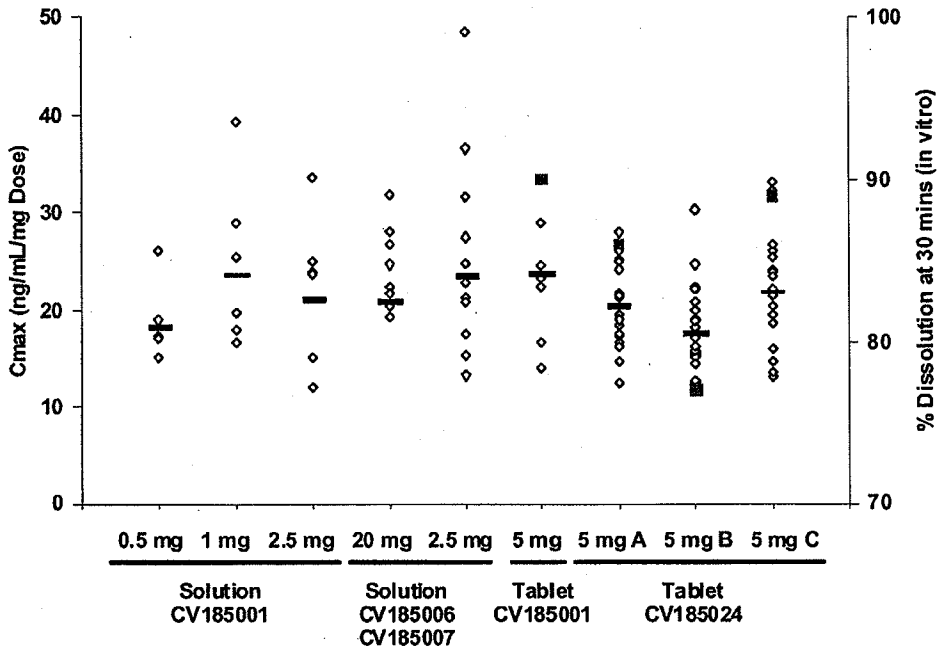


Source: CV185001, CV185006, CV185007, and CV185024 Clinical Study Reports

The solid line represents the geometric mean of AUC(INF) and the solid square represents the average %in-vitro dissolved at 30 minutes (using QC method in Table 1.2C). The X-axis represents the dose administered.

For CV185024, 5 mg A = Apixaban Phase 2 tablet (86% dissolution) 2x2.5 mg (reference formulation), 5 mg B = Apixaban Phase 2 tablet (77% dissolution) 2x2.5 mg, 5 mg C = Apixaban Phase 3 tablet (89% dissolution) 2x2.5 mg.

Figure 2: Scatter Plot of Individual Dose Normalized Cmax Values for Solutions (CV185001, CV185006, and CV185007) and Tablets (CV185001 and CV185024)



Source: CV185001, CV185006, CV185007, and CV185024 Clinical Study Reports

The solid line represents the geometric mean of Cmax and the solid square represents the average %in-vitro dissolved at 30 minutes (using QC method in Table 1.2C). The X-axis represents the dose administered.

For CV185024, 5 mg A = Apixaban Phase 2 tablet (86% dissolution) 2x2.5 mg (reference formulation), 5 mg B = Apixaban Phase 2 tablet (77% dissolution) 2x2.5 mg, 5 mg C = Apixaban Phase 3 tablet (89% dissolution) 2x2.5 mg.

Figure 3: Dissolution Rates of 2.5-mg Apixaban Tablets Using Drug Substance of Different Particle Size

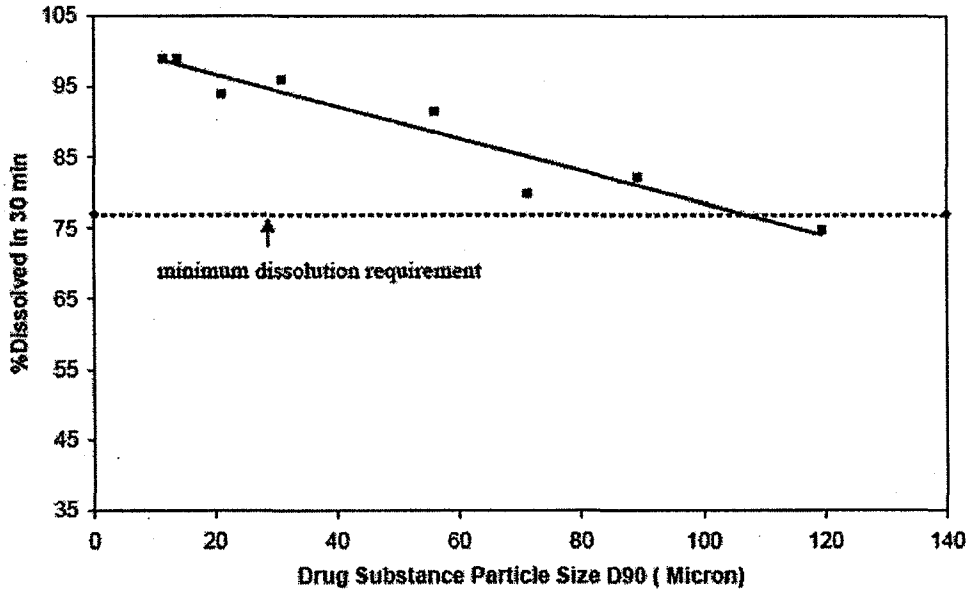
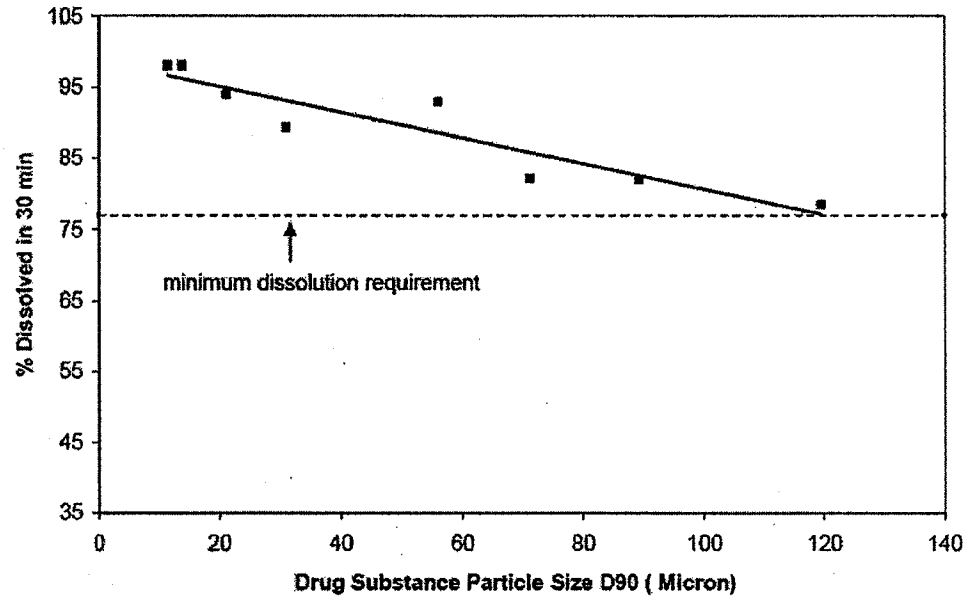


Figure 4: Dissolution Rates of 5-mg Apixaban Tablets Using Drug Substance of Different Particle Size



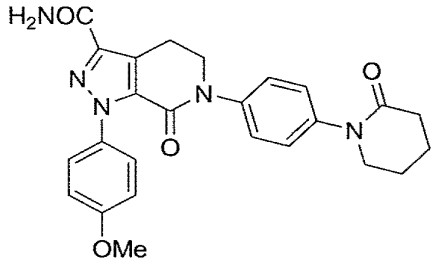
APIXABAN FORMULATIONS

FIELD OF THE INVENTION

[0001] This invention relates to apixaban pharmaceutical formulations comprising crystalline apixaban particles having a maximum size cutoff, and methods of using them, for example, for the treatment and/or prophylaxis of thromboembolic disorders.

BACKGROUND OF THE INVENTION

[0002] Apixaban is a known compound having the structure:



[0003] The chemical name for apixaban is 4,5,6,7-tetrahydro-1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxo-1-piperidinyl)phenyl]-1H-pyrazolo[3,4-c]pyridine-3-carboxamide (CAS name) or 1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxo-1-piperidinyl)phenyl]-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxamide (IUPAC name).

[0004] Apixaban is disclosed in U.S. Patent No. 6,967,208 (based on U.S. Application Serial No. 10/245,122 filed September 17, 2002), which is herein incorporated by reference in its entirety, has utility as a Factor Xa inhibitor, and is being developed for oral administration in a variety of indications that require the use of an antithrombotic agent.

[0005] The aqueous solubility (40 μg/mL at all physiological pH) of apixaban suggests that the tablets with less than 10 mg apixaban (dose/solubility ratio = 250 mL) should not demonstrate dissolution rate limited absorption since dissolution rate limitations are only expected when the dose/solubility ratio is greater than 250 mL. Based on this dose and solubility consideration, the particle size of the compound should not be critical for achieving consistent plasma profiles, according to the prediction based on the Biopharmaceutics Classification System (BCS; Amidon, G. L. et al., *Pharmaceutical Research*, 12: 413-420 (1995)). However, it was determined

that formulations that were made using a wet granulation process as well as those using large particles of apixaban drug substance resulted in less than optimal exposures, which can present quality control challenges.

SUMMARY OF THE INVENTION

[0006] Surprisingly and unexpectedly, it has been found that compositions for tablets comprising up to 5 mg, apixaban particles having a D_{90} (90% of the volume) less than 89 microns (μm) lead to consistent in-vivo dissolution in humans (at physiologic pH), hence, consistent exposure and consistent Factor Xa inhibition that will lead to consistency in therapeutic effect. Consistent exposure is defined as that where in-vivo exposure from tablets is similar to that from a solution and not affected by the differences in dissolution rates. The compositions were prepared using a dry granulation process. Accordingly, the invention provides a pharmaceutical composition comprising crystalline apixaban particles having a D_{90} equal to or less than about 89 μm as measured by laser light scattering method, and a pharmaceutically acceptable diluent or carrier. It is preferred that the apixaban particles in the composition have a D_{90} not exceeding 89 μm. It is noted the notation D_x means that X% of the volume of particles have a diameter less than a specified diameter D. Thus a D_{90} of 89 μm means that 90% of the volume of particles in an apixaban composition have a diameter less than 89 μm.

[0007] The range of particle sizes preferred for use in the invention is D_{90} less than 89 μm, more preferably D_{90} less than 50 μm, even more preferably D_{90} less than 30 μm, and most preferably D_{90} less than 25 μm. The particle sizes stipulated herein and in the claims refer to particle sizes were determined using a laser light scattering technique.

[0008] The invention further provides the pharmaceutical composition further comprising a surfactant from 0.25% to 2% by weight, preferably from 1% to 2% by weight. As regards the surfactant, it is generally used to aid in wetting of a hydrophobic drug in a tablet formulation to ensure efficient dissolution of the drug, for example, sodium lauryl sulfate, sodium stearate, polysorbate 80 and poloxamers, preferably sodium lauryl sulfate.

[0009] The invention further provides a method for the treatment or prophylaxis of thromboembolic disorders, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition comprising crystalline apixaban particles having a D_{90} equal to or less than about 89 μm as measured by laser light scattering, and a pharmaceutically acceptable carrier.

[0010] The present invention also provides a dry granulation process for preparing a composition comprising crystalline apixaban particles having a D_{90} equal to or less than about 89 μm as measured by laser light scattering, and a pharmaceutically acceptable carrier.

[0011] The formulations of this invention are advantageous because, *inter alia*, as noted above, they lead to consistent human in-vivo dissolution. The invention is surprising in this respect, however, in that exposures are variable even though apixaban has adequate aqueous solubility that would allow the drug to dissolve rapidly. That is, one would expect dissolution rate for a drug that has high solubility (as defined by the Biopharmaceutical Classification System) would not be limited by the particle size. It has surprisingly been found, however, that the particle size that impacts apixaban absorption rate is about a D_{90} of 89 μm. Thus apixaban can be formulated in a composition having a reasonable particle size using dry granulation process, to achieve and maintain relatively fine particles to facilitate consistent in vivo dissolution.

[0012] In a relative bioavailabiltiy study where various apixaban formulations were evaluated, it was determined that formulations made using a wet granulation process resulted in lower exposures compared to the exposures obtained from a dry granulation process. Additionally, tablets made using larger particles (D_{90} of 89 μm) had lower exposures compared to tablets made using the same process but with particle size of D_{90} of 50 μm. In a dry granulation process, water is not used during manufacturing to develop granules containing apixaban and the excipients.

[0013] Formulations according to this invention, when dissolution tested in vitro preferably exhibit the following dissolution criteria. That is, the formulation exhibits dissolution properties such that, when an amount of the drug equivalent to 77% therein dissolves within 30 minutes. Usually the test result is established as an average for a pre-determined number of dosages (e.g., tablets, capsules, suspensions,

or other dosage form), usually 6. The dissolution test is typically performed in an aqueous media bufferred to a pH range (1 to 7.4) observed in the gastrointestinal tract and controlled at 37° C (±1°C), together maintaining a physilogical relevance. It is noted that if the dosage form being tested is a tablet, typically paddles rotating at 50 - 75 rpm are used to test the dissolution rate of the tablets. The amount of dissolved apixaban can be determined conventionally by HPLC, as hereinafter described. The dissolution (in-vitro) test is developed to serve as a quality control tool, and more preferably to predict the biological (invivo) performance of the tablet, where invivo-invitro relationships (IVIVR) are established.

[0014] The term "particles" refers to individual drug substance particles whether the particles exist singly or are agglomerated. Thus, a composition comprising particulate apixaban may contain agglomerates that are well beyond the size limit of about 89 μm specified herein. However, if the mean size of the primary drug substance particles (i.e., apixaban) comprising the agglomerate are less than about 89 μm individually, then the agglomerate itself is considered to satisfy the particle size constraints defined herein and the composition is within the scope of the invention.

[0015] Reference to apixaban particles having "a mean particle size" (herein also used interchangeably with "VMD" for "volume mean diameter") equal to or less than a given diameter or being within a given particle size range means that the average of all apixaban particles in the sample have an estimated volume, based on an assumption of spherical shape, less than or equal to the volume calculated for a spherical particle with a diameter equal to the given diameter. Particle size distribution can be measured by laser light scattering technique as known to those skilled in the art and as further disclosed and discussed below.

[0016] "Bioequivalent" as employed herein means that if a dosage form is tested in a crossover study (usually comprising a cohort of at least 10 or more human subjects), the average Area under the Curve (AUC) and/or the C_{max} for each crossover group is at least 80% of the (corresponding) mean AUC and/or C_{max} observed when the same cohort of subjects is dosed with an equivalent formulation and that formulation differs only in that the apixaban has a preferred particle size with a D_{90} in the range from 30 to 89 μm. The 30 μm particle size is, in effect, a standard against which other different formulations can be compared. AUCs are plots of serum

concentration of apixaban along the ordinate (Y-axis) against time for the abscissa (X-axis). Generally, the values for AUC represent a number of values taken from all the subjects in a patient population and are, therefore, mean values averaged over the entire test population. C.sub.max, the observed maximum in a plot of serum level concentration of apixaban (Y-axis) versus time (X-axis) is likewise an average value.

[0017] Use of AUCs, C_{max}, and crossover studies is, of course otherwise well understood in the art. The invention can indeed be viewed in alternative terms as a composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 89 μm, as measured by Malvern light scattering, and a pharmaceutically acceptable carrier, said composition exhibiting a mean AUC and/or mean C_{max} which are at least 80% of the corresponding mean AUC and/or C_{max} values exhibited by a composition equivalent thereto (i.e., in terms of excipients employed and the amount of apixaban) but having an apixaban mean particle size of 30 μm. Use of the term "AUC" for purposes of this invention implies crossover testing within a cohort of at least 10 healthy subjects for all compositions tested, including the "standard" 30 μm particle size composition.

[0018] The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof. Thus, the above embodiments should not be considered limiting. Any and all embodiments of the present invention may be taken in conjunction with any other embodiment or embodiments to describe additional embodiments. Each individual element of the embodiments is its own independent embodiment. Furthermore, any element of an embodiment is meant to be combined with any and all other elements from any embodiment to describe an additional embodiment. In addition, the present invention encompasses combinations of different embodiment, parts of embodiments, definitions, descriptions, and examples of the invention noted herein.

DETAILED DESCRIPTION OF THE INVENTION

[0019] As previously stated, apixaban in any form which will crystallize can be used in this invention. Apixaban may be obtained directly via the synthesis described in U.S. Pat. No. 6,967,208 and/or US20060069258A1 (based on U.S. Application Serial No. 11/235,510 filed September 26, 2005), herein incorporated by reference.

[0020] Form N-1 (neat) and Form H2-2 (hydrate) of apixaban may be characterized by unit cell parameters substantially equal to the following shown in Table 1.

Table 1

Form	N-1	H2-2
Solvate	None	Dihydrate
T	+22	+22
a(Å)	10.233(1)	6.193(1)
b(Å)	13.852(1)	30.523(1)
c(Å)	15.806(1)	13.046(1)
α,°	90	90
β,°	92.98(1)	90.95(1)
γ,°	90	90
V(Å^3)	2237.4(5)	2466.0(5)
Z'	1	1
Vm	559	617
SG	$P2_1/n$	$P2_1/n$
Dcalc	1.364	1.335
R	0.05	0.09
Sol.sites	None	2 H_2O

Z' is the number of molecules per asymmetric unit.

T(°C) is the temperature for the crystallographic data.

Vm = V(unit cell) / (ZZ')

[0021] Characteristic X-ray diffraction peak positions (degrees 2θ±0.1) at room temperature, based on a high quality pattern collected with a diffractometer (CuKα) with a spinning capillary with 2θ calibrated with a NIST suitable standard are shown in Table 2 below.

Table 2

Form N-1	Form H2-2
10.0	5.8
10.6	7.4
12.3	16.0
12.9	20.2
18.5	23.5
27.1	25.2

[0022] It will be appreciated by those skilled in the art of manufacturing and granulation processes that there are numerous known methods which can be applied to producing apixaban solid dosage forms. The feature of this invention, however, involves processes that produce apixaban dosage forms with an ability to produce primary particles at the site of dissolution with a d90<89 μm. Examples of such methods include as well as dry granulation or wet-granulation by low or high-shear techniques

[0023] The dry granulation process that produces crystalline apixaban particles having a mean particle size equal to or less than about 89 μm, is believed to be novel, and is accordingly provided as a further feature of the invention. Thus, the invention provides a drug product manufacturing process, comprising the steps:

(1) Blend the raw materials required prior to granulation;

(2) Granulate the raw materials from Step 1 using a dry or wet granulation process;

(3) Blend the sized granules from step 3 with extragranular raw materials;

(4) Compress the blend from Step 3 into tablets; and

(5) Film coat the tablets from step 4.

[0024] In another embodiment, the invention provides a drug product manufacturing process, comprising the steps:

(1) Blend the raw materials, with apixaban of controlled particle size;

(2) Include intragranular portions of binder, disintegrant and other fillers in the mix from step (1);

(3) Granulate the materials from step (2) using process (3a) or (3b):
(3a) DRY GRANULATION: Delump the intragranular lubricant using a suitable screen or mill. Add the lubricant to the blend from step (2)

and blend. Compact the lubricated blend to ribbons of density in the range of 1.0 to 1.2 g/cc and size the compacted ribbons using a roller compactor; or

(3b) WET GRANULATION: Wet granulate the composition from step (2) using water to a target end point and optionally, size the wet-granules by passing through a screen/mill. Remove water for granulation by drying in a convection oven or a fluid-bed dryer. Size the dried granules by passing through a screen/mill;

(4) Blend the sized granules from step (3) and the extragranular disintegrant in a suitable blender;

(5) Delump the extragranular lubricant using a suitable screen/mill and blend with granules from step (4);

(6) Compress the blend from (5) into tablets;

(7) Film coat the tablets from step (6).

[0025] In a preferred embodiment, a dry granulation process is employed.

[0026] In a preferred embodiment, the surfactant (SLS) in the composition serves as a wetting aid for inherently hydrophobic apixaban drug substance (contact angle=54° with water), further exacerbated as part of air-jet milling process that is used to reduce apixaban particle size to the desired size.

[0027] The amount of apixaban contained in a tablet, capsule, or other dosage form containing a composition of this invention will usually be between 2.5 and 5 mg, usually administered orally twice a day, although amounts outside this range and different frequencies of administration are feasible for use in therapy as well. As previously mentioned, such dosage forms are useful, *inter alia,* in the prevention and/or treatment of thromboembolic disorders, for example, deep vein thrombosis, acute coronary syndrome, stroke, and pulmonary embolism, as disclosed in U.S. Pat . No. 6,967,208.

[0028] As noted, average particle size can be determined by Malvern light scattering, a laser light scattering technique. In the examples below, the particle size for apixaban drug substance was measured using a Malvern particle size analyzer.

[0029] Upon measurement completion, the sample cell was emptied and cleaned, refilled with suspending medium, and the sampling procedure repeated for a total of three measurements.

[0030] The dissolution test is performed in 900 mL of dissolution medium at 37 °C, using USP Apparatus 2 (paddles) method at a rotation speed of 75 rpm. Samples are removed after 10, 20, 30, 45, and 60 minutes from test initiation and analyzed for apixaban by HPLC at 280 nm. 0.1 N HCl or 0.05 M sodium phosphate pH 6.8 with 0.05% SDS solution has been used as dissolution medium during formulation development. While both methods serve the purposes as quality control tests (with adequate discrimination ability), and in establishing IVIVR, the latter was preferred from the standpoint of method robustness. A role of SDS (surfactant) in the latter dissolution medium is as a wetting aid to facilitate complete dissolution of hydrophobic apixaban from tablets, rather than to increase the solubility of apixaban. Dissolution data from both the tests are included in this invention record and unless otherwise specified, the results reported were averages of values from six tablets.

[0031] Blood samples are drawn at predetermined time points following drug administration as specified in the clinical study protocol. Concentrations of the samples are measured using a validated analytical method (Liquid Chromatography with Tandem Mass Spectrometry). Individual subject pharmacokinetic parameters (eg, Cmax, AUC, T-HALF) are derived by non-compartmental methods using Kinetica® software from the time-concentration profiles.

[0032] The invention is further exemplified and disclosed by the following non-limiting examples:

[0033] Table 3 shows apixaban tablet compositions prepared using the drygranulation process that were evaluated in bioequivalence (BE) study.

Table 3

Ingredients	Dry Granulation	
	5% w/w Drug Loaded Granulation (% w/w)	20 mg Tablet (mg/tablet)
Intragranular		
Apixaban	5.00	20.00
Lactose Anhydrous	49.25	197.00
Microcrystalline Cellulose	39.50	158.00
Croscarmellose Sodium	2.00	8.00
Magnesium Stearate	0.50	2.00
Sodium Lauryl Sulfate	1.00	4.00
Extragranular		
Croscarmellose Sodium	2.00	8.00
Magnesium Stearate	0.75	3.00
Total	100.00 mg	400 mg
Film Coat	3.5	14.0
Total	103.5 mg	414 mg

[0034] Table 4 shows apixaban tablet compositions prepared using the wet granulation process that were evaluated in BE study.

Table 4

Ingredients	Wet Granulation	
	5% w/w Drug Loaded Granulation (% w/w)	20 mg Tablet (mg/tablet)
Intragranular		
Apixaban	5.00	20.00
Lactose Monohydrate	70.00	280.00
Microcrystalline Cellulose	5.00	60.00
Croscarmellose Sodium	2.50	10.00
Povidone	4.50	18.00
Purified Water	17.40	69.60
Extragranular		
Croscarmellose Sodium	2.50	10.00
Magnesium Stearate	0.50	2.09
Microcrystalline Cellulose	10.00	10.09
Total	100.00	400.00
Film Coat	3.5	14.0
Total	103.5 mg	414.0

[0035] Table 5 and Table 5a show the dissolution data that indicates that having a dry granulation process will result in faster dissolution compared to that from a wet granulation process. As shown in Table 5, the 20 mg tablets made using a dry granulation process had 79% apixaban dissolved in 30 minutes versus 62% apixaban dissolved at 30 minutes for the 20 mg tablets made using a wet granulation process. Dissolution test in 0.1N HCl also indicated a similar behavior of faster dissolution from tablets made using dry granulation process (58% in 30min), compared to wet granulation process (45% in 30min).

Table 5

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.05% SLS in 50mM phosphate, pH 6.8)	
	Wet Granulation 20 mg Tablets	Dry Granulation 20 mg Tablets
10	38	47
20	54	70
30	62	79
45	71	86
60	76	90
API Particle Size D_{90} (μm)	83.8	83.8

Table 5a

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.1N HCl)	
	Wet Granulation 20 mg Tablets	Dry Granulation 20 mg Tablets
10	30	41
20	39	52
30	45	58
45	51	64
60	56	68
90	64	74
API Particle Size D_{90} (μm)	83.8	83.8

[0036] Table 6 and Table 6a provides the dissolution data from tablets made with different manufacturing pprocesses (wet and dry granulation) and drug substance different particle sizes. As shown Table 6, apixaban tablets that had 77% dissolved in 30 minutes or 86% dissolved in 30 minutes both had AUC values that met

bioequivalence criteria (Confidence Interval between 80% to 125%) when compared to the tablets that had 89% dissolved at 30 minutes. Similar rank order of the dissolution rates were observed for these tablets (A, B & C) when tested in 0.1N HCl.

Table 6

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.05% SLS in 50mM phosphate, pH 6.8)		
	Wet Granulation 2 x 2.5 mg Tablets (A)	Wet Granulation 2 x 2.5 mg Tablets (B)	Dry Granulation 2 x 2.5 mg Tablets (C)
10	63	42	70
20	79	64	84
30	86	77	89
45	91	87	94
60	94	93	96
C_{max} (ng/mL)	101.8 (21)	87.8 (24)	108.3 (24)
AUC(INF) (ng*hr/mL)	1088 (32)	1030 (25)	1153 (26)

Geomean (CV%) are presented for Cmax and AUC(INF)

Table 6a

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.1N HCl)		
	Wet Granulation 2 x 2.5 mg Tablets (A)	Wet Granulation 2 x 2.5 mg Tablets (B)	Dry Granulation 2 x 2.5 mg Tablets (C)
10	44	25	56
20	62	43	71
30	72	54	79
45	80	66	85
60	84	74	88
AUC(INF) (ng*hr/mL)	1088 (32)	1030 (25)	1153 (26)

Geomean (CV%) are presented for Cmax and AUC(INF)

[0037] The results of clinical studies demonstrated that, for tablets with similar dissolution rates (89% and 86% at 30 min in pH 6.8 phosphate buffer containing 0.05% SLS), Cmax and AUC of the coated Phase 3 tablet (C) relative to the uncoated Phase 2 tablet (A), met bioequivalence criteria. Tablets with different dissolution rates (77% and 86% at 30 min) had similar AUCs, but did not meet equivalence criteria for Cmax. The lower boundary of the 90% confidence interval of ratio of

geometric mean Cmax was 0.788, indicating the rate of absorption, as defined by Cmax, was lower for the slower dissolving tablet (77% at 30 min). Since the oral bioavailability from these tablets is shown to be comparable to that from solution (see Figures 1 and 2 below), this dissolution rate (77% in 30min) is defined as the threshold for achieving consistent exposure.

[0038] Figures 3 and 4 illustrate the dissolution data that shows that while particle size impacts dissolution, controlling the particle size to less than 89 microns will result in a dissolution rate that will ensure consistent in-vivo exposures. As indicated in Figures 3 and 4, consistent exposures are expected once apixaban tablets have greater than 77% apixaban dissolved in 30 minutes. Since the tablets with 89 microns have >77% dissolved at 30 minutes, these tablets will also exhibit exposures that are equivalent to the exposures from tablets made with smaller particles (such as the tablets with 10 micron particles shown below). Whilst dissolution rate at an apixaban particle size of 119 microns is marginally greater than 77% in 30-min for the 5-mg apixaban tablets (Figure-4), the particle size threshold claimed is less than 89 microns. This allows for the typical variability (RSD=2 to 3%) in the dissolution results, such that the oral bioavailability from tablets consistently matches that from solution.

WHAT IS CLAIMED IS:

1. A composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 89 μm and a pharmaceutically acceptable diluent or carrier.

2. A composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 85 μm and a pharmaceutically acceptable diluent or carrier.

3. A composition as defined in claim 1 or claim 2, wherein said composition comprises Form N-1 of apixaban.

4. A composition as defined in claim 1, wherein particles with a D_{90} equal to or less than 89 μm.

5. A composition as defined in claim 2, wherein particles with a D_{90} equal to or less than 85 μm.

6. A composition as defined in any one of claims 1-5, wherein particles with a D_{90} equal to or less than 50 μm.

7. A composition as defined in any one of claims 1-5, wherein particles with a D_{90} equal to or less than 30 μm.

8. A composition as defined in any one of claims 1-5, wherein particles with a D_{90} equal to or less than 25 μm.

9. A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the apixaban mean particle size is 89 μm.

10. A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the apixaban mean particle size is 85 μm.

11. A composition as defined in any one of claims 1-10, further comprising:
from 1% to 2 % by weight of a surfactant.

12. A composition as defined in claim 11, wherein the surfactant is sodium lauryl sulfate.

13. A composition as defined in any one of claims 1-12 for use in treating a thromboembolic disorder.

14. Use of a composition as defined in any one of claims 1-12 in the treatment of a thromboembolic disorder.

15. Use of a composition as defined in any one of claims 1-12 in the preparation of a medicament for use in treating a thromboembolic disorder.

16. A process of manufacturing apixaban tablets having a composition as defined in any one of claims 1-12, comprising the steps of:

(1) blending raw materials prior to granulation;
(2) granulating the raw materials from the step (1) using a wet or dry granulation process;
(3) blending the granules obtained in the step (2) with extragranular raw materials;
(4) compressing the blend from the step (3) into tablets; and
(5) film coating the tablets from the step (4).

17. A process of manufacturing apixaban tablets having a composition as defined in any one of claims 1-12, comprising the steps of:

(1) blending raw materials with apixaban of controlled particle size to form a mix;

(2) adding intragranular portions of a binder, a disintegrant and at least one filler to the mix from the step (1) to form a blend;

(3) granulating the materials from the step (2) using a dry granulation process or a wet granulation process,

wherein the dry granulation process comprises:

delumping an intragranular lubricant using a screen or mill;

adding the intragranular lubricant to the blend from the step (2) and blending to form a lubricated blend;

compacting the lubricated blend to ribbons of density in a range of 1.1 to 1.2 g/cc and sizing the compacted ribbons using a roller compactor, and

wherein the wet granulation process comprises:

wet granulating the blend from the step (2) using water to a target end point and, optionally, sizing the wet-granules by passing through a screen or mill;

removing the water from the granulation by drying in a convection oven or a fluid-bed dryer; and

sizing the dried granules by passing through a screen or mill;

(4) blending the granules obtained in the step (3) and an extragranular disintegrant in a blender;

(5) delumping an extragranular lubricant using a screen or mill and blending with granules from the step (4);

(6) compressing the blend from the step (5) into tablets; and

(7) film coating the tablets from the step (6).

18. A process of manufacturing apixaban tablets according to claim 17, wherein the dry granulation process is used.

ABSTRACT

Compositions comprising crystalline apixaban particles having a D_{90} equal to or less than 89 μm, and a pharmaceutically acceptable carrier, are substantially bioequivalent and can be used to for the treatment and/or prophylaxis of thromboembolic disorders.

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office Use Only

PCT/US11/25994
International Application No.

24 FEBRUARY 2011 (02.24.11)
International Filing Date

PCT INTERNATIONAL APPLICATION RO/US
Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 03822.000060.PC

Box No. I TITLE OF INVENTION

APIXABAN FORMULATIONS

Box No. II APPLICANT ☐ This person is also inventor.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BRISTOL-MYERS SQUIBB COMPANY
Rt. 206 & Province Line Road
Princeton, New Jersey 08543-4000
USA

Telephone No.

Facsimile No.

Applicant's registration No. with the Office

E-mail authorization: Marking one of the check-boxes below authorizes the receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, notifications issued in respect of this international application to that e-mail address if those offices are willing to do so.

☐ as advance copies followed by paper notifications; or ☐ exclusively in electronic form (no paper notifications will be sent).

E-mail address:

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

OKUN, Jason M.
Fitzpatrick, Cella, Harper & Scinto
1290 Avenue of the Americas
New York, NY 10104-3801, USA

(see sheet 3 for additional representatives)

Telephone No. 212-218-2100

Facsimile No. 212-218-2200

Agent's registration No. with the Office

48,512

E-mail authorization: Marking one of the check-boxes below authorizes the receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, notifications issued in respect of this international application to that e-mail address if those offices are willing to do so.

☒ as advance copies followed by paper notifications; or ☐ exclusively in electronic form (no paper notifications will be sent).

E-mail address: **docketing@fchs.com**

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

PFIZER INC.
234 East 42nd Street
New York, NY 10017
USA

This person is:
☒ applicant only
☐ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

PATEL, Jatin
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
US

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ The United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

FROST, Charles
c/o Bristol-Myer Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543
US

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

JIA, Jingpin
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
US

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

VEMA-VARAPU, Chandra
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
US

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: IN

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:

☐ applicant only

☐ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

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This person is:

☐ applicant only

☐ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

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State *(that is, country)* of residence:

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This person is:

☐ applicant only

☐ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ The United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Supplemental Box *If the Supplemental Box is not used, this sheet need not be included in the request.*

1. *If, in any of the Boxes, except Boxes Nos. VIII(i) to (v) for which a special continuation box is provided* ***the space is insufficient*** *to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:*

(i) ***if more than one person is to be indicated as applicants and/or inventors*** *and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;*

(ii) *if, in Box No. II or in any of the sub-boxes of Box No. III, the indication* ***"the States indicated in the Supplemental Box"*** *is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;*

(iii) *if, in Box No. II or in any of the sub-boxes of Box No. III,* ***the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America:*** *in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;*

(iv) *if, in addition to the agent(s) indicated in Box No. IV, there are* ***further agents:*** *in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;*

(v) *if, in Box No. VI, there are* ***more than three earlier applications whose priority is claimed:*** *in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.*

2. *If the applicant intends to make an indication of the wish that the international application be treated, in certain designated States, as an application for a patent of addition, certificate of addition, inventor's certificate of addition or utility certificate of addition: in such a case, write the name or two-letter code of each designated State concerned and the indication* ***"patent of addition," "certificate of addition," "inventor's certificate of addition"****, or* ***"utility certificate of addition,"*** *the number of the parent application or parent patent or other parent grant and the date of grant of the parent patent or other patent grant or the date of filing of the parent application (Rules 4.11(a)(iii) and 49bis.1(a) or (b)).*

3. *If the applicant intends to make an indication of the wish that the international application be treated, in the United States of America, as a continuation or continuation-in-part of an earlier application: in such a case, write "United States of America" or "US" and the indication* ***"continuation"*** *or* ***"continuation-in-part"*** *and the number and the filing date of the parent application (Rules 4.11(a)(iv) and 49bis.1(d)).*

4. *If the applicant wishes to request the receiving Office or the International Bureau to obtain a priority document from a digital library but* ***that document is only held in a digital library in connection with another application*** *which also relied upon that priority document to support a priority claim (and unless that digital library is to be accessed through the Digital Access Service for Priority Documents), in such cases write "Continuation of Box No. VI", indicate for each earlier application concerned the same type of information as required in Box. No. VI and indicate the number under which the application is stored (and, if known, the digital library concerned) (Section 716(a)(ii)).*

FITZPATRICK, Joseph M. (Registration No. 17,398), SCINTO, Lawrence F. (Registration No. 18,973), BAECHTOLD, Robert L. (Registration No. 20,860), KRAUSE, John A. (Registration No. 24,613), SAXON, Peter (Registration, No. 24,947), RENK, Henry J. (Registration No. 25,499), RAZZANO, Pasquale A. (Reg. No. 25,512), BAKER, Charles P. (Registration No. 26,702), CLAYTON, Ronald A. (Registration No. 26,718), ZUPCIC, Anthony M. (Registration No. 27,276), OLSEN, Warren E. (Registration No. 27,290), WANNISKY, William M. (Registration No. 28,373), JACOBS, Gary M. (Registration No. 28,861), VASSALLO, Edward E. (Registration No. 29,117), DIANA, Leonard P. (Registration No. 29,296), MURNANE, John D. (Registration No. 29,836), FISCHER, Robert H. (Registration No. 30,051), STAHL, Lawrence A. (Registration No. 30,110), KALLAS, Nicholas N. (Registration No. 31,530), PERRY, Lawrence S. (Registration No. 31,865), REED, Scott K. (Registration No. 32,433), MALPEDE, Scott D. (Registration No. 32,533), O'NEILL, Michael K. (Registration No. 32,622), HAAS, Bruce C. (Registration No. 32,734), WARNER, Steven E. (Registration No. 33,326), WILLIAMSON, Mark A. (Registration No. 33,628), CONDE, Dominick A. (Registration No. 33,856), MANDRA, Raymond R. (Registration No. 34,382), SANDONATO, Michael P. (Registration No. 35,345), KLOCK, Brian L. (Registration No. 36,570), CARLIN, John D. (Registration No. 37,292), PENSABENE, Marc J. (Registration No. 37,416), GLUECK, Daniel S. (Registration No. 37,838), YU-JAHNES, Lock See (Registration No. 38,667), SMITH-LUNDY, Leisa M. (Registration No. 39,378), SHARROTT, Douglas (Registration No. 39,832), CIRE, Frank L. (Registration No. 42,419), DELUCIA, Frank A., Jr. (Registration No. 42,476), HOLOWACZ, Elizabeth F. (Registration No. 42,667), KMETT, Edward A. (Registration No. 42,746), SHAPIRO, Peter (Registration No. 43,107), MEE, Brendan (Registration No. 43,391), HAUGHEY III, Edmund J. (Registration No. 44,749), WOLFE, Lori A. (Registration No. 44,840), OLIVER, Justin J. (Registration No. 44,986), LOH, Christopher E. (Registration No. 46,000), RUSSO, Alicia A. (Registration No. 46,192), BELISLE, Stephen E. (Registration No. 46,546), BERSCHADSKY, Jonathan (Registration No. 46,551), ROBERTS, Simon (Registration No. 47,342), OKUN, Jason M. (Registration No. 48,512), TRACY, Colleen (Registration No. 52,295), VADNAIS, Damond E. (Registration No. 52,310), CHEVALIER, Charles H. (Registration No. 52,735), GREGORY, Dennis (Registration No. 52,967), MINION, Daniel (Registration No. 53,329), PIERONI, Joseph P. (Registration No. 53,469), PUPPA, Thomas (Registration No. 54,379), KIRKLAND, John (Registration No. 54,595), LAU, Dana (Registration No. 55,361), O'REILLY, Brian (Registration No. 55,974), DAVIS, Joshua A. (Registration No. 56,180), JOHNSON, Jason (Registration No. 56,887), GABRIEL, Thomas (Registration No. 57,851), XU, Feng (Registration No. 58,230), MANNINO, Christian (Registration No. 58,373), VATHYAM, Sujatha (Registration No. 58,918), McGRAW, Michael P. (Registration No. 58,977), BECKMAN, Christopher V. (Registration No. 59,050), HECKENBERG, Donald Jr. (Registration No. 60,081), WAKELEY, John J. (Registration No. 60,418), TYNDALE, Jamar W. (Registration No. 61,451), KENNEDY, Troy A. (Registration No. 61,492), TCHAKERIAN, Shant (Registration No. 61,825), SULLIVAN, Stephen (Registration No. 43,171), GAVIN, Kimberley (Registration No. 51,723), MAGLUYAN, John (Registration No. 56,867), PARSONS, Michael (Registration No. 58,767), PIERSON, Robert Jr. (Registration No. 60,310), CARPENTER, James (Registration No. 62,747), WALSH, Sean (Registration No. 63,510), HADIKUSUMO, Sugiarto (Registration No. 63,691), BUTLER, Lisa (Registration No. 63,828), BARKLEY, Christopher (Registration No. 64,329), HEARD, Preston (Registration No. 64,675), KUSHNER, Leslie (Registration No. 64,724), HEINLE, Courtney (Registration No. 64,891), O'MALLEY, Brendan (Registration No. 64,905), BARRY, Daniel (Registration No. 65,423), BINNS, Michael (Registration No. 65,836), and MARCOVICI, Leila (Registration No. 66,066),.all at:

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
United States of America

Box No. V DESIGNATIONS

The filing of this request **constitutes under Rule 4.9(a), the designation** of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.

However,

☐ DE Germany **is not designated** for any kind of national protection

☐ JP Japan **is not designated** for any kind of national protection

☐ KR Republic of Korea **is not designated** for any kind of national protection

(The check-boxes above may be used to exclude (irrevocably) the designations concerned if, at the time of filing or subsequently under rule 26bis.1, the international application contains in Box No. VI a priority claim to an earlier national application filed in the particular State concerned, in order to avoid the ceasing of the effect, under the national law, of this earlier national application.)

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application:* regional Office	international application: receiving Office
item (1) 25-Feb-2010	61/308,056	US		
item (2)				
item (3)				

☐ Further priority claims are indicated in the Supplemental Box.

☐ The **International Bureau** is requested to obtain from a digital library, a certified copy of the earlier application(s) (if the earlier application(s) is available to it from a digital library) identified above as:

☐ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box

☒ The **receiving Office** is requested to prepare and transmit to the International Bureau a certified copy of the earlier applications(s) *(if the earlier appliation(s) was filed with the Office which for the purposes of this international application is the receiving Office)* or to obtain a certified copy of the earlier application(s) from a digital library and transmit a copy of it to the International Bureau *(if the earlier application(s) is available to the receiving Office from a digital library)*, identified above as: *

☒ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box

* Where the certified copy of the earlier application(s) is not stored in a digital library under the number of the earlier application indicated above but under the application number of another application which also claims priority from it, indicate that number in the supplemental sheet (item 4).

Restore the right of priority: the receiving Office is requested to restore the right of priority for the earlier application(s) identified above or in the Supplemental Box as item(s) (_____). *(See also the Notes to Box No. VI; further information must be provided to support a request to restore the right of priority.)*

Incorporation by reference: where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*:

ISA/ **EP** .....

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application **contains the following**::		Number of sheets
(a) request form PCT/RO/101 (including any declarations and supplemental sheets)	:	6
(b) description (excluding any sequence listing part of the description, see (f), below)	:	13
(c) claims	:	3
(d) abstract	:	1
(e) drawings (if any)	:	4
(f) sequence listing part of the description (if any)	:	
Total number of sheets	:	27

This international application is **accompanied by** the following items(s) (mark the applicable *check-boxes below and indicate in right column the number of each items)*:

		Number of items
1. ☒	fee calculation sheet	1
2. ☐	original separate power of attorney	
3. ☐	original general power of attorney	
4. ☐	copy of general power of attorney; reference number	
5. ☐	statement explaining lack of signature	
6. ☐	priority document(s) identified in Box No. VI as item(s)	
7. ☐	translation of international application into (*language*)	
8. ☐	separate indications concerning deposited microorganism or other biological material	
9. ☐	copy in electronic form (Annex C/ST.25 text file) on physical data carrier(s) of the sequence listing, not forming part of the international application, which is **furnished for the purposes of international search** under Rule 13*ter* (*type and number of physical data carriers*) :	
10. ☐	a statement confirming that "the information recorded in electronic form submitted under Rule 13ter is identical to the sequence listing as contained in the international application" as filed on paper	
11. ☐	copy of results of earlier search(es) (Rule 12*bis*.1(a))	
12. ☐	other (*specify*)	

Figure of the drawings which should accompany the abstract: Fig. 3

Language of filing of the international application: ENGLISH

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

/Jason M. Okun/

Jason M. Okun
Reg. No. 48,512

(24.02.11)

For receiving Office use only

1.	Date of actual receipt of the purported international application:		2. Drawings:
3.	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		☐ received:
4.	Date of timely receipt of the required corrections under PCT Article 11(2):		☐ not received:
5.	International Searching Authority (if two or more are competent): **ISA/** EP	6. ☐ Transmittal of search copy delayed until search fee is paid	

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92*bis*.1 and Administrative Instructions, Section 422)

To:

OKUN, Jason, M.
Fitzpatrick, Cella, Harper & Scinto
1290 Avenue Of The Americas
New York, NY 10104-3801
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)*
14 August 2012 (14.08.2012)

Applicant's or agent's file reference
03822.000060.PC

IMPORTANT NOTIFICATION

International application No.
PCT/US2011/025994

International filing date *(day/month/year)*
24 February 2011 (24.02.2011)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address
PATEL, Jatin
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
Facsimile No.:
E-mail address:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address
PATEL, Jatin
c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
Facsimile No.:
E-mail address:
☐ Notifications by e-mail authorized

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☐ the Authority(ies) specified for supplementary search
☐ the International Preliminary Examining Authority
☒ the designated Offices concerned
☐ the elected Offices concerned
☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 70 90

Authorized officer
Sontag Frederic
e-mail pt01.pct@wipo.int
Telephone No. +41 22 338 74 01

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office Use Only

PCT/US11/25994
International Application No.

24 FEBRUARY 2011 (02.24.11)
International Filing Date

PCT INTERNATIONAL APPLICATION RO/US
Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 03822.000060.PC

Box No. I TITLE OF INVENTION

APIXABAN FORMULATIONS

Box No. II APPLICANT ☐ This person is also inventor.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BRISTOL-MYERS SQUIBB COMPANY
Rt. 206 & Province Line Road
Princeton, New Jersey 08543-4000
USA

Telephone No.

Facsimile No.

Applicant's registration No. with the Office

E-mail authorization: Marking one of the check-boxes below authorizes the receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, notifications issued in respect of this international application to that e-mail address if those offices are willing to do so.

☐ as advance copies followed by paper notifications; or ☐ exclusively in electronic form (no paper notifications will be sent).

E-mail address:

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

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☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

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Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

OKUN, Jason M.
Fitzpatrick, Cella, Harper & Scinto
1290 Avenue of the Americas
New York, NY 10104-3801, USA

(see sheet 3 for additional representatives)

Telephone No. 212-218-2100

Facsimile No. 212-218-2200

Agent's registration No. with the Office

48,512

E-mail authorization: Marking one of the check-boxes below authorizes the receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority to use the e-mail address indicated in this Box to send, notifications issued in respect of this international application to that e-mail address if those offices are willing to do so.

☒ as advance copies followed by paper notifications; or ☐ exclusively in electronic form (no paper notifications will be sent).

E-mail address: **docketing@fchs.com**

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

PFIZER INC.
234 East 42nd Street
New York, NY 10017
USA

This person is:
☒ applicant only
☐ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

PATEL, Jatin
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
US

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ The United States of America only ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

FROST, Charles
c/o Bristol-Myer Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543
US

This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

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JIA, Jingpin
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
US

This person is:
☐ applicant only
☒ applicant and inventor
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☒ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTORS

If none of the following sub-boxes is used, this sheet is not to be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

VEMA-VARAPU, Chandra
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
US

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: IN

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

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☐ applicant only

☐ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

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Applicant's registration No. with the Office

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This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ The United States of America only ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Supplemental Box *If the Supplemental Box is not used, this sheet need not be included in the request.*

1. *If, in any of the Boxes, except Boxes Nos. VIII(i) to (v) for which a special continuation box is provided* ***the space is insufficient*** *to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:*

(i) ***if more than one person is to be indicated as applicants and/or inventors*** *and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;*

(ii) *if, in Box No. II or in any of the sub-boxes of Box No. III, the indication* ***"the States indicated in the Supplemental Box"*** *is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;*

(iii) *if, in Box No. II or in any of the sub-boxes of Box No. III,* ***the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America:*** *in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;*

(iv) *if, in addition to the agent(s) indicated in Box No. IV, there are* ***further agents:*** *in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;*

(v) *if, in Box No. VI, there are* ***more than three earlier applications whose priority is claimed:*** *in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.*

2. *If the applicant intends to make an indication of the wish that the international application be treated, in certain designated States, as an application for a patent of addition, certificate of addition, inventor's certificate of addition or utility certificate of addition: in such a case, write the name or two-letter code of each designated State concerned and the indication* ***"patent of addition," "certificate of addition," "inventor's certificate of addition"****, or* ***"utility certificate of addition,"*** *the number of the parent application or parent patent or other parent grant and the date of grant of the parent patent or other patent grant or the date of filing of the parent application (Rules 4.11(a)(iii) and 49bis.1(a) or (b)).*

3. *If the applicant intends to make an indication of the wish that the international application be treated, in the United States of America, as a continuation or continuation-in-part of an earlier application: in such a case, write "United States of America" or "US" and the indication* ***"continuation"*** *or* ***"continuation-in-part"*** *and the number and the filing date of the parent application (Rules 4.11(a)(iv) and 49bis.1(d)).*

4. *If the applicant wishes to request the receiving Office or the International Bureau to obtain a priority document from a digital library but* ***that document is only held in a digital library in connection with another application*** *which also relied upon that priority document to support a priority claim (and unless that digital library is to be accessed through the Digital Access Service for Priority Documents), in such cases write "Continuation of Box No. VI", indicate for each earlier application concerned the same type of information as required in Box. No. VI and indicate the number under which the application is stored (and, if known, the digital library concerned) (Section 716(a)(ii)).*

FITZPATRICK, Joseph M. (Registration No. 17,398), SCINTO, Lawrence F. (Registration No. 18,973), BAECHTOLD, Robert L. (Registration No. 20,860), KRAUSE, John A. (Registration No. 24,613), SAXON, Peter (Registration, No. 24,947), RENK, Henry J. (Registration No. 25,499), RAZZANO, Pasquale A. (Reg. No. 25,512), BAKER, Charles P. (Registration No. 26,702), CLAYTON, Ronald A. (Registration No. 26,718), ZUPCIC, Anthony M. (Registration No. 27,276), OLSEN, Warren E. (Registration No. 27,290), WANNISKY, William M. (Registration No. 28,373), JACOBS, Gary M. (Registration No. 28,861), VASSALLO, Edward E. (Registration No. 29,117), DIANA, Leonard P. (Registration No. 29,296), MURNANE, John D. (Registration No. 29,836), FISCHER, Robert H. (Registration No. 30,051), STAHL, Lawrence A. (Registration No. 30,110), KALLAS, Nicholas N. (Registration No. 31,530), PERRY, Lawrence S. (Registration No. 31,865), REED, Scott K. (Registration No. 32,433), MALPEDE, Scott D. (Registration No. 32,533), O'NEILL, Michael K. (Registration No. 32,622), HAAS, Bruce C. (Registration No. 32,734), WARNER, Steven E. (Registration No. 33,326), WILLIAMSON, Mark A. (Registration No. 33,628), CONDE, Dominick A. (Registration No. 33,856), MANDRA, Raymond R. (Registration No. 34,382), SANDONATO, Michael P. (Registration No. 35,345), KLOCK, Brian L. (Registration No. 36,570), CARLIN, John D. (Registration No. 37,292), PENSABENE, Marc J. (Registration No. 37,416), GLUECK, Daniel S. (Registration No. 37,838), YU-JAHNES, Lock See (Registration No. 38,667), SMITH-LUNDY, Leisa M. (Registration No. 39,378), SHARROTT, Douglas (Registration No. 39,832), CIRE, Frank L. (Registration No. 42,419), DELUCIA, Frank A., Jr. (Registration No. 42,476), HOLOWACZ, Elizabeth F. (Registration No. 42,667), KMETT, Edward A. (Registration No. 42,746), SHAPIRO, Peter (Registration No. 43,107), MEE, Brendan (Registration No. 43,391), HAUGHEY III, Edmund J. (Registration No. 44,749), WOLFE, Lori A. (Registration No. 44,840), OLIVER, Justin J. (Registration No. 44,986), LOH, Christopher E. (Registration No. 46,000), RUSSO, Alicia A. (Registration No. 46,192), BELISLE, Stephen E. (Registration No. 46,546), BERSCHADSKY, Jonathan (Registration No. 46,551), ROBERTS, Simon (Registration No. 47,342), OKUN, Jason M. (Registration No. 48,512), TRACY, Colleen (Registration No. 52,295), VADNAIS, Damond E. (Registration No. 52,310), CHEVALIER, Charles H. (Registration No. 52,735), GREGORY, Dennis (Registration No. 52,967), MINION, Daniel (Registration No. 53,329), PIERONI, Joseph P. (Registration No. 53,469), PUPPA, Thomas (Registration No. 54,379), KIRKLAND, John (Registration No. 54,595), LAU, Dana (Registration No. 55,361), O'REILLY, Brian (Registration No. 55,974), DAVIS, Joshua A. (Registration No. 56,180), JOHNSON, Jason (Registration No. 56,887), GABRIEL, Thomas (Registration No. 57,851), XU, Feng (Registration No. 58,230), MANNINO, Christian (Registration No. 58,373), VATHYAM, Sujatha (Registration No. 58,918), McGRAW, Michael P. (Registration No. 58,977), BECKMAN, Christopher V. (Registration No. 59,050), HECKENBERG, Donald Jr. (Registration No. 60,081), WAKELEY, John J. (Registration No. 60,418), TYNDALE, Jamar W. (Registration No. 61,451), KENNEDY, Troy A. (Registration No. 61,492), TCHAKERIAN, Shant (Registration No. 61,825), SULLIVAN, Stephen (Registration No. 43,171), GAVIN, Kimberley (Registration No. 51,723), MAGLUYAN, John (Registration No. 56,867), PARSONS, Michael (Registration No. 58,767), PIERSON, Robert Jr. (Registration No. 60,310), CARPENTER, James (Registration No. 62,747), WALSH, Sean (Registration No. 63,510), HADIKUSUMO, Sugiarto (Registration No. 63,691), BUTLER, Lisa (Registration No. 63,828), BARKLEY, Christopher (Registration No. 64,329), HEARD, Preston (Registration No. 64,675), KUSHNER, Leslie (Registration No. 64,724), HEINLE, Courtney (Registration No. 64,891), O'MALLEY, Brendan (Registration No. 64,905), BARRY, Daniel (Registration No. 65,423), BINNS, Michael (Registration No. 65,836), and MARCOVICI, Leila (Registration No. 66,066),.all at:

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
United States of America

Box No. V DESIGNATIONS

The filing of this request **constitutes under Rule 4.9(a), the designation** of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.

However,

☐ DE Germany **is not designated** for any kind of national protection

☐ JP Japan **is not designated** for any kind of national protection

☐ KR Republic of Korea **is not designated** for any kind of national protection

(The check-boxes above may be used to exclude (irrevocably) the designations concerned if, at the time of filing or subsequently under rule 26bis.1, the international application contains in Box No. VI a priority claim to an earlier national application filed in the particular State concerned, in order to avoid the ceasing of the effect, under the national law, of this earlier national application.)

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is:		
		national application: country or Member of WTO	regional application:* regional Office	international application: receiving Office
item (1) 25-Feb-2010	61/308,056	US		
item (2)				
item (3)				

☐ Further priority claims are indicated in the Supplemental Box.

☐ The **International Bureau** is requested to obtain from a digital library, a certified copy of the earlier application(s) (if the earlier application(s) is available to it from a digital library) identified above as:

☐ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box

☒ The **receiving Office** is requested to prepare and transmit to the International Bureau a certified copy of the earlier applications(s) *(if the earlier appliation(s) was filed with the Office which for the purposes of this international application is the receiving Office)* or to obtain a certified copy of the earlier application(s) from a digital library and transmit a copy of it to the International Bureau *(if the earlier application(s) is available to the receiving Office from a digital library)*, identified above as: *

☒ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ other, see Supplemental Box

* Where the certified copy of the earlier application(s) is not stored in a digital library under the number of the earlier application indicated above but under the application number of another application which also claims priority from it, indicate that number in the supplemental sheet (item 4).

Restore the right of priority: the receiving Office is requested to restore the right of priority for the earlier application(s) identified above or in the Supplemental Box as item(s) (_____). *(See also the Notes to Box No. VI; further information must be provided to support a request to restore the right of priority.)*

Incorporation by reference: where an element of the international application referred to in Article 11(1)(iii)(d) or (e) or a part of the description, claims or drawings referred to in Rule 20.5(a) is not otherwise contained in this international application but is completely contained in an earlier application whose priority is claimed on the date on which one or more elements referred to in Article 11(1)(iii) were first received by the receiving Office, that element or part is, subject to confirmation under Rule 20.6, incorporated by reference in this international application for the purposes of Rule 20.6.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*:

ISA/ **EP** .....

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application **contains the following**::	Number of sheets
(a) request form PCT/RO/101 (including any declarations and supplemental sheets)	6
(b) description (excluding any sequence listing part of the description, see (f), below)	13
(c) claims	3
(d) abstract	1
(e) drawings (if any)	4
(f) sequence listing part of the description (if any)	
Total number of sheets	27

This international application is **accompanied by** the following items(s) (mark the applicable *check-boxes below and indicate in right column the number of each items)*:

		Number of items
1.	☒ fee calculation sheet	1
2.	☐ original separate power of attorney	
3.	☐ original general power of attorney	
4.	☐ copy of general power of attorney; reference number	
5.	☐ statement explaining lack of signature	
6.	☐ priority document(s) identified in Box No. VI as item(s)	
7.	☐ translation of international application into (*language*)	
8.	☐ separate indications concerning deposited microorganism or other biological material	
9.	☐ copy in electronic form (Annex C/ST.25 text file) on physical data carrier(s) of the sequence listing, not forming part of the international application, which is **furnished for the purposes of international search** under Rule 13*ter* (*type and number of physical data carriers*)	
10.	☐ a statement confirming that "the information recorded in electronic form submitted under Rule 13ter is identical to the sequence listing as contained in the international application" as filed on paper	
11.	☐ copy of results of earlier search(es) (Rule 12*bis*.1(a))	
12.	☐ other (*specify*)	

Figure of the drawings which should accompany the abstract: Fig. 3

Language of filing of the international application: ENGLISH

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

/Jason M. Okun/

Jason M. Okun
Reg. No. 48,512

(24.02.11)

For receiving Office use only

1.	Date of actual receipt of the purported international application: 24 FEBRUARY 2011 (24.02.11)		2. Drawings:
3.	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:		☐ received:
4.	Date of timely receipt of the required corrections under PCT Article 11(2):		☐ not received:
5.	International Searching Authority (if two or more are competent): **ISA/** EP	6. ☐ Transmittal of search copy delayed until search fee is paid	

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92*bis*.1 and Administrative Instructions, Section 422)

To:

OKUN, Jason, M.
Fitzpatrick, Cella, Harper & Scinto
1290 Avenue Of The Americas
New York, NY 10104-3801
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)*
14 August 2012 (14.08.2012)

Applicant's or agent's file reference
03822.000060.PC

IMPORTANT NOTIFICATION

International application No.
PCT/US2011/025994

International filing date *(day/month/year)*
24 February 2011 (24.02.2011)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address
JIA, Jingpin
c/o Bristol-Myer Squibb Company
1 Squibb Drive
New Brunswick, NJ 08903
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
Facsimile No.:
E-mail address:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address
JIA, Jingpin
c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road
Princeton, NJ 08543
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
Facsimile No.:
E-mail address:
☐ Notifications by e-mail authorized

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☐ the Authority(ies) specified for supplementary search
☐ the International Preliminary Examining Authority
☒ the designated Offices concerned
☐ the elected Offices concerned
☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 70 90

Authorized officer
Sontag Frederic
e-mail pt01.pct@wipo.int
Telephone No. +41 22 338 74 01

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From the INTERNATIONAL BUREAU

PCT

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(PCT Rule 92*bis*.1 and Administrative Instructions, Section 422)

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Name and Address
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c/o Bristol-Myer Squibb Company
Route 206 And Province Line Road
Princeton, NJ 08543
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
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☒ the designated Offices concerned
☐ the elected Offices concerned
☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 70 90

Authorized officer
Sontag Frederic
e-mail pt01.pct@wipo.int
Telephone No. +41 22 338 74 01

ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92*bis*.1 and Administrative Instructions, Section 422)

To:

OKUN, Jason, M.
Fitzpatrick, Cella, Harper & Scinto
1290 Avenue Of The Americas
New York, NY 10104-3801
ETATS-UNIS D'AMERIQUE

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Name and Address
VEMA-VARAPU, Chandra
c/o Bristol-Myer Squibb Company
1 Squibb Drive
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United States of America

State of Nationality: IN
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☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

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United States of America

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Telephone No.:
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☐ Notifications by e-mail authorized

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☒ the designated Offices concerned
☐ the elected Offices concerned
☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 70 90

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Sontag Frederic
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ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

PCT

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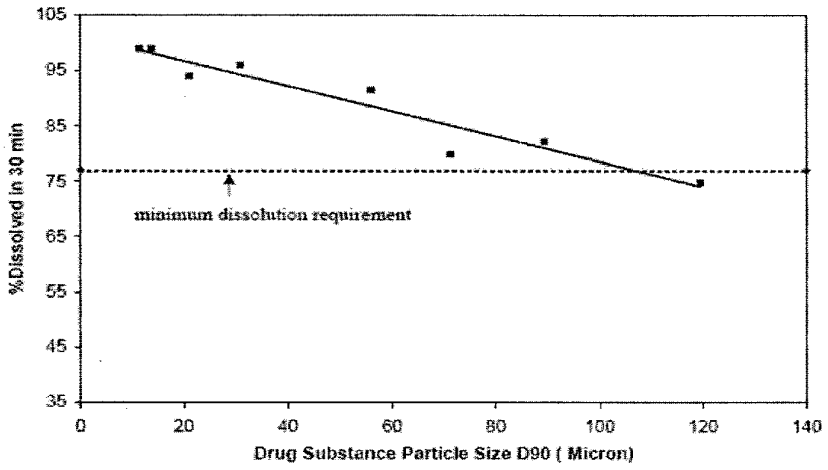
[Continued on next page]

(54) Title: APIXABAN FORMULATIONS

Figure 3: Dissolution Rates of 2.5-mg Apixaban Tablets Using Drug Substance of Different Particle Size



(57) Abstract: Compositions comprising crystalline apixaban particles having a D_{90} equal to or less than 89 μm, and a pharmaceutically acceptable carrier, are substantially bioequivalent and can be used to for the treatment and/or prophylaxis of thromboembolic disorders.

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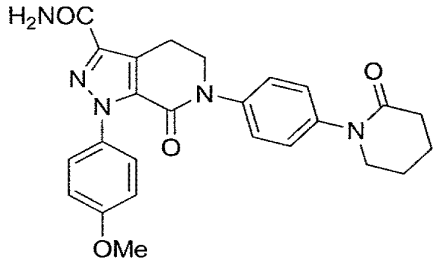
APIXABAN FORMULATIONS

FIELD OF THE INVENTION

[0001] This invention relates to apixaban pharmaceutical formulations comprising crystalline apixaban particles having a maximum size cutoff, and methods of using them, for example, for the treatment and/or prophylaxis of thromboembolic disorders.

BACKGROUND OF THE INVENTION

[0002] Apixaban is a known compound having the structure:



[0003] The chemical name for apixaban is 4,5,6,7-tetrahydro-1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxo-1-piperidinyl)phenyl]-1H-pyrazolo[3,4-c]pyridine-3-carboxamide (CAS name) or 1-(4-methoxyphenyl)-7-oxo-6-[4-(2-oxo-1-piperidinyl)phenyl]-4,5,6,7-tetrahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxamide (IUPAC name).

[0004] Apixaban is disclosed in U.S. Patent No. 6,967,208 (based on U.S. Application Serial No. 10/245,122 filed September 17, 2002), which is herein incorporated by reference in its entirety, has utility as a Factor Xa inhibitor, and is being developed for oral administration in a variety of indications that require the use of an antithrombotic agent.

[0005] The aqueous solubility (40 μg/mL at all physiological pH) of apixaban suggests that the tablets with less than 10 mg apixaban (dose/solubility ratio = 250 mL) should not demonstrate dissolution rate limited absorption since dissolution rate limitations are only expected when the dose/solubility ratio is greater than 250 mL. Based on this dose and solubility consideration, the particle size of the compound should not be critical for achieving consistent plasma profiles, according to the prediction based on the Biopharmaceutics Classification System (BCS; Amidon, G. L. et al., *Pharmaceutical Research*, 12: 413-420 (1995)). However, it was determined

that formulations that were made using a wet granulation process as well as those using large particles of apixaban drug substance resulted in less than optimal exposures, which can present quality control challenges.

SUMMARY OF THE INVENTION

[0006] Surprisingly and unexpectedly, it has been found that compositions for tablets comprising up to 5 mg, apixaban particles having a D_{90} (90% of the volume) less than 89 microns (μm) lead to consistent in-vivo dissolution in humans (at physiologic pH), hence, consistent exposure and consistent Factor Xa inhibition that will lead to consistency in therapeutic effect. Consistent exposure is defined as that where in-vivo exposure from tablets is similar to that from a solution and not affected by the differences in dissolution rates. The compositions were prepared using a dry granulation process. Accordingly, the invention provides a pharmaceutical composition comprising crystalline apixaban particles having a D_{90} equal to or less than about 89 μm as measured by laser light scattering method, and a pharmaceutically acceptable diluent or carrier. It is preferred that the apixaban particles in the composition have a D_{90} not exceeding 89 μm. It is noted the notation D_x means that X% of the volume of particles have a diameter less than a specified diameter D. Thus a D_{90} of 89 μm means that 90% of the volume of particles in an apixaban composition have a diameter less than 89 μm.

[0007] The range of particle sizes preferred for use in the invention is D_{90} less than 89 μm, more preferably D_{90} less than 50 μm, even more preferably D_{90} less than 30 μm, and most preferably D_{90} less than 25 μm. The particle sizes stipulated herein and in the claims refer to particle sizes were determined using a laser light scattering technique.

[0008] The invention further provides the pharmaceutical composition further comprising a surfactant from 0.25% to 2% by weight, preferably from 1% to 2% by weight. As regards the surfactant, it is generally used to aid in wetting of a hydrophobic drug in a tablet formulation to ensure efficient dissolution of the drug, for example, sodium lauryl sulfate, sodium stearate, polysorbate 80 and poloxamers, preferably sodium lauryl sulfate.

[0009] The invention further provides a method for the treatment or prophylaxis of thromboembolic disorders, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition comprising crystalline apixaban particles having a D_{90} equal to or less than about 89 μm as measured by laser light scattering, and a pharmaceutically acceptable carrier.

[0010] The present invention also provides a dry granulation process for preparing a composition comprising crystalline apixaban particles having a D_{90} equal to or less than about 89 μm as measured by laser light scattering, and a pharmaceutically acceptable carrier.

[0011] The formulations of this invention are advantageous because, *inter alia*, as noted above, they lead to consistent human in-vivo dissolution. The invention is surprising in this respect, however, in that exposures are variable even though apixaban has adequate aqueous solubility that would allow the drug to dissolve rapidly. That is, one would expect dissolution rate for a drug that has high solubility (as defined by the Biopharmaceutical Classification System) would not be limited by the particle size. It has surprisingly been found, however, that the particle size that impacts apixaban absorption rate is about a D_{90} of 89 μm. Thus apixaban can be formulated in a composition having a reasonable particle size using dry granulation process, to achieve and maintain relatively fine particles to facilitate consistent in vivo dissolution.

[0012] In a relative bioavailabiltiy study where various apixaban formulations were evaluated, it was determined that formulations made using a wet granulation process resulted in lower exposures compared to the exposures obtained from a dry granulation process. Additionally, tablets made using larger particles (D_{90} of 89 μm) had lower exposures compared to tablets made using the same process but with particle size of D_{90} of 50 μm. In a dry granulation process, water is not used during manufacturing to develop granules containing apixaban and the excipients.

[0013] Formulations according to this invention, when dissolution tested in vitro preferably exhibit the following dissolution criteria. That is, the formulation exhibits dissolution properties such that, when an amount of the drug equivalent to 77% therein dissolves within 30 minutes. Usually the test result is established as an average for a pre-determined number of dosages (e.g., tablets, capsules, suspensions,

or other dosage form), usually 6. The dissolution test is typically performed in an aqueous media bufferred to a pH range (1 to 7.4) observed in the gastrointestinal tract and controlled at 37° C (±1°C), together maintaining a physilogical relevance. It is noted that if the dosage form being tested is a tablet, typically paddles rotating at 50 - 75 rpm are used to test the dissolution rate of the tablets. The amount of dissolved apixaban can be determined conventionally by HPLC, as hereinafter described. The dissolution (in-vitro) test is developed to serve as a quality control tool, and more preferably to predict the biological (invivo) performance of the tablet, where invivo-invitro relationships (IVIVR) are established.

[0014] The term "particles" refers to individual drug substance particles whether the particles exist singly or are agglomerated. Thus, a composition comprising particulate apixaban may contain agglomerates that are well beyond the size limit of about 89 μm specified herein. However, if the mean size of the primary drug substance particles (i.e., apixaban) comprising the agglomerate are less than about 89 μm individually, then the agglomerate itself is considered to satisfy the particle size constraints defined herein and the composition is within the scope of the invention.

[0015] Reference to apixaban particles having "a mean particle size" (herein also used interchangeably with "VMD" for "volume mean diameter") equal to or less than a given diameter or being within a given particle size range means that the average of all apixaban particles in the sample have an estimated volume, based on an assumption of spherical shape, less than or equal to the volume calculated for a spherical particle with a diameter equal to the given diameter. Particle size distribution can be measured by laser light scattering technique as known to those skilled in the art and as further disclosed and discussed below.

[0016] "Bioequivalent" as employed herein means that if a dosage form is tested in a crossover study (usually comprising a cohort of at least 10 or more human subjects), the average Area under the Curve (AUC) and/or the C_{max} for each crossover group is at least 80% of the (corresponding) mean AUC and/or C_{max} observed when the same cohort of subjects is dosed with an equivalent formulation and that formulation differs only in that the apixaban has a preferred particle size with a D_{90} in the range from 30 to 89 μm. The 30 μm particle size is, in effect, a standard against which other different formulations can be compared. AUCs are plots of serum

concentration of apixaban along the ordinate (Y-axis) against time for the abscissa (X-axis). Generally, the values for AUC represent a number of values taken from all the subjects in a patient population and are, therefore, mean values averaged over the entire test population. C.sub.max, the observed maximum in a plot of serum level concentration of apixaban (Y-axis) versus time (X-axis) is likewise an average value.

[0017] Use of AUCs, C_{max}, and crossover studies is, of course otherwise well understood in the art. The invention can indeed be viewed in alternative terms as a composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 89 μm, as measured by Malvern light scattering, and a pharmaceutically acceptable carrier, said composition exhibiting a mean AUC and/or mean C_{max} which are at least 80% of the corresponding mean AUC and/or C_{max} values exhibited by a composition equivalent thereto (i.e., in terms of excipients employed and the amount of apixaban) but having an apixaban mean particle size of 30 μm. Use of the term "AUC" for purposes of this invention implies crossover testing within a cohort of at least 10 healthy subjects for all compositions tested, including the "standard" 30 μm particle size composition.

[0018] The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof. Thus, the above embodiments should not be considered limiting. Any and all embodiments of the present invention may be taken in conjunction with any other embodiment or embodiments to describe additional embodiments. Each individual element of the embodiments is its own independent embodiment. Furthermore, any element of an embodiment is meant to be combined with any and all other elements from any embodiment to describe an additional embodiment. In addition, the present invention encompasses combinations of different embodiment, parts of embodiments, definitions, descriptions, and examples of the invention noted herein.

DETAILED DESCRIPTION OF THE INVENTION

[0019] As previously stated, apixaban in any form which will crystallize can be used in this invention. Apixaban may be obtained directly via the synthesis described in U.S. Pat. No. 6,967,208 and/or US20060069258A1 (based on U.S. Application Serial No. 11/235,510 filed September 26, 2005), herein incorporated by reference.

[0020] Form N-1 (neat) and Form H2-2 (hydrate) of apixaban may be characterized by unit cell parameters substantially equal to the following shown in Table 1.

Table 1

Form	N-1	H2-2
Solvate	None	Dihydrate
T	+22	+22
a(Å)	10.233(1)	6.193(1)
b(Å)	13.852(1)	30.523(1)
c(Å)	15.806(1)	13.046(1)
α,°	90	90
β,°	92.98(1)	90.95(1)
γ,°	90	90
V(Å^3)	2237.4(5)	2466.0(5)
Z'	1	1
Vm	559	617
SG	$P2_1/n$	$P2_1/n$
Dcalc	1.364	1.335
R	0.05	0.09
Sol.sites	None	2 H_2O

Z' is the number of molecules per asymmetric unit.

T(°C) is the temperature for the crystallographic data.

Vm = V(unit cell) / (ZZ')

[0021] Characteristic X-ray diffraction peak positions (degrees 2θ±0.1) at room temperature, based on a high quality pattern collected with a diffractometer (CuKα) with a spinning capillary with 2θ calibrated with a NIST suitable standard are shown in Table 2 below.

Table 2

Form N-1	Form H2-2
10.0	5.8
10.6	7.4
12.3	16.0
12.9	20.2
18.5	23.5
27.1	25.2

[0022] It will be appreciated by those skilled in the art of manufacturing and granulation processes that there are numerous known methods which can be applied to producing apixaban solid dosage forms. The feature of this invention, however, involves processes that produce apixaban dosage forms with an ability to produce primary particles at the site of dissolution with a d90<89 μm. Examples of such methods include as well as dry granulation or wet-granulation by low or high-shear techniques

[0023] The dry granulation process that produces crystalline apixaban particles having a mean particle size equal to or less than about 89 μm, is believed to be novel, and is accordingly provided as a further feature of the invention. Thus, the invention provides a drug product manufacturing process, comprising the steps:

(1) Blend the raw materials required prior to granulation;

(2) Granulate the raw materials from Step 1 using a dry or wet granulation process;

(3) Blend the sized granules from step 3 with extragranular raw materials;

(4) Compress the blend from Step 3 into tablets; and

(5) Film coat the tablets from step 4.

[0024] In another embodiment, the invention provides a drug product manufacturing process, comprising the steps:

(1) Blend the raw materials, with apixaban of controlled particle size;

(2) Include intragranular portions of binder, disintegrant and other fillers in the mix from step (1);

(3) Granulate the materials from step (2) using process (3a) or (3b):
(3a) DRY GRANULATION: Delump the intragranular lubricant using a suitable screen or mill. Add the lubricant to the blend from step (2)

and blend. Compact the lubricated blend to ribbons of density in the range of 1.0 to 1.2 g/cc and size the compacted ribbons using a roller compactor; or

(3b) WET GRANULATION: Wet granulate the composition from step (2) using water to a target end point and optionally, size the wet-granules by passing through a screen/mill. Remove water for granulation by drying in a convection oven or a fluid-bed dryer. Size the dried granules by passing through a screen/mill;

(4) Blend the sized granules from step (3) and the extragranular disintegrant in a suitable blender;

(5) Delump the extragranular lubricant using a suitable screen/mill and blend with granules from step (4);

(6) Compress the blend from (5) into tablets;

(7) Film coat the tablets from step (6).

[0025] In a preferred embodiment, a dry granulation process is employed.

[0026] In a preferred embodiment, the surfactant (SLS) in the composition serves as a wetting aid for inherently hydrophobic apixaban drug substance (contact angle=54° with water), further exacerbated as part of air-jet milling process that is used to reduce apixaban particle size to the desired size.

[0027] The amount of apixaban contained in a tablet, capsule, or other dosage form containing a composition of this invention will usually be between 2.5 and 5 mg, usually administered orally twice a day, although amounts outside this range and different frequencies of administration are feasible for use in therapy as well. As previously mentioned, such dosage forms are useful, *inter alia,* in the prevention and/or treatment of thromboembolic disorders, for example, deep vein thrombosis, acute coronary syndrome, stroke, and pulmonary embolism, as disclosed in U.S. Pat . No. 6,967,208.

[0028] As noted, average particle size can be determined by Malvern light scattering, a laser light scattering technique. In the examples below, the particle size for apixaban drug substance was measured using a Malvern particle size analyzer.

[0029] Upon measurement completion, the sample cell was emptied and cleaned, refilled with suspending medium, and the sampling procedure repeated for a total of three measurements.

[0030] The dissolution test is performed in 900 mL of dissolution medium at 37 °C, using USP Apparatus 2 (paddles) method at a rotation speed of 75 rpm. Samples are removed after 10, 20, 30, 45, and 60 minutes from test initiation and analyzed for apixaban by HPLC at 280 nm. 0.1 N HCl or 0.05 M sodium phosphate pH 6.8 with 0.05% SDS solution has been used as dissolution medium during formulation development. While both methods serve the purposes as quality control tests (with adequate discrimination ability), and in establishing IVIVR, the latter was preferred from the standpoint of method robustness. A role of SDS (surfactant) in the latter dissolution medium is as a wetting aid to facilitate complete dissolution of hydrophobic apixaban from tablets, rather than to increase the solubility of apixaban. Dissolution data from both the tests are included in this invention record and unless otherwise specified, the results reported were averages of values from six tablets.

[0031] Blood samples are drawn at predetermined time points following drug administration as specified in the clinical study protocol. Concentrations of the samples are measured using a validated analytical method (Liquid Chromatography with Tandem Mass Spectrometry). Individual subject pharmacokinetic parameters (eg, Cmax, AUC, T-HALF) are derived by non-compartmental methods using Kinetica® software from the time-concentration profiles.

[0032] The invention is further exemplified and disclosed by the following non-limiting examples:

[0033] Table 3 shows apixaban tablet compositions prepared using the drygranulation process that were evaluated in bioequivalence (BE) study.

Table 3

Ingredients	Dry Granulation	
	5% w/w Drug Loaded Granulation (% w/w)	20 mg Tablet (mg/tablet)
Intragranular		
Apixaban	5.00	20.00
Lactose Anhydrous	49.25	197.00
Microcrystalline Cellulose	39.50	158.00
Croscarmellose Sodium	2.00	8.00
Magnesium Stearate	0.50	2.00
Sodium Lauryl Sulfate	1.00	4.00
Extragranular		
Croscarmellose Sodium	2.00	8.00
Magnesium Stearate	0.75	3.00
Total	100.00 mg	400 mg
Film Coat	3.5	14.0
Total	103.5 mg	414 mg

[0034] Table 4 shows apixaban tablet compositions prepared using the wet granulation process that were evaluated in BE study.

Table 4

Ingredients	Wet Granulation	
	5% w/w Drug Loaded Granulation (% w/w)	20 mg Tablet (mg/tablet)
Intragranular		
Apixaban	5.00	20.00
Lactose Monohydrate	70.00	280.00
Microcrystalline Cellulose	5.00	60.00
Croscarmellose Sodium	2.50	10.00
Povidone	4.50	18.00
Purified Water	17.40	69.60
Extragranular		
Croscarmellose Sodium	2.50	10.00
Magnesium Stearate	0.50	2.09
Microcrystalline Cellulose	10.00	10.09
Total	100.00	400.00
Film Coat	3.5	14.0
Total	103.5 mg	414.0

[0035] Table 5 and Table 5a show the dissolution data that indicates that having a dry granulation process will result in faster dissolution compared to that from a wet granulation process. As shown in Table 5, the 20 mg tablets made using a dry granulation process had 79% apixaban dissolved in 30 minutes versus 62% apixaban dissolved at 30 minutes for the 20 mg tablets made using a wet granulation process. Dissolution test in 0.1N HCl also indicated a similar behavior of faster dissolution from tablets made using dry granulation process (58% in 30min), compared to wet granulation process (45% in 30min).

Table 5

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.05% SLS in 50mM phosphate, pH 6.8)	
	Wet Granulation 20 mg Tablets	Dry Granulation 20 mg Tablets
10	38	47
20	54	70
30	62	79
45	71	86
60	76	90
API Particle Size D_{90} (μm)	83.8	83.8

Table 5a

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.1N HCl)	
	Wet Granulation 20 mg Tablets	Dry Granulation 20 mg Tablets
10	30	41
20	39	52
30	45	58
45	51	64
60	56	68
90	64	74
API Particle Size D_{90} (μm)	83.8	83.8

[0036] Table 6 and Table 6a provides the dissolution data from tablets made with different manufacturing pprocesses (wet and dry granulation) and drug substance different particle sizes. As shown Table 6, apixaban tablets that had 77% dissolved in 30 minutes or 86% dissolved in 30 minutes both had AUC values that met

bioequivalence criteria (Confidence Interval between 80% to 125%) when compared to the tablets that had 89% dissolved at 30 minutes. Similar rank order of the dissolution rates were observed for these tablets (A, B & C) when tested in 0.1N HCl.

Table 6

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.05% SLS in 50mM phosphate, pH 6.8)		
	Wet Granulation 2 x 2.5 mg Tablets (A)	Wet Granulation 2 x 2.5 mg Tablets (B)	Dry Granulation 2 x 2.5 mg Tablets (C)
10	63	42	70
20	79	64	84
30	86	77	89
45	91	87	94
60	94	93	96
C_{max} (ng/mL)	101.8 (21)	87.8 (24)	108.3 (24)
AUC(INF) (ng*hr/mL)	1088 (32)	1030 (25)	1153 (26)

Geomean (CV%) are presented for Cmax and AUC(INF)

Table 6a

Time (minutes)	% apixaban dissolved (USP II, 75 rpm, 0.1N HCl)		
	Wet Granulation 2 x 2.5 mg Tablets (A)	Wet Granulation 2 x 2.5 mg Tablets (B)	Dry Granulation 2 x 2.5 mg Tablets (C)
10	44	25	56
20	62	43	71
30	72	54	79
45	80	66	85
60	84	74	88
AUC(INF) (ng*hr/mL)	1088 (32)	1030 (25)	1153 (26)

Geomean (CV%) are presented for Cmax and AUC(INF)

[0037] The results of clinical studies demonstrated that, for tablets with similar dissolution rates (89% and 86% at 30 min in pH 6.8 phosphate buffer containing 0.05% SLS), Cmax and AUC of the coated Phase 3 tablet (C) relative to the uncoated Phase 2 tablet (A), met bioequivalence criteria. Tablets with different dissolution rates (77% and 86% at 30 min) had similar AUCs, but did not meet equivalence criteria for Cmax. The lower boundary of the 90% confidence interval of ratio of

geometric mean Cmax was 0.788, indicating the rate of absorption, as defined by Cmax, was lower for the slower dissolving tablet (77% at 30 min). Since the oral bioavailability from these tablets is shown to be comparable to that from solution (see Figures 1 and 2 below), this dissolution rate (77% in 30min) is defined as the threshold for achieving consistent exposure.

[0038] Figures 3 and 4 illustrate the dissolution data that shows that while particle size impacts dissolution, controlling the particle size to less than 89 microns will result in a dissolution rate that will ensure consistent in-vivo exposures. As indicated in Figures 3 and 4, consistent exposures are expected once apixaban tablets have greater than 77% apixaban dissolved in 30 minutes. Since the tablets with 89 microns have >77% dissolved at 30 minutes, these tablets will also exhibit exposures that are equivalent to the exposures from tablets made with smaller particles (such as the tablets with 10 micron particles shown below). Whilst dissolution rate at an apixaban particle size of 119 microns is marginally greater than 77% in 30-min for the 5-mg apixaban tablets (Figure-4), the particle size threshold claimed is less than 89 microns. This allows for the typical variability (RSD=2 to 3%) in the dissolution results, such that the oral bioavailability from tablets consistently matches that from solution.

WHAT IS CLAIMED IS:

1. A composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 89 μm and a pharmaceutically acceptable diluent or carrier.

2. A composition comprising crystalline apixaban particles having a mean particle size equal to or less than about 85 μm and a pharmaceutically acceptable diluent or carrier.

3. A composition as defined in claim 1 or claim 2, wherein said composition comprises Form N-1 of apixaban.

4. A composition as defined in claim 1, wherein particles with a D_{90} equal to or less than 89 μm.

5. A composition as defined in claim 2, wherein particles with a D_{90} equal to or less than 85 μm.

6. A composition as defined in any one of claims 1-5, wherein particles with a D_{90} equal to or less than 50 μm.

7. A composition as defined in any one of claims 1-5, wherein particles with a D_{90} equal to or less than 30 μm.

8. A composition as defined in any one of claims 1-5, wherein particles with a D_{90} equal to or less than 25 μm.

9. A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the apixaban mean particle size is 89 μm.

10. A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the apixaban mean particle size is 85 μm.

11. A composition as defined in any one of claims 1-10, further comprising:
from 1% to 2 % by weight of a surfactant.

12. A composition as defined in claim 11, wherein the surfactant is sodium lauryl sulfate.

13. A composition as defined in any one of claims 1-12 for use in treating a thromboembolic disorder.

14. Use of a composition as defined in any one of claims 1-12 in the treatment of a thromboembolic disorder.

15. Use of a composition as defined in any one of claims 1-12 in the preparation of a medicament for use in treating a thromboembolic disorder.

16. A process of manufacturing apixaban tablets having a composition as defined in any one of claims 1-12, comprising the steps of:

(1) blending raw materials prior to granulation;
(2) granulating the raw materials from the step (1) using a wet or dry granulation process;
(3) blending the granules obtained in the step (2) with extragranular raw materials;
(4) compressing the blend from the step (3) into tablets; and
(5) film coating the tablets from the step (4).

17. A process of manufacturing apixaban tablets having a composition as defined in any one of claims 1-12, comprising the steps of:

(1) blending raw materials with apixaban of controlled particle size to form a mix;

(2) adding intragranular portions of a binder, a disintegrant and at least one filler to the mix from the step (1) to form a blend;

(3) granulating the materials from the step (2) using a dry granulation process or a wet granulation process,

wherein the dry granulation process comprises:

delumping an intragranular lubricant using a screen or mill;

adding the intragranular lubricant to the blend from the step (2) and blending to form a lubricated blend;

compacting the lubricated blend to ribbons of density in a range of 1.1 to 1.2 g/cc and sizing the compacted ribbons using a roller compactor, and

wherein the wet granulation process comprises:

wet granulating the blend from the step (2) using water to a target end point and, optionally, sizing the wet-granules by passing through a screen or mill;

removing the water from the granulation by drying in a convection oven or a fluid-bed dryer; and

sizing the dried granules by passing through a screen or mill;

(4) blending the granules obtained in the step (3) and an extragranular disintegrant in a blender;

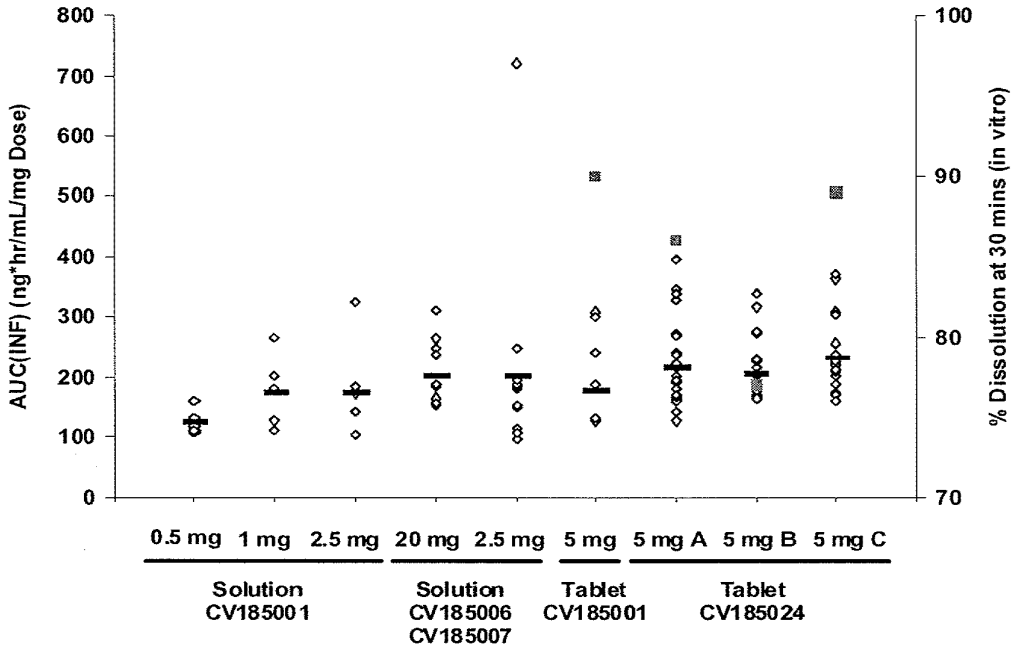
(5) delumping an extragranular lubricant using a screen or mill and blending with granules from the step (4);

(6) compressing the blend from the step (5) into tablets; and

(7) film coating the tablets from the step (6).

18. A process of manufacturing apixaban tablets according to claim 17, wherein the dry granulation process is used.

Figure 1: Scatter Plot of Individual Dose-Normalized AUC(INF) Values for Solutions (CV185001, CV185006, and CV185007) and Tablets (CV185001 and CV185024)

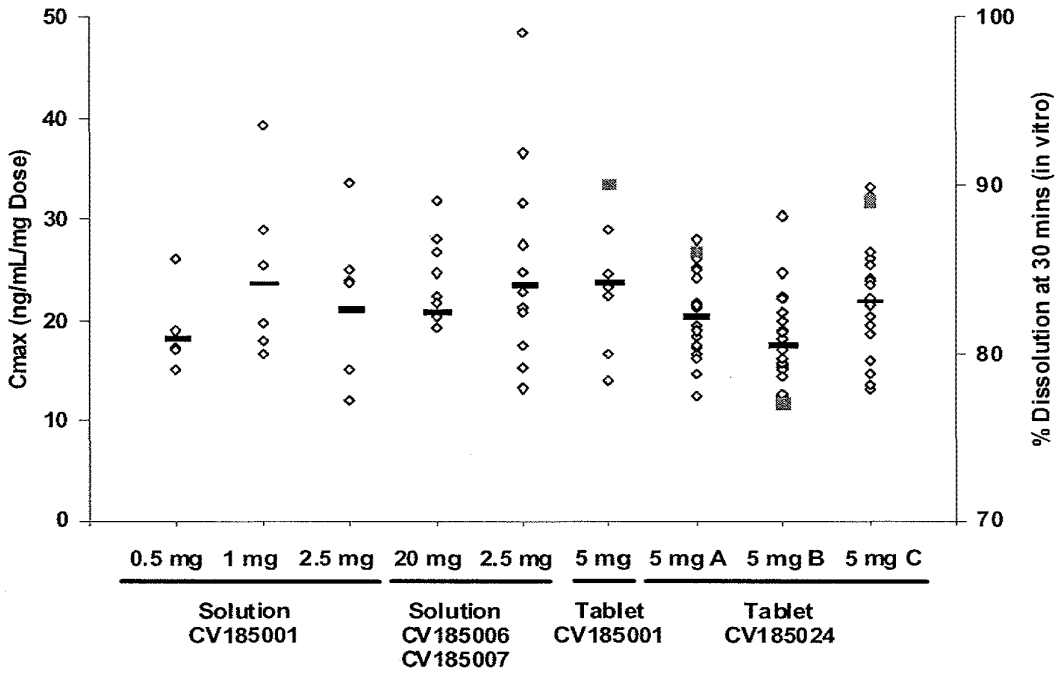


Source: CV185001, CV185006, CV185007, and CV185024 Clinical Study Reports

The solid line represents the geometric mean of AUC(INF) and the solid square represents the average %in-vitro dissolved at 30 minutes (using QC method in Table 1.2C). The X-axis represents the dose administered.

For CV185024, 5 mg A = Apixaban Phase 2 tablet (86% dissolution) 2x2.5 mg (reference formulation), 5 mg B = Apixaban Phase 2 tablet (77% dissolution) 2x2.5 mg, 5 mg C = Apixaban Phase 3 tablet (89% dissolution) 2x2.5 mg.

Figure 2: Scatter Plot of Individual Dose Normalized Cmax Values for Solutions (CV185001, CV185006, and CV185007) and Tablets (CV185001 and CV185024)



Source: CV185001, CV185006, CV185007, and CV185024 Clinical Study Reports

The solid line represents the geometric mean of Cmax and the solid square represents the average %in-vitro dissolved at 30 minutes (using QC method in Table 1.2C). The X-axis represents the dose administered.

For CV185024, 5 mg A = Apixaban Phase 2 tablet (86% dissolution) 2x2.5 mg (reference formulation), 5 mg B = Apixaban Phase 2 tablet (77% dissolution) 2x2.5 mg, 5 mg C = Apixaban Phase 3 tablet (89% dissolution) 2x2.5 mg.

Figure 3: Dissolution Rates of 2.5-mg Apixaban Tablets Using Drug Substance of Different Particle Size

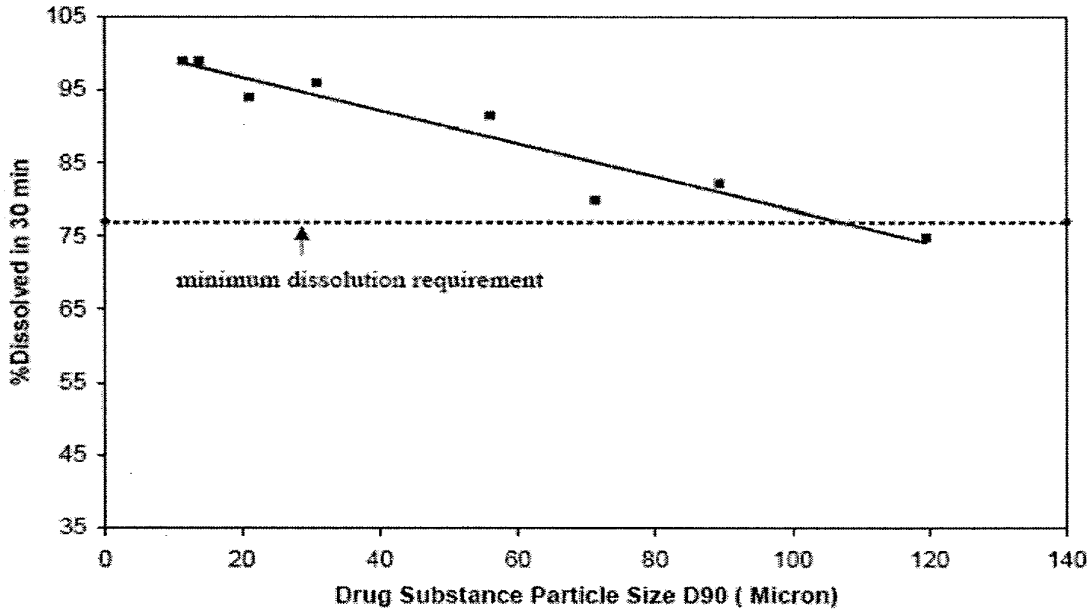
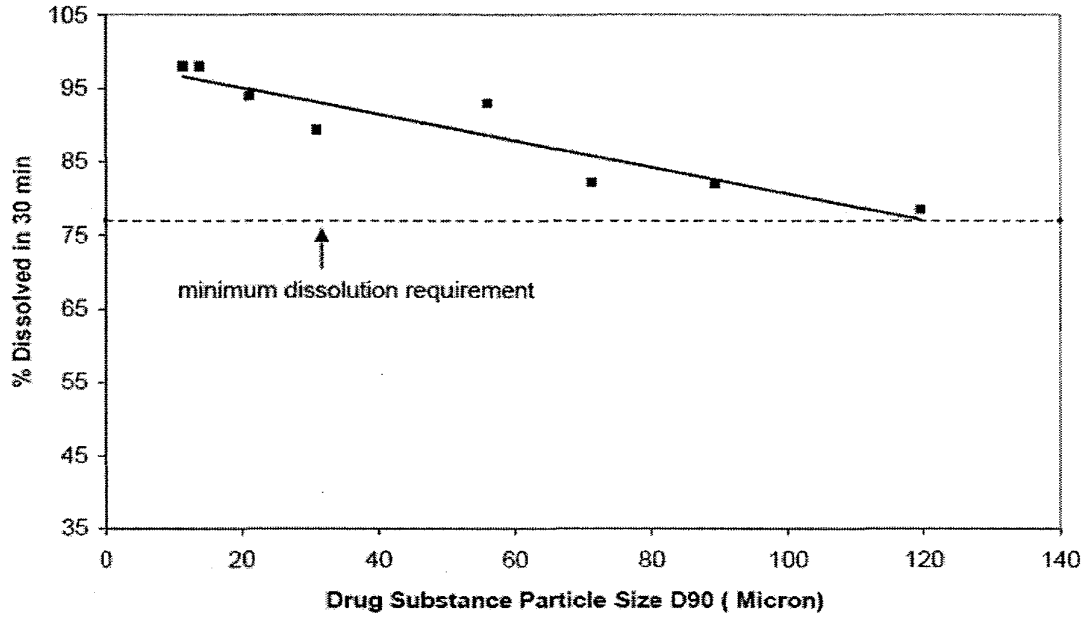


Figure 4: Dissolution Rates of 5-mg Apixaban Tablets Using Drug Substance of Different Particle Size



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(71) Applicants *(for all designated States except US)*: **BRISTOL-MYERS SQUIBB COMPANY** [US/US]; Rt. 206 & Province Line Road, Princeton, NJ 08543-4000 (US). **PFIZER INC.** [US/US]; 234 East 42nd Street, New York, NY 10017 (US).

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(75) Inventors/Applicants *(for US only)*: **PATEL, Jatin** [US/US]; c/o Bristol-Myer Squibb Company, 1 Squibb Drive, New Brunswick, NJ 08903 (US). **FROST, Charles** [US/US]; c/o Bristol-Myer Squibb Company, Route 206 And Province Line Road, Princeton, NJ 08543 (US). **JIA, Jingpin** [US/US]; c/o Bristol-Myer Squibb Company, 1 Squibb Drive, New Brunswick, NJ 08903 (US). **VEMAVARAPU, Chandra** [IN/US]; c/o Bristol-Myer Squibb Company, 1 Squibb Drive, New Brunswick, NJ 08903 (US).

(74) Agents: **OKUN, Jason, M.** et al.; Fitzpatrick, Cella, Harper & Scinto, 1290 Avenue Of The Americas, New York, NY 10104-3801 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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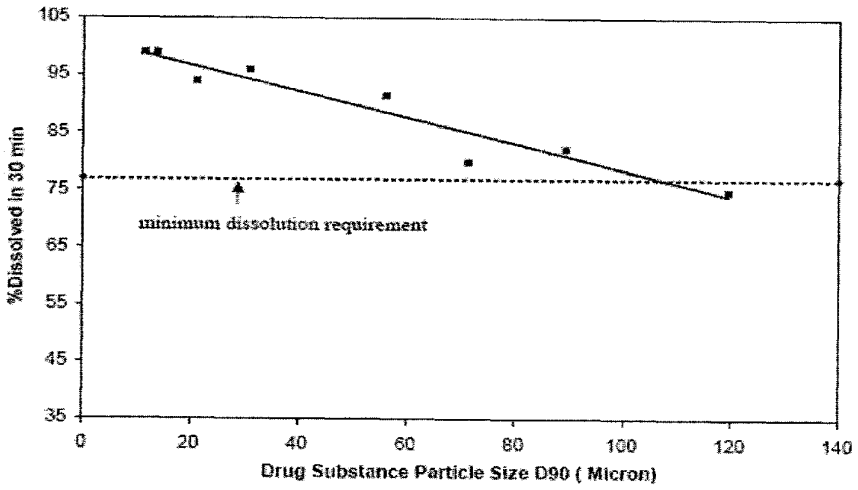
[Continued on next page]

(54) Title: APIXABAN FORMULATIONS

Figure 3: Dissolution Rates of 2.5-mg Apixaban Tablets Using Drug Substance of Different Particle Size



(57) Abstract: Compositions comprising crystalline apixaban particles having a D_{90} equal to or less than 89 μm, and a pharmaceutically acceptable carrier, are substantially bioequivalent and can be used to for the treatment and/or prophylaxis of thromboembolic disorders.

WO 2011/106478 A3

WO 2011/106478 A3

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
13/579,796	Jatin Patel	03822.000060.

5514
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

INTERNATIONAL APPLICATION NO.	
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I.A. FILING DATE	PRIORITY DATE
02/24/2011	02/25/2010

CONFIRMATION NO. 2947
371 FORMALITIES LETTER

OC000000056251706

Date Mailed: 08/29/2012

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated Office (37 CFR 1.494):

- Priority Document
- Copy of the International Application filed on 08/17/2012
- Copy of the International Search Report filed on 08/17/2012
- Preliminary Amendments filed on 08/17/2012
- U.S. Basic National Fees filed on 08/17/2012
- Priority Documents filed on 08/17/2012

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is $**130** for a Large Entity:

- $**130** Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
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TONI M HOOD

Telephone: (571) 272-3654

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/579,796

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	380
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	490
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	250
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3			OR	x 60 =	180
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 250 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1300

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

Substitute for Form PTO-1360
(For use with Form PTO/SB/06)

Application Number	Filing Date
13579796	

Applicant(s) Jatin Patel

* May be used for additional claims or amendments

CLAIMS	AS FILED		AFTER FIRST AMENDMENT		AFTER SECOND AMENDMENT	
	Indep	Depend	Indep	Depend	Indep	Depend
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2	1		1			
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Total Indep	2		2		0	
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Total Claims	19		23		0	

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PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	N.Y.A.
Examiner Name	N.Y.A.
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	6967208	B2	2005-11-22	PINTO ET AL.	

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	1	20060160841	A1	2006-07-20	WEI ET AL.	
	2	20120087978	A1	2012-04-12	NAUSE	

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	1	2008/031782	WO	A1	2008-03-20	GLAXO GROUP LTD.		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	N.Y.A.
	Examiner Name	N.Y.A.
	Attorney Docket Number	03822.000060.

	2	2010/003811	WO	A1	2010-01-14	BASF SE		☐
	3	2009/135947	WO	A2	2009-11-12	ATACAMA LABS OY		☐
	4	2006/108643	WO	A2	2006-10-19	NOVARTIS AG		☐
	5	2007/022165	WO	A2	2007-02-22	BRISTOL-MYERS SQUIBB COMPANY		☐
	6	2010/147978	WO	A1	2010-12-23	PFIZER INC.; BRISTOL-MYERS SQUIBB COMPANY		☐

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	1	Amidon et al., "A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of in Vitro Drug Product Dissolution and in Vivo Bioavailability", Pharmaceutical Research, Vol. 12, pp. 413-420, 1995.	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	N.Y.A.
	Examiner Name	N.Y.A.
	Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2012-09-25
Name/Print	Jason M. Okun	Registration Number	48512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Not Yet Assigned
JATIN PATEL ET AL.	)	
	:	Group Art Unit: Not Yet Assigned
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	September 25, 2012

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of the foreign patent documents and non-patent literature are provided.

This Information Disclosure Statement is, in part, to make of record documents cited in the specification and in the International Search Report and the Written Opinion issued during the international stage of the subject national stage application. Copies of the International Search Report and the Written Opinion were submitted upon entry into the U.S. national stage.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Acknowledgement Receipt

EFS ID:	13829140
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	25-SEP-2012
Filing Date:	
Time Stamp:	14:14:28
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	IDSRef1.pdf	1602381 46f55cce2eaea5016a87efe39bd10af97be844d0	no	36

Warnings:	
Information:	

2	Foreign Reference	IDSRef2.pdf	1738946 78a3231ad7627be15dac6ec7c01d78b6f696f31c	no	32
Warnings:					
Information:					
3	Foreign Reference	IDSRef3.pdf	4331890 5bc131f1bc97c89cae9eb68e4b966c783d3728db	no	69
Warnings:					
Information:					
4	Foreign Reference	IDSRef4.pdf	1470087 0968b0815793530bc2580b3bdfced461f884dd35	no	34
Warnings:					
Information:					
5	Foreign Reference	IDSRef5.pdf	1124519 453de153fb85fc4190e063885a9599a7e282f5e7	no	26
Warnings:					
Information:					
6	Foreign Reference	IDSRef6.pdf	4820037 45f41b926b40cad0e87bf28e63e7d81b6510b7e2	no	90
Warnings:					
Information:					
7	Non Patent Literature	IDSRef7.pdf	2884687 f963e866f829ecf946cf029b8d9ac9175a00a13e	no	8
Warnings:					
Information:					
8	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.PDF	542067 a271b7e4debfc761e9db43c7a8876c0a1bbbd6ab	no	4
Warnings:					
Information:					
9	Transmittal Letter	IDSTRANS03822000060USA600.pdf	55178 fdc60bb49039fa105eea1010cb4e0bb0dcba985c	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	18569792	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Not Yet Assigned
JATIN PATEL ET AL.	)	
	:	Group Art Unit: Not Yet Assigned
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	October 10, 2012

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTENTION: APPLICATION PROCESSING DIVISION, SPECIAL PROCESSING AND CORRESPONDENCE BRANCH

RESPONSE TO NOTIFICATION OF MISSING
REQUIRMENTS UNDER 35 U.S.C. 371

Sir:

In response to the NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371, mailed August 29, 2012, submitted herewith is an executed Declaration/Power of Attorney form. The $130 fee is being paid concurrently via Deposit Account 50-3939. The Commissioner is authorized to charge any deficiency in this fee, or credit any overpayment, to the same Deposit Account.

Since this communication is submitted via EFS-Web, a copy of the NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 is not returned.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Nancy Ramadan
Attorney Docket Number:	03822.000060.

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Oath/decl > 30 months from priority date	1617	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**130**

Electronic Acknowledgement Receipt

EFS ID:	13949475
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	10-OCT-2012
Filing Date:	
Time Stamp:	14:35:16
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$130
RAM confirmation Number	962
Deposit Account	503939
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	DEC03822000060.pdf	306747 410db943eecd6ba3ccba741a24195c0a0d3c152c	no	8
Warnings:					
Information:					
2	Applicant Response to Pre-Exam Formalities Notice	RESPNFMREQ03822000060.pdf	80944 9c5309fb8ac45e18187a39214c5ed4364a2aea97	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30041 55b1480b5d42e3d50ba82e1984dc420c603aff44	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	417732		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

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COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION
(Page 1)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

APIXABAN FORMULATIONS

the specification of which ☐ is attached hereto ☒ was filed on 24 February 2011
as United States Application No. or PCT International Application No. PCT/US2011/025994 (U.S. Application No. 13/579,796)
and was amended on 17 August 2012 (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application No.	Filed (Day/Mo./Yr.)
61/308,056	25 February 2010

I hereby appoint the practitioners associated with the firm and Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to the address associated with that Customer Number:

FITZPATRICK, CELLA, HARPER & SCINTO
Customer Number: 05514

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole or First Inventor: Jatin PATEL
Inventor's signature:
Date: Citizen/Subject of: US
Residence: West Windsor, New Jersey
Post Office Address: c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Second Joint Inventor, if any: Charles FROST
Second Inventor's signature:
Date: Citizen/Subject of: US
Residence: Yardley, Pennsylvania
Post Office Address: c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Third Joint Inventor, if any Jingpin JIA

Second Inventor's signature Li Jia

Date 28 September 2012 Citizen/Subject of US

Residence Belle Mead, New Jersey

Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Fourth Joint Inventor, if any Chandra VEMA-VARAPU

Second Inventor's signature

Date Citizen/Subject of IN

Residence Hillsborough, New Jersey

Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION
(Page 1)

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FITZPATRICK, CELLA, HARPER & SCINTO
Customer Number: 05514

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Full Name of Sole or First Inventor Jatin PATEL
Inventor's signature
Date Citizen/Subject of US
Residence West Windsor, New Jersey
Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Second Joint Inventor, if any Charles FROST
Second Inventor's signature
Date 3-Oct-2012 Citizen/Subject of US
Residence Yardley, Pennsylvania
Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Third Joint Inventor, if any Jingpin JIA

Second Inventor's signature

Date Citizen/Subject of US

Residence Belle Mead, New Jersey

Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Fourth Joint Inventor, if any Chandra VEMA-VARAPU

Second Inventor's signature

Date Citizen/Subject of IN

Residence Hillsborough, New Jersey

Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION
(Page 1)

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FITZPATRICK, CELLA, HARPER & SCINTO
Customer Number: 05514

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole or First Inventor Jatin PATEL
Inventor's signature Jmpatel 26 SEPT 2012
Date 26 SEPT. 2012 Citizen/Subject of US
Residence West Windsor, New Jersey
Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Second Joint Inventor, if any Charles FROST
Second Inventor's signature
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Residence Yardley, Pennsylvania
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COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
(Page 2)

Full Name of Third Joint Inventor, if any Jingpin JIA

Second Inventor's signature

Date Citizen/Subject of US

Residence Belle Mead, New Jersey

Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Fourth Joint Inventor, if any Chandra VEMA-VARAPU

Second Inventor's signature

Date Citizen/Subject of IN

Residence Hillsborough, New Jersey

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(Page 1)

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APIXABAN FORMULATIONS

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FITZPATRICK, CELLA, HARPER & SCINTO
Customer Number: 05514

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole or First Inventor: Jatin PATEL
Inventor's signature:
Date: Citizen/Subject of: US
Residence: West Windsor, New Jersey
Post Office Address: c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Second Joint Inventor, if any: Charles FROST
Second Inventor's signature:
Date: Citizen/Subject of: US
Residence: Yardley, Pennsylvania
Post Office Address: c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
(Page 2)

Full Name of Third Joint Inventor, if any Jingpin JIA

Second Inventor's signature

Date Citizen/Subject of US

Residence Belle Mead, New Jersey

Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

Full Name of Fourth Joint Inventor, if any Chandra ~~VEMA VARAPU~~ VEMAVARAPU CV 27 Sept, 12

Second Inventor's signature

Date 27 Sept, 2012 Citizen/Subject of ~~IN~~ US

Residence Hillsborough, New Jersey

Post Office Address c/o Bristol-Myers Squibb Company
Route 206 and Province Line Road, Princeton, NJ 08543

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	N.Y.A.
Examiner Name	N.Y.A.
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6150366	A	2000-11-21	ARENSON ET AL.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	N.Y.A.
	Examiner Name	N.Y.A.
	Attorney Docket Number	03822.000060.

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	N.Y.A.
Examiner Name	N.Y.A.
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2012-10-24
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	14073319
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	25-OCT-2012
Filing Date:	
Time Stamp:	16:16:36
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.PDF	541581 2e5015ec0638362 1b62d7fae0203b52f316f 7810	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	541581

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
13/579,796	Jatin Patel	03822.000060.

5514
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

INTERNATIONAL APPLICATION NO.	
PCT/US11/25994	
I.A. FILING DATE	PRIORITY DATE
02/24/2011	02/25/2010

CONFIRMATION NO. 2947
371 ACCEPTANCE LETTER

OC000000057560762

Date Mailed: 11/14/2012

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

10/10/2012	10/10/2012
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 08/17/2012
- Copy of the International Search Report filed on 08/17/2012
- Preliminary Amendments filed on 08/17/2012
- Information Disclosure Statements filed on 10/25/2012
- Oath or Declaration filed on 10/10/2012
- U.S. Basic National Fees filed on 08/17/2012
- Priority Documents filed on 08/17/2012

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

TONI M HOOD

Telephone: (571) 272-3654

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/579,796

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	390
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	250
TOTAL CLAIMS (37 CFR 1.16(i))	23 minus 20 =	* 3			OR	x 62 =	186
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 250 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1326

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/579,796	10/10/2012		1430	03822.000060.	23	2

CONFIRMATION NO. 2947

5514
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

FILING RECEIPT

OC000000057560761

Date Mailed: 11/14/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Jatin Patel, West Windsor, NJ;
Charles Frost, Yardley, PA;
Jingpin Jia, Belle Mead, NJ;
Chandra Vema-Varapu, Hillsborough, NJ;

Applicant(s)

Jatin Patel, West Windsor, NJ;
Charles Frost, Yardley, PA;
Jingpin Jia, Belle Mead, NJ;
Chandra Vema-Varapu, Hillsborough, NJ;

Assignment For Published Patent Application

BRISTOL-MYERS SQUIBB COMPANY, Princeton, NJ
PFIZER, INC., New York, NY

Power of Attorney: The patent practitioners associated with Customer Number 05514

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US11/25994 02/24/2011
which claims benefit of 61/308,056 02/25/2010

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 11/09/2012
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/579,796**

Projected Publication Date: 02/21/2013

Non-Publication Request: No

Early Publication Request: No
Title

APIXABAN FORMULATIONS

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Not Yet Assigned
JATIN PATEL ET AL.	)	
	:	Group Art Unit: Not Yet Assigned
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	November 19, 2012

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CORRECTED FILING RECEIPT

Sir:

Applicants' attorneys have received an official Filing Receipt in the above-identified application on which the last name of the fourth inventor is incorrect.

Specifically, the Filing Receipt lists the last name of the fourth inventor as "Vema-Varapu". As indicated above the signature of the fourth inventor on the Combined Declaration filed October 10, 2012, the correct spelling of the last name of the fourth inventor is "Vemavarapu". Therefore, the name of the fourth inventor and Applicant on the Filing Receipt should read as follows:

--Chandra Vemavarapu, Hillsborough, NJ--.

Issuance of a corrected Filing Receipt, corrected as shown above, is accordingly respectfully requested. To assist the Office in making the corrections, Applicants submit herewith an updated Application Data Sheet. Also, a marked-up copy of the Filing Receipt showing the above change is attached.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	TOT CLAIMS	IND CLAIMS
13/579,796	10/10/2012		1430	03822.00006	23	2

CONFIRMATION NO. 2947

5514
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

FILING RECEIPT

Date Mailed: 11/14/2012

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Inventor(s)

Jatin Patel, West Windsor, NJ;
Charles Frost, Yardley, PA;
Jingpin Jia, Belle Mead, NJ; **Vemavarapu**
Chandra ~~Vema-Varapu~~, Hillsborough, NJ;

Applicant(s)

Jatin Patel, West Windsor, NJ;
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Chandra ~~Vema-Varapu~~, Hillsborough, NJ;

Assignment For Published Patent Application

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PFIZER, INC., New York, NY

Power of Attorney: The patent practitioners associated with Customer Number 05514

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which claims benefit of 61/308,056 02/25/2010

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If Required, Foreign Filing License Granted: 11/09/2012
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/579,796**

Projected Publication Date: 02/21/2013

Non-Publication Request: No

Early Publication Request: No
Title

APIXABAN FORMULATIONS

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

Electronic Acknowledgement Receipt

EFS ID:	14261280
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	19-NOV-2012
Filing Date:	10-OCT-2012
Time Stamp:	16:06:26
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	CRTDADS03822000060.PDF	1089082 cc947f0259725b831db9a5af6a57d33990a8fb52	no	6

Warnings:	
Information:	

2	Request for Corrected Filing Receipt	REQCRTDFILRCPT03822000060.pdf	54839 2977e18a8155f3c246ae632eda747ea6cd5a8b10	no	2
Warnings:					
Information:					
3	Request for Corrected Filing Receipt	MarkedupOFR03822000060.pdf	689260 91cceb2448fded1226d4693e507a378136977557	no	3
Warnings:					
Information:					
			Total Files Size (in bytes):	1833181	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/14 (11-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jatin		Patel	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	West Windsor	State/Province	NJ	Country of Residence[i]	US

Citizenship under 37 CFR 1.41(b)[i] US

Mailing Address of Applicant:

Address 1	c/o Bristol-Myers Squibb Company
Address 2	Route 206 and Province Line Road

City	Princeton	State/Province	NJ
Postal Code	08543	Country[i]	US

Applicant 2 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Charles		Frost	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Yardley	State/Province	PA	Country of Residence[i]	US

Citizenship under 37 CFR 1.41(b)[i] US

Mailing Address of Applicant:

Address 1	c/o Bristol-Myers Squibb Company
Address 2	Route 206 and Province Line Road

City	Princeton	State/Province	NJ
Postal Code	08543	Country[i]	US

Applicant 3 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jingpin		Jia	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Belle Mead	State/Province	NJ	Country of Residence[i]	US

PTO/SB/14 (11-08)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

Citizenship under 37 CFR 1.41(b) i	US				
Mailing Address of Applicant:					
Address 1	c/o Bristol-Myers Squibb Company				
Address 2	Route 206 and Province Line Road				
City	Princeton	**State/Province**	NJ		
Postal Code	08543	**Country**i	US		

Applicant 4 Remove

Applicant Authority (•) Inventor ( ) Legal Representative under 35 U.S.C. 117 ( ) Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Chandra		Vemavarapu	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Hillsborough	**State/Province**	NJ	**Country of Residence** i	US
Citizenship under 37 CFR 1.41(b) i	US				
Mailing Address of Applicant:					
Address 1	c/o Bristol-Myers Squibb Company				
Address 2	Route 206 and Province Line Road				
City	Princeton	**State/Province**	NJ		
Postal Code	08543	**Country**i	US		

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	05514		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	APIXABAN FORMULATIONS		
Attorney Docket Number	03822.000060.	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	4	**Suggested Figure for Publication (if any)**	

PTO/SB/14 (11-08)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	05514		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	a 371 of international	PCT/US2011/025994	2011-02-24
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
PCT/US2011/025994	non provisional of	61308056	2010-02-25

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			◉ Yes ○ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

PTO/SB/14 (11-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1 Remove

If the Assignee is an Organization check here. ☒			
Organization Name	Bristol-Myers Squibb Company		
Mailing Address Information:			
Address 1	Route 206 and Province Line Road		
Address 2			
City	Princeton	**State/Province**	NJ
Country [i]	US	Postal Code	08543
Phone Number		Fax Number	
Email Address			

Assignee 2 Remove

If the Assignee is an Organization check here. ☒			
Organization Name	Pfizer, Inc.		
Mailing Address Information:			
Address 1	235 East 42nd Street		
Address 2			
City	New York	**State/Province**	NY
Country [i]	US	Postal Code	10017
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the **Add** button. Add

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/			Date (YYYY-MM-DD)	2012-11-19
First Name	Jason	Last Name	Okun	Registration Number	48512

PTO/SB/14 (11-08)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	03822.000060.
	Application Number	
Title of Invention	APIXABAN FORMULATIONS	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/579,796	10/10/2012		1430	03822.000060.	23	2

CONFIRMATION NO. 2947

CORRECTED FILING RECEIPT

5514
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

OC000000057709290

Date Mailed: 11/20/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Jatin Patel, West Windsor, NJ;
Charles Frost, Yardley, PA;
Jingpin Jia, Belle Mead, NJ;
Chandra Vemavarapu, Hillsborough, NJ;

Applicant(s)

Jatin Patel, West Windsor, NJ;
Charles Frost, Yardley, PA;
Jingpin Jia, Belle Mead, NJ;
Chandra Vemavarapu, Hillsborough, NJ;

Assignment For Published Patent Application

BRISTOL-MYERS SQUIBB COMPANY, Princeton, NJ
PFIZER, INC., New York, NY

Power of Attorney: The patent practitioners associated with Customer Number 05514

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US11/25994 02/24/2011
which claims benefit of 61/308,056 02/25/2010

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 11/09/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/579,796**

Projected Publication Date: 02/21/2013

Non-Publication Request: No

Early Publication Request: No
Title

APIXABAN FORMULATIONS

Preliminary Class

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

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For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/579,796	10/10/2012	Jatin Patel	03822.000060.

CONFIRMATION NO. 2947

5514
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

PUBLICATION NOTICE

OC000000059443068

Title:APIXABAN FORMULATIONS

Publication No.US-2013-0045245-A1
Publication Date:02/21/2013

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	First Examination Report in New Zealand Application No. 601738 (April 29, 2013).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2013-05-14
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	May 14, 2013

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of this document is provided.

This Information Disclosure Statement is to submit a copy of an Examination Report that was issued on April 29, 2013 in a corresponding New Zealand application. All documents cited in this Examination Report are from the International

Preliminary Report on Patentability that was issued during the international stage of the subject national stage application and are already of record.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Acknowledgement Receipt

EFS ID:	15770757
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/Yuvindra Mankaran
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	17-MAY-2013
Filing Date:	10-OCT-2012
Time Stamp:	17:05:07
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	541616 8e632593bafda18c2d1fa97208b8b39fd7dc79dd	no	4

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A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	Other Reference-Patent/App/Search documents	IDSDOC.PDF	132132 c5103c5dc68f25586d5558b4d73bef50582ce611	no	2
Warnings:					
Information:					
3	Transmittal Letter	IDSTRANS03822000060.pdf	54455 3fe0af0a0943108f677cf19cda44a7ab17b6626f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	728203		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Official Action in Mexican Application No. MX/2012/060772 (issued June 14, 2013).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	13579796
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Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

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OR

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2013-07-29
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	16451101
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	30-JUL-2013
Filing Date:	10-OCT-2012
Time Stamp:	14:34:42
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDSTRANS03822000060USA600.pdf	55560 7d82d7f98c2ff20c17f8569b8da1f36ed37256c1	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.PDF	541589 4cf27f9eb0a960a1d62fdab0ba09eaa2e546d43a	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

3	Non Patent Literature	IDSDoc.pdf	974338 d26732bc42537d1414dfdd8cf56cdab1ba8e61d5	no	20

Warnings:

Information:

Total Files Size (in bytes):	1571487

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	July 29, 2013

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of this document is provided.

This Information Disclosure Statement is to submit a copy of an Official Action that was issued on June 14, 2013 in a corresponding Mexican application. All documents cited in this Official Action are already of record (US 2006/0069258 A1 is a pre-grant publication of U.S. Patent No. 7,396,932 B2).

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Communication pursuant to Article 94(3) EPC in European Application No. 11707284.3 (issued June 28, 2013).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2013-08-16
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	August 16, 2013

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of this document is provided.

This Information Disclosure Statement is to submit a copy of an Examination Report that was issued on June 28, 2013 in a corresponding European application. All documents cited in this European Examination Report are already of record (US 2006/0069258 A1 is a pre-grant publication of U.S. Patent No. 7,396,932 B2).

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Acknowledgement Receipt

EFS ID:	16609330
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	16-AUG-2013
Filing Date:	10-OCT-2012
Time Stamp:	13:54:41
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	541636 442cdf9765cc701dd97fb24febfabd62f4ddd968	no	4

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A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	Other Reference-Patent/App/Search documents	IDSDoc.PDF	493734 78a8d0df0611a6f27b0474b871691327f4167886	no	11
Warnings:					
Information:					
3	Transmittal Letter	IDSTRANS03822000060.pdf	55580 90b50305d135e69baa2f77877e6fe66b1cd2da18	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1090950		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	101516355	CN	A	2009-08-26	GLAXO GROUP LTD.		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	First Office Action in Chinese Application No. 201180011229.X (issued August 9, 2013).	☒

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2013-09-25
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	16950271
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	25-SEP-2013
Filing Date:	10-OCT-2012
Time Stamp:	14:56:48
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDSTRANS03822000060.pdf	55815 652f200166899770926e4f1bbdf9b4bd368e008c	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.PDF	541682 c0679aace740b37fa0a74855a2e7e8c85fd38e81	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
3	Foreign Reference	IDSRef1.pdf	3191071 045c3ce7a2c643f96f1e89ed62bc6307da065ac9	no	30
Warnings:					
Information:					
4	Non Patent Literature	IDSDoc.PDF	496394 1db2977c50322714cc0ffcdd94df6bd68f9ac0e8	no	14
Warnings:					
Information:					
			Total Files Size (in bytes):	4284962	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	September 25, 2013

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of these documents are provided.

This Information Disclosure Statement is to submit a copy of a first Office Action that was issued on August 9, 2013 in a corresponding Chinese application. An English language translation of the Chinese Office Action is provided.

The concise explanation of relevance for CN 101516355 may be found in the English language abstract attached thereto, in its corresponding WIPO publication WO 2008/031782 (already of record), and/or in the aforementioned English language translation of the Chinese Office Action.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 10/29/2013

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
BARHAM, BETHANY P	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/29/2013	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/579,796	Applicant(s) PATEL ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-13 and 16-25* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) _____ is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☒ Claim(s) *1-13 and 16-25* are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some * c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Election/Restrictions

REQUIREMENT FOR UNITY OF INVENTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-4, and 6-12, drawn to a composition.

Group II, claim(s) 2, and 19-24, drawn to a different composition.

Group III, claim(s) 13, drawn to a method for treatment with the composition.

Group I, claim(s) 16, drawn to a method of making.

Group V, claim(s) 17-18, drawn to a different method of making.

Group VI, claim(s) 25, drawn to a method for treatment with the different composition.

There is no special technical feature, as the groups of inventions are not linked to form a single special technical feature. Firstly, Group I and Group II have different sizes and as such the common technical feature is “[a] composition comprising crystalline apixaban particles and a pharmaceutically acceptable diluent or carrier” and secondly this common technical feature is known in the art as evidenced by at least US

2006/0160841 which teaches a slurry of PG and water comprising N-1 form of apixaban particles of D_{90} of less than 20 microns (see Examples).

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Rejoinder

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims

that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BETHANY BARHAM whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bethany Barham/
Primary Examiner, Art Unit 1615

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	January 27, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT,
AMENDMENT, AND PETITION FOR EXTENSION OF TIME

Sir:

Applicants petition to extend the time for response to the Office Action dated October 29, 2013 to January 29, 2014. The fee for the extension is paid concurrently herewith. Please charge any additional fee required for the extension, and credit any overpayment, to Deposit Account 50-3939.

In response to the Office Action dated October 29, 2013, please amend the above-captioned application as follows.

CLAIMS

A complete listing of all the claims appears below; this listing replaces all earlier amendments and listings of the claims.

1. (Currently Amended) A pharmaceutical composition comprising apixaban and a pharmaceutically acceptable diluent or carrier,

wherein the apixaban is in particulate and crystalline form, and

wherein apixaban particles in the pharmaceutical composition have a D_{90} ~~having a mean particle size~~ equal to or less than about 89 μm ~~and a pharmaceutically acceptable diluent or carrier~~.

2. (Cancelled)

3. (Previously Presented) A composition as defined in claim 1, wherein said composition comprises Form N-1 of apixaban.

4. (Cancelled)

5. (Currently Amended) A composition as defined in claim 1 ~~claim 2~~, wherein the ~~particles with a~~ D_{90} is equal to or less than 85 μm.

6. (Currently Amended) A composition as defined in claim 1, wherein the ~~particles with a~~ D_{90} is equal to or less than 50 μm.

7. (Currently Amended) A composition as defined in claim 1, wherein the ~~particles with a~~ D_{90} is equal to or less than 30 μm.

8. (Currently Amended) A composition as defined in claim 1, wherein the ~~particles with a~~ D_{90} is equal to or less than 25 μm.

9. (Currently Amended) A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the D_{90}~~apixaban mean particle size~~ is 89 μm.

10. (Currently Amended) A composition as defined in claim 1 which exhibits an AUC and/or C_{max} that is at least 80% of the mean AUC and/or C_{max} observed for an equivalent formulation differing only in that the D_{90}~~apixaban mean particle size~~ is 85 μm.

11. (Previously Presented) A composition as defined in claim 1, further comprising:

from 1% to 2 % by weight of a surfactant.

12. (Original) A composition as defined in claim 11, wherein the surfactant is sodium lauryl sulfate.

13. (Previously Presented) A method for the treatment or prophylaxis of a thromboembolic disorder, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition as defined in claim 1.

14-15. (Cancelled)

16. (Previously Presented) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials prior to granulation;

(2) granulating the raw materials from the step (1) using a wet or dry granulation process;

(3) blending the granules obtained in the step (2) with extragranular raw materials;

(4) compressing the blend from the step (3) into tablets; and

(5) film coating the tablets from the step (4).

17. (Previously Presented) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials with apixaban of controlled particle size to form a mix;

(2) adding intragranular portions of a binder, a disintegrant and at least one filler to the mix from the step (1) to form a blend;

(3) granulating the materials from the step (2) using a dry granulation process or a wet granulation process,

wherein the dry granulation process comprises:

delumping an intragranular lubricant using a screen or mill;

adding the intragranular lubricant to the blend from the step (2) and blending to form a lubricated blend;

compacting the lubricated blend to ribbons of density in a range of 1.1 to 1.2 g/cc and sizing the compacted ribbons using a roller compactor, and

wherein the wet granulation process comprises:

wet granulating the blend from the step (2) using water to a target end point and, optionally, sizing the wet-granules by passing through a screen or mill;

removing the water from the granulation by drying in a convection oven or a fluid-bed dryer; and

sizing the dried granules by passing through a screen or mill;

(4) blending the granules obtained in the step (3) and an extragranular disintegrant in a blender;

(5) delumping an extragranular lubricant using a screen or mill and blending with granules from the step (4);

(6) compressing the blend from the step (5) into tablets; and

(7) film coating the tablets from the step (6).

18. (Original) A process of manufacturing apixaban tablets according to claim 17, wherein the dry granulation process is used.

19-25. (Cancelled)

REMARKS

The claims are 1, 3, 5-13, and 16-18, with claim 1 being independent. Claims 2, 4, and 19-25 have been cancelled without prejudice or disclaimer. Claim 1 has been amended to clarify the claimed invention. Support for this amendment may be found, *inter alia*, in cancelled claim 4, as well as in the specification at paragraphs [0007] and [0014]. Claim 5 has been amended to reflect the cancellation of claim 2. Claims 6-10 have been amended to reflect the changes made in claim 1. No new matter has been added. Favorable consideration of the claims is respectfully requested.

The Office Action has alleged that the claims do not satisfy the unity of invention requirement and required election of one of the following VI groups of claims:

Group I: Claims 1, 3, 4, and 6-12, drawn to a composition;

Group II: Claims 2, 5, and 19-24, drawn to a different composition;

Group III: Claim 13, drawn to a method for treatment with the composition;

Group IV: Claim 16, drawn to a method of making;

Group V: Claims 17 and 18, drawn to a different method of making; and

Group VI: Claim 25, drawn to a method for treatment with the different composition.

Applicants hereby provisionally elect Group I, claims 1, 3, 4, and 6-12, with traverse.

In particular, the Office Action based the lack of unity on the alleged disclosure by U.S. Patent Application Publication No. 2006/0160841 A1 (Wei) of a slurry of PG and water comprising N-1 form of apixaban and on the disclosure of particles with a D_{90} of less than 20 microns mentioned in the Examples. However, the claims as presented herein refer to a pharmaceutical composition that includes, aside from apixaban particles with the specific D_{90}, a pharmaceutically acceptable carrier or diluent. It is clear that the slurry as disclosed in Wei is not such a pharmaceutical composition.

Accordingly, Applicants respectfully submit that all claims are linked by a special technical feature, which is neither disclosed nor suggested by the prior art. Thus, the claims do not lack unity and should be examined together.

Wherefore, withdrawal of the restriction requirement and examination of all claims on the merits is respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun
Attorney Docket Number:	03822.000060.

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with $0 paid	1252	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt

EFS ID:	18029543
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	27-JAN-2014
Filing Date:	10-OCT-2012
Time Stamp:	15:37:33
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$600
RAM confirmation Number	2386
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.PDF	541576 210f22786305b0af72820545a1cba30472200241	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Other Reference-Patent/App/Search documents	IDSDoc.PDF	649677 f047424ddb4e8428a3cb3eeeb5550d13afc39f8a	no	18
Warnings:					
Information:					
3	Transmittal Letter	IDSTRANS03822000060.pdf	54791 00d71cca17c2a884636fd10a4ad644f8c9b7f15e	no	2
Warnings:					
Information:					
4		AMDEXTRESTRQ03822000060.pdf	98296 d2357992019b41ef2b0fce0468f3ea8954f0ccd3	yes	9

Multipart Description/PDF files in .zip description

Document Description	Start	End
Response to Election / Restriction Filed	1	1
Claims	2	6
Amendment/Req. Reconsideration-After Non-Final Reject	7	9

Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30443 037f834ed97c8dce7027a4c5e7816d2c4aab8328	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1374783	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Office Action in Colombian Application No. 12.152.138 (issued Nov. 5, 2013).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2014-01-24
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	January 24, 2013

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of this document is provided.

This Information Disclosure Statement is to submit a copy of an Office Action that was issued on November 5, 2013 in a corresponding Colombian application. An English language translation of the Colombian Office Action is provided. All

documents cited in this Columbian Office Action are already of record in the present application.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 02/28/2014

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
BARHAM, BETHANY P	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/28/2014	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/579,796	Applicant(s) PATEL ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/27/14*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1,3,5-13 and 16-18* is/are pending in the application.

5a) Of the above claim(s) *13 and 16-18* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3 and 5-12* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Summary

The present application is being examined under the pre-AIA first to invent provisions. Receipt of the multiple IDSs filed is acknowledged. Receipt of the Claim Amendments and Response filed on 01/27/14 is also acknowledged. Claims 1, 3, 5-13 and 16-18 are pending.

Election/Restrictions

Applicant's election with traverse of Group in the reply filed on 01/27/14 is acknowledged. The traversal is on the ground(s) that a single special technical feature now claimed is not taught by US 2006/0160841. This is not found persuasive because the claims as originally presented lack a special technical feature and Groups I-VI differ in scope and have different modes of operation, effects, and functions. Specifically, as pointed out in the 10/29/13 Election/Restriction requirement, Group I and Group II have different sizes and as such the common technical feature is "[a] composition comprising crystalline apixaban particles and a pharmaceutically acceptable diluent or carrier" and secondly this common technical feature is known in the art as evidenced by at least US 2006/0160841 which teaches a slurry of PG and water comprising N-1 form of apixaban particles of D90 of less than 20 microns (see Examples). As such, claims 13 and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim.

Claims 1, 3, and 5-12 will be examined in the instant application. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/27/14. The requirement is still deemed proper and is therefore made FINAL.

Priority- ***Claim Rejections - 35 USC § 112***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of 35 U.S.C. 112(a) or the first paragraph of pre-AIA 35 U.S.C. 112, except for the best mode requirement. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 61/308056, fails to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph for one or more claims of this application. There is no support for "D_{90} equal to or less than about 89 μm" of claim 1 from which all other claims depends.

As such the priority of claim 1 and dependent claims thereon is the filing date of the instant application.

NEW-Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims claim functional language without any actual structure. The claims claim AUC and/or Cmax that is at least 80% of the mean AUC and/or Cmax observed for an equivalent formulation differing only in that the D_{90} is 89microns which has to do with the specific structural components in the composition i.e. excipients like specific granulating agents such as microcrystalline cellulose, lubricants, etc. such as those in instant Tables 3-5, but such functional limitations of

AUC/Cmax, etc. in the absence of such structure limitations % cellulose, type of lubricant, etc. do not further limit the structure of the instant claims. This is a written description rejection.

For the purpose of prior art any composition that contains apixaban and a pharmaceutically acceptable diluent or carrier, wherein the apixaban particles which are crystalline and have a D_{90} of less than about 89microns meets the functional limitations of AUC/Cmax in instant claims 9-10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, and 5-10 are rejected under 35 U.S.C. 102(a) as being anticipated by US 2006/016841 ('841).

- '841 teaches apixaban particles which are crystalline and have a D_{90} of less than about 20microns which are then washed with water Examples 1-3, meeting the limitations of the instant claims 1, 5-8.

- '841 teaches that the composition has the N-1 form of apixaban in Examples 1-3, according to the limitations of instant claim 3.
- With regard to claims 9-10 which are directed to a release profile, since the composition is the same (i.e. apixaban crystalline particles of D_{90} of less than about 20microns in a pharmaceutically acceptable carrier (water)) then the release profile, AUC and/or Cmax would naturally be the same since a product is not separable from its physical properties.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2006/016841 ('841) in view of US 2012/0087978 ('978) (which has priority to 06/16/09).

- '841 is taught above.
- '841 does not teach formulations with surfactants such as SLS, but does teach crystalline apixaban with D_{90} less than 20microns dispersed in water.

- '978 claims a dosage form comprising solubility improved apixaban such as crystalline forms and according to '978 apixaban formulations of diameter of 900nm or less are formulated a stabilization aid such as a surfactant and discloses that sodium lauryl sulfate (SLS) is a known surfactant ([0066, 0149], claims 1 and 6; Ex. 7 Table 8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '841 with '978. The combination of a known particulate crystalline apixaban product of '841 with a known technique of formulating apixaban in particulate crystalline forms with surfactants such as SLS for a similar purpose of improved apixaban is within the purview of the skilled artisan and would yield predictable results. The skilled artisan would know how to combine of a known product with a known technique for a similar purpose with predictable results.

Claims 1, 3, and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2010/003811 ('811).

- '811 teaches modification of a bio-active substance such as axipaban with an amphiphilic protein (a surfactant), such that it reduces the crystallite size to 5-5000nm, especially 2-2000nm and that such a reduction in crystal size is known to improve bioavailability or dissolution (abstract, pg. 1, lines 6-20; pg. 5, lines 5-18; pg. 12, lines 20; claim 14).
- With regard to claims 9-10 which are directed to a release profile, since the composition is the same (i.e. apixaban crystalline particles of D_{90} of less than

about 89 microns in a surfactant) then the release profile, AUC and/or Cmax would naturally be the same since a product is not separable from its physical properties.

- '811 does not teach a specific example with axipaban.

A reference is analyzed using its broadest teachings. MPEP 2123 [R-5].

"[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to rearrange the disclosed Examples and modify axipaban a disclosed bioactive of '811 with an amphiphilic protein (a surfactant), such that it

reduces the crystallite size to 5-5000nm, especially 2-2000nm and that such a reduction in crystal size is known to improve bioavailability or dissolution with predictable results.

Claims 1, 3, and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2010/003811 ('811) in view of US 2009/0285887 ('887).

- '811 is taught above.
- '811 does not teach other surfactants other than the amphiphilic protein.
- '887 teaches known surfactants include SLS [0051].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '811 with '887. The simple substitution of the surfactant of '811 with surfactants such as SLS of '887 would yield predictable results. The skilled artisan would know how to one surfactant for another with predictable results.

Claims 1, 3, and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2010/003811 ('811) in view of US 2012/0087978 ('978) (which has priority to 06/16/09).

- '811 is taught above.
- '811 does not teach other surfactants other than the amphiphilic protein.
- '978 claims a dosage form comprising solubility improved apixaban such as crystalline forms and according to '978 apixaban formulations of diameter of 900nm or less are formulated a stabilization aid such as a surfactant and

discloses that sodium lauryl sulfate (SLS) is a known surfactant ([0066, 0149], claims 1 and 6; Ex. 7 Table 8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '811 with '978. The combination of a known particulate crystalline apixaban product of '811 with a known technique of formulating apixaban in particulate crystalline forms with specific surfactants such as SLS for a similar purpose of improved apixaban is within the purview of the skilled artisan and would yield predictable results. The skilled artisan would know how to combine of a known product with a known technique for a similar purpose with predictable results.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BETHANY BARHAM/
Primary Examiner, Art Unit 1615

Notice of References Cited	Application/Control No. 13/579,796	Applicant(s)/Patent Under Reexamination PATEL ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2009/0285887	11-2009	Abu-Baker et al.	424/469
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"20120087978".pn. and apixaban and (crystal or crystalline) and (micron or ".mu.m")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/21 19:06
L2	2	"20120087978".pn. and (crystal or crystalline)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/21 19:11
S1	2	US-6150366-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; DERWENT	ADJ	ON	2014/02/18 17:55
S2	6	US-7396932-$.DID. OR US-6967208-$.DID. OR US-20060160841-$.DID.	US-PGPUB; USPAT; USOCR; FPRS; DERWENT	ADJ	ON	2014/02/18 17:56
S3	3	"20120087978".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 17:56
S4	8	"200803172".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 17:56
S5	0	WO "200803172"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 17:57
S6	2	"20090285887".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 17:57
S7	29	"2010003811".pn. or "2009135947".pn. or "2006108643".pn. or "2008031782".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 17:58
S8	282	apixaban and (crystal or crystalline)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:03
S9	45	apixaban and (crystal or crystalline) and (micron or ".un.m")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:04
S10	33	S9 and @ay<="2011"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:04
S11	246	apixaban and (crystal or crystalline) and (micron or ".mu.m")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:06
S12	208	S11 and @ay<="2011"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:06
S13	3	S12 and N-1	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:06
S14	3682	S12 and D90 or "D.sub.90"	US-PGPUB; USPAT;	ADJ	ON	2014/02/18

			USOCR; FPRS; EPO; JPO; DERWENT			19:08
S15	1	S12 and (D90 or "D.sub.90")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:08
S16	2	S12 and (D90 or "D.sub.90" or D50 or "D.sub.50")	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/18 19:08
S17	3	"20060069258".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/19 17:37
S18	5	"2010147978".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/19 17:54
S19	3	"20120087978".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/02/19 17:55

2/21/2014 7:14:22 PM
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Receipt date: 07/30/2013
Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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Receipt date: 07/30/2013		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Official Action in Mexican Application No. MX/2012/060772 (issued June 14, 2013).	☒

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Examiner Signature	/Bethany Barham/	Date Considered	02/18/2014

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	101516355	CN	A	2009-08-26	GLAXO GROUP LTD.		☐

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Receipt date: 09/25/2013	Application Number	13579796 13579796 - GAU: 1615
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	First Office Action in Chinese Application No. 201180011229.X (issued August 9, 2013).	☒

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Examiner Signature	/Bethany Barham/	Date Considered	02/18/2014

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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Receipt date: 05/17/2013	Application Number	13579796 13579796 - GAU: 1615
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	First Examination Report in New Zealand Application No. 601738 (April 29, 2013).	☐

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Examiner Signature	/Bethany Barham/	Date Considered	02/18/2014

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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13579796	PATEL ET AL.
	Examiner	Art Unit
	BETHANY BARHAM	1615

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/19/2014								
	1	✓								
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	3	✓								
	4	-								
	5	✓								
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	9	✓								
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	18	N								
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	24	-								
	25	-								

Receipt date: 01/27/2014
Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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Receipt date: 01/27/2014	Application Number	13579796
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-10-10
(Not for submission under 37 CFR 1.99)	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Office Action in Colombian Application No. 12.152.138 (issued Nov. 5, 2013).	☒

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	N.Y.A.
Examiner Name	N.Y.A.
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6150366	A	2000-11-21	ARENSON ET AL.	

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Receipt date: 10/25/2012	Application Number	13579796 13579796 - GAU: 1615
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	N.Y.A.
	Examiner Name	N.Y.A.
	Attorney Docket Number	03822.000060.

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Receipt date: 08/16/2013
Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Receipt date: 08/16/2013		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Communication pursuant to Article 94(3) EPC in European Application No. 11707284.3 (issued June 28, 2013).	☐

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Examiner Signature	/Bethany Barham/	Date Considered	02/18/2014

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13579796	PATEL ET AL.
	Examiner	Art Unit
	BETHANY BARHAM	1615

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East (see attached search notes)	02/18/14	BB
Palm Inventors Search (all inventors)	02/18/14	BB

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	N.Y.A.
Examiner Name	N.Y.A.
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7396932	B2	2008-07-08	SHAPIRO ET AL.	
	2	6967208	B2	2005-11-22	PINTO ET AL.	

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	1	20060160841	A1	2006-07-20	WEI ET AL.	
	2	20120087978	A1	2012-04-12	NAUSE	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2008/031782	WO	A1	2008-03-20	GLAXO GROUP LTD.		☐

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Receipt date: 09/25/2012	Application Number	13579796	13579796 - GAU: 1615
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2011-02-24	
(Not for submission under 37 CFR 1.99)	First Named Inventor	JATIN PATEL ET AL.	
	Art Unit	N.Y.A.	
	Examiner Name	N.Y.A.	
	Attorney Docket Number	03822.000060.	

	2	2010/003811	WO	A1	2010-01-14	BASF SE		☐
	3	2009/135947	WO	A2	2009-11-12	ATACAMA LABS OY		☐
	4	2006/108643	WO	A2	2006-10-19	NOVARTIS AG		☐
	5	2007/022165	WO	A2	2007-02-22	BRISTOL-MYERS SQUIBB COMPANY		☐
	6	2010/147978	WO	A1	2010-12-23	PFIZER INC.; BRISTOL-MYERS SQUIBB COMPANY		☐

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	1	Amidon et al., "A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of in Vitro Drug Product Dissolution and in Vivo Bioavailability", Pharmaceutical Research, Vol. 12, pp. 413-420, 1995.	☐

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Examiner Signature	/Bethany Barham/	Date Considered	02/18/2014

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.B./

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	June 24, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND PETITION FOR EXTENSION OF TIME

Sir:

Applicants petition to extend the time for response to the Office Action dated February 28, 2014 in the above-captioned application to June 28, 2014. The fee for the extension is paid concurrently herewith. Please charge any additional fee required for the extension, and credit any overpayment, to Deposit Account 50-3939.

In response to the Office Action dated February 28, 2014, please amend the above-captioned application as follows.

CLAIMS

A complete listing of all the claims appears below; this listing replaces all earlier amendments and listings of the claims.

1. (Previously Presented) A pharmaceutical composition comprising apixaban and a pharmaceutically acceptable diluent or carrier,

wherein the apixaban is in particulate and crystalline form, and

wherein apixaban particles in the pharmaceutical composition have a D_{90} equal to or less than about 89 μm.

2. (Cancelled)

3. (Previously Presented) A composition as defined in claim 1, wherein said composition comprises Form N-1 of apixaban.

4. (Cancelled)

5. (Previously Presented) A composition as defined in claim 1, wherein the D_{90} is equal to or less than 85 μm.

6. (Previously Presented) A composition as defined in claim 1, wherein the D_{90} is equal to or less than 50 μm.

7. (Previously Presented) A composition as defined in claim 1, wherein the D_{90} is equal to or less than 30 μm.

8. (Previously Presented) A composition as defined in claim 1, wherein the D_{90} is equal to or less than 25 μm.

9-10. (Cancelled)

11. (Previously Presented) A composition as defined in claim 1, further comprising:

from 1% to 2 % by weight of a surfactant.

12. (Original) A composition as defined in claim 11, wherein the surfactant is sodium lauryl sulfate.

13. (Withdrawn) A method for the treatment or prophylaxis of a thromboembolic disorder, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition as defined in claim 1.

14-15. (Cancelled)

16. (Withdrawn) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials prior to granulation;

(2) granulating the raw materials from the step (1) using a wet or dry granulation process;

(3) blending the granules obtained in the step (2) with extragranular raw materials;

(4) compressing the blend from the step (3) into tablets; and

(5) film coating the tablets from the step (4).

17. (Withdrawn) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials with apixaban of controlled particle size to form a mix;

(2) adding intragranular portions of a binder, a disintegrant and at least one filler to the mix from the step (1) to form a blend;

(3) granulating the materials from the step (2) using a dry granulation process or a wet granulation process,

wherein the dry granulation process comprises:

delumping an intragranular lubricant using a screen or mill;

adding the intragranular lubricant to the blend from the step (2) and blending to form a lubricated blend;

compacting the lubricated blend to ribbons of density in a range of 1.1 to 1.2 g/cc and sizing the compacted ribbons using a roller compactor, and

wherein the wet granulation process comprises:

wet granulating the blend from the step (2) using water to a target end point and, optionally, sizing the wet-granules by passing through a screen or mill;

removing the water from the granulation by drying in a convection oven or a fluid-bed dryer; and

sizing the dried granules by passing through a screen or mill;

(4) blending the granules obtained in the step (3) and an extragranular disintegrant in a blender;

(5) delumping an extragranular lubricant using a screen or mill and blending with granules from the step (4);

(6) compressing the blend from the step (5) into tablets; and

(7) film coating the tablets from the step (6).

18. (Withdrawn) A process of manufacturing apixaban tablets according to claim 17, wherein the dry granulation process is used.

19-25. (Cancelled)

REMARKS

The claims are 1, 3, 5-8, 11-13, and 16-18, with claim 1 being independent. Claims 9 and 10 have been cancelled without prejudice or disclaimer. Claims 13 and 16-18 have been withdrawn from consideration as being directed to non-elected subject matter. No new matter has been added. Reconsideration of the claims is respectfully requested.

Claims 9 and 10 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite.

Since claims 9 and 10 have been cancelled, this rejection is moot and should be withdrawn. Applicants reiterate that the cancellation was made without prejudice or disclaimer and should not be construed as acquiescence with the rejection.

Claims 1, 3, and 5-10 stand rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by U.S. Patent Application Publication No. 2006/0160841 A1 (Wei). Claims 1, 3, and 5-11 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from WO 2010/003811 A1 (Hafner).[1] Claims 1, 3, and 5-12 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Wei or Hafner in view of U.S. Patent Application Publication No. 2012/0087978 A1 (Nause). Claims 1, 3, and 5-12 also stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Hafner in view of U.S. Patent Application Publication No. 2009/0285887 A1 (Abu-Baker). The grounds of rejection are respectfully traversed.

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[1] The Office Action refers to US 2010/003811 ('811). It is Applicants' understanding, however, that the intended publication is WO 2010/003811.

Prior to addressing the merits of rejection, Applicants would like to discuss briefly some of the features and advantages of the presently claimed invention. That invention, in pertinent part, is related to a pharmaceutical composition comprising apixaban and a pharmaceutically acceptable diluent or carrier. Apixaban in this composition is in particulate and crystalline form and has a $D_{90} \leq 89$ μm.

Based on the aqueous solubility of apixaban and its dose/solubility ratio, prior to the present invention apixaban was not expected to demonstrate dissolution rate limited absorption. Therefore, particle size was not expected to be critical for achieving consistent plasma profiles, according to the prediction based on the Biopharmaceutics Classification System (specification, paragraphs [0005]). However, as mentioned in the specification at paragraph [0006], Applicants have surprisingly determined that the particle size of crystalline apixaban affects plasma profiles, and that having a $D_{90} \leq 89$ μm leads to consistent in-vivo dissolution in humans (at physiologic pH).

Hence, the presently claimed invention allows for consistent exposure and consistent Factor Xa inhibition, which can lead to consistency in therapeutic effect. To the contrary, formulations made using a wet granulation process as well as those using large particles of apixaban drug substance resulted in less than optimal exposures (specification, paragraph [0005]).

Wei is related to a process for transforming one apixaban polymorph to another apixaban polymorph. This reference, however, does not teach any pharmaceutical composition, much less one that includes crystalline apixaban and a pharmaceutically acceptable diluent or carrier. Wei is not concerned with any such composition. Instead,

this reference teaches a slurry containing apixaban particles, which is not a pharmaceutical composition as claimed.

Moreover, Wei does not teach including only crystalline apixaban particles with a $D_{90} \leq 89$ μm in a pharmaceutical composition. In fact, at paragraph [0020] Wei states that either of its polymorphs can be more thermodynamically stable than the other (i.e., Wei teaches that a polymorph with a D_{90} above 100 μm can be more thermodynamically stable).

Wei is silent as to the particle size of crystalline apixaban having any affects plasma profiles, and does not disclose or suggest that when the $D_{90} \leq 89$ μm, consistent in-vivo dissolution in humans (at physiologic pH) can be achieved. Thus, Applicants respectfully submit that the presently claimed invention is patentable over Wei.

Hafner is directed to modification of morphology and/or polymorphism of solid organic compounds. This reference recites a laundry list of different APIs on pages 12 and 13, yet fails to disclose or suggest any pharmaceutical composition that includes apixaban. Instead, Hafner discloses generally compositions that contain an organic bio-active substance and an amphiphilic protein, especially hydrophobin.

Moreover, Hafner does not disclose or suggest crystalline apixaban with a $D_{90} \leq 89$ μm. While Hafner mentions various mean particle sizes generally, such as 0.1 to 1,000 μm, for organic bio-active substances, this reference does not disclose or suggest a D_{90} for any of these particles. Furthermore, Hafner is silent as to particles with a $D_{90} \leq 89$ μm leading to consistent in-vivo dissolution in humans (at physiologic pH). Therefore,

Applicants respectfully submit that Hafner cannot affect the patentability of the presently claimed invention.

Nause cannot cure the deficiencies of Wei and Hafner. Nause teaches, *inter alia*, amorphous dispersions of apixaban. Solid amorphous dispersions are clearly different from the crystalline apixaban particles recited in the present claims. Thus, Nause also does not disclose or suggest a pharmaceutical composition in which crystalline apixaban particles have a $D_{90} \leq 89$ μm.

Lastly, Abu-Baker also cannot provide the teaching missing in the other cited references as discussed above at least because it also fails to disclose or suggest crystalline apixaban particles having a $D_{90} \leq 89$ μm. Applicants respectfully submit that Abu-Baker does not teach a D_{90} of any active substance.

Abu-Baker is directed to a modified-release pharmaceutical formulation. Specifically, Abu-Baker describes so-called mini-tablets having a diameter of less than 5 mm and comprising a therapeutically effective amount of a Factor Xa inhibitor within a polymer matrix. These mini-tablets are made by compressing granules having a particle size D_{50} (median particle size) between 50-300 microns. Thus, both the granules and the mini-tablets do not comprise only an active substance, but also include at least a polymer. Therefore, the size of the mini-tablets or the size of the granules is not the particle size of the active substance in Abu-Baker. Therefore, Abu-Baker fails to teach compositions wherein a factor Xa inhibitor has a defined particle size.

Moreover, the two specific Factor Xa inhibitors with which Abu-Baker is concerned are not apixaban. Therefore, a skilled artisan would not have looked to this reference for guidance with respect to apixaban particles.

Accordingly, Applicants respectfully submit that the cited documents, whether considered separately or in any permissible combination, do not disclose or suggest the claimed invention and do not render it unpatentable.

Wherefore, withdrawal of the outstanding rejections and allowance of the claims is respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Nancy Ramadan
Attorney Docket Number:	03822.000060.

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	200	200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt

EFS ID:	19393644
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	24-JUN-2014
Filing Date:	10-OCT-2012
Time Stamp:	15:16:20
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$200
RAM confirmation Number	1730
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		AMDEXT03822000060.pdf	135430 3cba3c55849e230403e05e344602c2875ddb7c19	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	10

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30432 1a6373c7e1bfa9e2be98472a55ef41ce0e1fde34	no	2

Warnings:

Information:

Total Files Size (in bytes):	165862

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/579,796	Filing Date 10/10/2012	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **06/24/2014**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 12	Minus	** 23	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/FREDERICK BRISCOE/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Office Action in Mexican Application No. MX/a/2012/009244 (issued June 6, 2014).	☒
	2	J. Thompson, PRÁCTICA CONTEMPORÁNEA EN FARMACIA (2nd edition), p. 287 (2006).	☐
	3	Alfonso R. Gennaro, Remington, FARMACIA. Médica Panamericana (20th edition), Chapter I, p. 1005 (2000).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2014-07-15
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	July 15, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of these documents are provided.

This Information Disclosure Statement is to submit documents cited in an Office Action that was issued on June 6, 2014 in a corresponding Mexican application, which documents are not yet of record in the present application. Copies of this Office Action and its English language translation are provided.

The concise explanation of relevance for the non-English language documents may be found, *inter alia*, in the aforementioned Mexican Office Action. Also, the concise explanation of relevance for the Remington publication may be found in what Applicants believe to the corresponding English language version thereof, which is provided.

STATEMENT UNDER 37 C.F.R. § 1.97(e) and 1.704(d)

Each item of information in this information disclosure statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing date of this Statement, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Acknowledgement Receipt

EFS ID:	19585761
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	15-JUL-2014
Filing Date:	10-OCT-2012
Time Stamp:	17:36:21
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.PDF	541826 5f236d709e16d8936f3e7f3e1d741cd3da291d10	no	4

Warnings:	
Information:	

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

2	Non Patent Literature	IDSRef2.pdf	91609 d3b120e88ca2dbbd138d39fee7d09a0b7e8fb23f	no	1
Warnings:					
Information:					
3	Non Patent Literature	IDSRef3.PDF	657820 0968398820c19029042735 99aa71d79c91bb8a5f	no	8
Warnings:					
Information:					
4	Transmittal Letter	IDSTRANS03822000060.pdf	78604 884f611b711a654efe3ff43c741dce1d17161c84	no	3
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	IDSRef1.PDF	552141 25f18dcf20f5aefc73e8995f4cf69d5c0ad704e2	no	14
Warnings:					
Information:					
		Total Files Size (in bytes):	1922000		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	00/39131	WO	A1	2000-07-06	DU PONT PHARMACEUTICALS COMPANY		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2014-07-15
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	19588348
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun
Filer Authorized By:	
Attorney Docket Number:	03822.000060.
Receipt Date:	15-JUL-2014
Filing Date:	10-OCT-2012
Time Stamp:	18:30:04
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDSTRANS203822000060.pdf	50525 8ae7fc1cc6fca32b81bae2abfd2366364823 3ed9	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	IDS203822000060USA600.PDF	541653 70a2aacba9053d2698e51e0b408bc626274cdfbe	no	4

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3	Foreign Reference	IDSRef1a.PDF	12515690 1f6c985262926e85642c3e6b835b52ce38ac0f30	no	333

Warnings:

Information:

Total Files Size (in bytes):	13107868

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	July 15, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of this document is provided.

STATEMENT UNDER 37 C.F.R. § 1.97(e) and 1.704(d)

Each item of information in this information disclosure statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing date of this Statement, and this

communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 07/18/2014

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
BARHAM, BETHANY P	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/18/2014	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/579,796	Applicant(s) PATEL ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/24/14*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1,3,5-8,11-13 and 16-18* is/are pending in the application.

5a) Of the above claim(s) *13 and 16-18* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3,5-8,11 and 12* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Summary

The present application is being examined under the pre-AIA first to invent provisions. Receipt of the multiple IDSs filed is acknowledged. Receipt of the Claim Amendments and Response filed on 06/24/14 is also acknowledged. Claims 1, 3, 5-8, 11-13 and 16-18 are pending. Claims 13 and 16-18 remain withdrawn. Claims 1, 3, 5-8 and 11-12 are rejected.

Due to the claim amendments the previous 112 rejections over claims 9-10 are hereby withdrawn.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, and 5-8 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by US 2006/016841 ('841).

- '841 teaches apixaban particles which are crystalline and have a D_{90} of less than about 20microns which are then washed with water Examples 1-3, meeting the limitations of the instant claims 1 and 5-8.
- '841 teaches that the composition has the N-1 form of apixaban in Examples 1-3, according to the limitations of instant claim 3.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-8 and 11-12 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over US 2006/016841 ('841) in view of US 2012/0087978 ('978) (which has priority to 06/16/09).

- '841 is taught above.
- '841 does not teach formulations with surfactants such as SLS, but does teach crystalline apixaban with D_{90} less than 20microns dispersed in water.
- '978 claims a dosage form comprising solubility improved apixaban such as crystalline forms and according to '978 apixaban formulations of diameter of 900nm or less are formulated a stabilization aid such as a surfactant and

discloses that sodium lauryl sulfate (SLS) is a known surfactant ([0066, 0149], claims 1 and 6; Ex. 7 Table 8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '841 with '978. The combination of a known particulate crystalline apixaban product of '841 with a known technique of formulating apixaban in particulate crystalline forms with surfactants such as SLS for a similar purpose of improved apixaban formulation is within the purview of the skilled artisan and would yield predictable results. The skilled artisan would know how to combine of a known product with a known technique for a similar purpose with predictable results.

Claims 1, 3, 5-8 and 11 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over WO 2010/003811 ('811).

- '811 teaches modification of a bio-active substance such as apixaban with an amphiphilic protein (a surfactant), such that it reduces the crystallite size to 5-5000nm, especially 2-2000nm and that such a reduction in crystal size is known to improve bioavailability or dissolution (abstract, pg. 1, lines 6-20; pg. 5, lines 5-18; pg. 12, lines 20; claim 14).
- '811 does not teach a specific example with apixaban.

A reference is analyzed using its broadest teachings. MPEP 2123 [R-5].

"[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727,

1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to rearrange the disclosed Examples and modify apixaban a disclosed bioactive of '811 with an amphiphilic protein (a surfactant), such that it reduces the crystallite size to 5-5000nm, especially 2-2000nm and that such a reduction in crystal size is known to improve bioavailability or dissolution with predictable results.

Claims 1, 3, 5-8 and 11-12 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over WO 2010/003811 ('811) in view of US 2009/0285887 ('887).

- '811 is taught above.
- '811 does not teach other surfactants other than the amphiphilic protein.
- '887 teaches known surfactants include SLS [0051].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '811 with '887. The simple substitution of the surfactant of '811 with surfactants such as SLS of '887 would yield predictable results. The skilled artisan would know how to one surfactant for another with predictable results.

Claims 1, 3, 5-8 and 11-12 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over WO 2010/003811 ('811) in view of US 2012/0087978 ('978) (which has priority to 06/16/09).

- '811 is taught above.
- '811 does not teach other surfactants other than the amphiphilic protein.
- '978 claims a dosage form comprising solubility improved apixaban such as crystalline forms and according to '978 apixaban formulations of diameter of 900nm or less are formulated a stabilization aid such as a surfactant and discloses that sodium lauryl sulfate (SLS) is a known surfactant ([0066, 0149], claims 1 and 6; Ex. 7 Table 8).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '811 with '978. The combination of a known particulate crystalline apixaban product of '811 with a known technique of formulating apixaban in particulate crystalline forms with specific surfactants such as SLS for a similar purpose of improved apixaban is within the purview of the skilled artisan and would yield predictable results. The skilled artisan would know how to combine of a known product with a known technique for a similar purpose with predictable results.

Cited As Interest

US 2008/0279845 (‘845) teaches that known pharmaceutical formulations include liquid suspensions or solutions using a liquid such as water, tablets, capsules, etc. [0163, 0165].

US 2009/0123390 (‘390) teaches that pharmaceutical compositions comprising drug microparticles of 1-20microns mean diameter (at least 95% of particles less than 10 microns) are formulated into a liquid, capsule, tablet, suspension, slurry, etc. wherein the diluent is water for suspensions, etc. ([0049, 0086, 0113], claims 1 and 16).

US 2013/0072512 (‘512) teaches oral liquid dosage forms and that a ready to use suspension comprising a suspension base of water and micronized drug with D_{90} of less than about 40microns (abstract, [0015, 0021, 0025-0030].

Response to Arguments

Applicant's arguments with respect to the instant claims have been considered but are not persuasive. Applicant argues that ‘841 does not teach ‘any pharmaceutical composition, much less one that includes crystalline apixaban and a pharmaceutically acceptable diluent or carrier’ and that the reference teaches 'a slurry containing apixaban particles, which is not a pharmaceutical composition as claimed'. The Examiner respectfully points out that the claims are given the broadest reasonable interpretation and that the instant claims only require the crystalline apixaban particles of D_{90}<=89microns and a “a pharmaceutically acceptable diluent or carrier”, which ‘841

embodies in its examples when the particles of crystalline apixaban particles of D_{90}<=20 microns in water. Water meets the limitation of 'a pharmaceutically acceptable diluent or carrier' and further a slurry (or suspension) is a 'pharmaceutical composition' or formulation (see cited as interest above for support wherein '845, '390 and '512 all disclose aqueous solutions, suspensions, and/or slurries of microparticles of drugs are in fact pharmaceutical compositions/formulations). Applicant argues that '841 "is silent as to the particle size of the crystalline apixaban having any affects plasma profile…consistent in-vivo dissolution in humans"….etc. The Examiner respectfully points out that the prior art teaches the identical composition in the 102 rejection of record as instant claimed and the silence of the reference to 'characteristics' of the composition is a not a teaching away and as such the rejections are maintained.

Further, Applicants arguments with regard to their 'surprisingly determined' particle size which affects plasma profiles, etc. is not persuasive for the instant specification teaches a specific formulation of a tablet, with specific amounts of SLS, lactose, etc. in the formulation and these components are not all instant claimed and as such the instant claims are not commensurate with unexpected results. Also, the Examiner respectfully points out that these results are not all that surprising or unexpected in light of '811 which teaches that controlling crystallization, crystal purity and crystal size/shape enables optimization of the dissolution rate and maximizes benefits such as bioavailability, etc. and '811 discloses apixaban, which would makes the instant results expected and unsurprising (pg. 1, lines 6-20, pg. 5, lines 5-18; pg. 12, lines 20; claim 14). Applicant also argues that '978 does not 'disclose or suggest

crystalline apixaban with a D_{90}<=89 microns' and teaches 'amorphous dispersions'. The Examiner respectfully points out that '841 is relied upon for the teaching of crystalline apixaban with a D_{90}<=89 microns in a diluent and that it is combined with '978 which teaches apixaban and crystalline drug forms and micronized drug forms generally but specifically discloses excipients that are known to be used with apixaban include SLS a known surfactant ([0066, 0149], claims 1 and 6; Ex. 7 Table 8) and the Examiner respectfully points out that Applicant's argue against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It should be noted that the motivation to combine references can be different from the ones set forth by Applicant. That is, as long as motivation exists to combine the elements, the problem to be solved does not have to involve the same reason. As such, the Examiner respectfully submits that the rationale to combine the teachings of a known particulate crystalline apixaban product of '841 with a known technique of formulating apixaban in particulate crystalline forms with surfactants such as SLS for a similar purpose of improved apixaban formulation is within the purview of the skilled artisan and would yield predictable results. The skilled artisan would know how to combine of a known product with a known technique for a similar purpose with predictable results. The fact that '978 also discloses amorphous drug forms is immaterial as it clearly teaches also crystalline forms (claim 6) and '841 is relied upon

specifically for the crystalline apixaban with a D_{90}<=89 microns and '811 is relied upon for excipients and formulation techniques. As such Applicant's arguments are not persuasive. Similarly with regard to the separate arguments of '811, '877 and '978 by Applicant, the Examiner respectfully points out that '811 in view of '887 or '978 is obvious via the KSR rationale of simple substitution (see MPEP 2141), wherein the simple substitution of the one surfactant of '811 with another surfactant such as SLS of '887 or '978 would yield predictable results. The skilled artisan would know how to one surfactant for another with predictable results. The burden is on Applicant to show the criticality of the claimed surfactant and ranges as instant claimed via a showing of factual evidence on the record. Until such time the rejections of record are hereby maintained.

Conclusions

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BETHANY BARHAM/
Primary Examiner, Art Unit 1615

Notice of References Cited	Application/Control No. 13/579,796	Applicant(s)/Patent Under Reexamination PATEL ET AL.	
	Examiner BETHANY BARHAM	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2013/0072512	03-2013	Jahagirdar et al.	514/279
*	B	US-2008/0279845	11-2008	Conley et al.	424/130.1
*	C	US-2009/0123390	05-2009	Hill, Malcolm	424/45
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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	O					
	P					
	Q					
	R					
	S					
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13579796	PATEL ET AL.
	Examiner	Art Unit
	BETHANY BARHAM	1615

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	02/19/2014	07/16/2014							
	1	✓	✓							
	2	-	-							
	3	✓	✓							
	4	-	-							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	-							
	10	✓	-							
	11	✓	✓							
	12	✓	✓							
	13	N	N							
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	15	-	-							
	16	N	N							
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	24	-	-							
	25	-	-							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S81	218463	(pharmaceutical or pharmaceutically) same (slurry or suspension or dispersion)	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 14:51
S82	153416	(pharmaceutical or pharmaceutically) same (slurry or suspension or dispersion) same (aqueous or water)	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 14:51
S83	23698	S82 and (particle same (micron or mircometer or ".mu.m"))	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 14:52
S84	414	S83 and ("D90" or Dsub"90")	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 14:52
S85	352	S84 and @ay<="2012"	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 14:53
S86	295631	(slurry or suspension or dispersion) and (particle same (micron or mircometer or ".mu.m"))	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 14:53
S87	352	S85 and S86	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 14:53
S89	15	S87 and (factor Xa)	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:04
S90	13	S87 and (factor adj2 inhibitor)	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:04
S91	15371	(slurry and (suspension or dispersion) and (tablet or capsule)) and (particle same (micron or mircometer or ".mu.m"))	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:08
S92	117	S85 and S91	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:08
S93	138	(pharmaceutical or pharmaceutically) same (slurry or suspension or dispersion) same (aqueous or water) and apixaban	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:22

S94	115	S93 and @ay<="2012"	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:22
S95	5969	S94 and ((size or particle or diameter) same (micron or mircometer or ".mu.m")) or ("D90" or Dsub"90")	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:23
S96	41	S94 and (((size or particle or diameter) same (micron or mircometer or ".mu.m")) or ("D90" or Dsub"90"))	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 15:23
S102	2353	(slurry and (suspension or dispersion) and (tablet or capsule)) and (particle same (micron or mircometer or ".mu.m")).clm.	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 16:21
S104	11	S102 and (factor Xa)	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 16:21
S105	19	((slurry and (suspension or dispersion) and (tablet or capsule)) and (particle same (micron or mircometer or ".mu.m"))).clm.	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 16:22
S106	57	((slurry and (suspension or dispersion) and (tablet or capsule)).clm. and (particle same (micron or mircometer or ".mu.m")))	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 16:23
S107	57	((slurry and (suspension or dispersion) and (tablet or capsule)).clm. and (particle same (micron or mircometer or ".mu.m"))) and (water or aqueous)	US-PGPUB; USPAT; USOCR	ADJ	ON	2014/07/16 16:27

7/ 16/ 2014 5:13:43 PM
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Receipt date: 07/15/2014
Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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	1	00/39131	WO	A1	2000-07-06	DU PONT PHARMACEUTICALS COMPANY		☐

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	13579796	PATEL ET AL.
	Examiner	Art Unit
	BETHANY BARHAM	1615

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East (see attached search notes)	07/16/14	BB
Palm Inventors Search (all inventors)	07/16/14	BB

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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	1	Office Action in Mexican Application No. MX/a/2012/009244 (issued June 6, 2014).	☒
	2	J. Thompson, PRÁCTICA CONTEMPORÁNEA EN FARMACIA (2nd edition), p. 287 (2006).	☐
	3	Alfonso R. Gennaro, Remington, FARMACIA. Médica Panamericana (20th edition), Chapter I, p. 1005 (2000).	☒

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	Examiner Name	BETHANY P. BARHAM
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	1	Third Party Observations in European Application No. 11707284.3 (dated July 30, 2014).	☐
	2	Third Party Observations in European Application No. 11707284.3 (dated July 15, 2014).	☐
	3	Third Party Observations in European Application No. 11707284.3 (dated August 18, 2014).	☐
	4	European Pharmacopoeia 6.0; Section 2.9.31 - "Particle Size Analysis by Laser Light Diffraction", pp. 311-314 (July 2007).	☐
	5	European Pharmacopoeia 7.0; Section 2.9.31 - "Particle Size Analysis by Laser Light Diffraction", pp. 295-299 (July 2010).	☐

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Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2014-08-27
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	August 27, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of these documents are provided.

This Information Disclosure Statement is to submit three sets of Third Party Observations filed in a corresponding European application, as well as two non-patent publications mentioned in the Third Party Observations filed August 18, 2014.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Yolanda Sharper
Attorney Docket Number:	03822.000060.

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	19976155
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	27-AUG-2014
Filing Date:	10-OCT-2012
Time Stamp:	13:08:41
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	14306
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.pdf	541688 c8801932ee670f6fc14c23a626e02cc3c3827fd1	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	IDSDoc1.pdf	226634 14053937e3ce884348472fa013597c8b4ac6c4b0	no	4
Warnings:					
Information:					
3	Non Patent Literature	IDSDoc2.pdf	229838 0c824b23acac3da657169c9aef3a48a47c17fa9e	no	4
Warnings:					
Information:					
4	Non Patent Literature	IDSDoc3.pdf	414797 db31d26c775bcc083685d333f6c4c77c424022b0	no	11
Warnings:					
Information:					
5	Transmittal Letter	IDSTRANS03822000060USA600.pdf	50282 b1dd1691c05af4dd6051fe9995435072c59d775c	no	2
Warnings:					
Information:					
6	Non Patent Literature	IDSDoc4.pdf	303329 70aaa2135fd30eb52bcda260632181634d1f694e	no	5
Warnings:					
Information:					
7	Non Patent Literature	IDSDoc5.pdf	573484 89d923f7734a6cd4f0fc8c39cad7adbe0634983c	no	11
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	30510 673899a14bf20b072559a2e2f5f1947da3b77ea8	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	2370562

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Resolution Nº 61405 in Colombian Application No. 12.152.138 (dated Oct. 14, 2014).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

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OR

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☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2014-11-13
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	November 13, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of this document is provided.

This Information Disclosure Statement is to submit a copy of Resolution N° 61405 that was issued in a corresponding Colombian application. An English language translation of the Resolution is provided. All documents cited in this Colombian

Resolution are already of record in the present application (US 2006/0069258 A1 is a pre-grant publication of U.S. Patent No. 7,396,932 B2).

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun
Attorney Docket Number:	03822.000060.

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	20683163
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	13-NOV-2014
Filing Date:	10-OCT-2012
Time Stamp:	16:41:43
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	3430
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	541638 0f0179a26cc0f8d1a83e47b4c9521038bfd2df8c	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	Ref1.pdf	764518 40b5b411419230b9a6727455f4f4761fd3fc4b77	no	22
Warnings:					
Information:					
3	Transmittal Letter	IDSTRANS03822000060.pdf	49142 5d7e02dcbf957eea5afa9001bb313f9cd4322854	no	2
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30262 74f21a81dbb559682d84b7e4673b1262b527a661	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1385560		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Summons to attend oral proceedings pursuant to Rule 115(1) EPC in European Application No. 11707284.3 (dated Nov. 14, 2014).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2014-11-18
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bethany P. Barham
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	November 18, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of this document is provided.

This Information Disclosure Statement is to submit a copy of Summons to attend oral proceedings pursuant to Rule 115(1) EPC in a corresponding European application. All documents cited in this Summons are already of record in the present

application (US 2006/0069258 A1 is a pre-grant publication of U.S. Patent No. 7,396,932 B2).

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Yolanda Sharper
Attorney Docket Number:	03822.000060.

Filed as Large Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	20724783
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	18-NOV-2014
Filing Date:	10-OCT-2012
Time Stamp:	11:58:03
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	10406
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	IDSDoc1.pdf	1020971 d30b857d1ecda686bcaea62d3322c8bd9bbf18ab	no	13
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.pdf	541695 51ab657e4bbb5209b729a40d5ff5631cfcedacc3	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
3	Transmittal Letter	IDSTRANS03822000060USA600.pdf	54802 631c9708ac7ed5459d9bf6b08fcd4ba25556b0de	no	2
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30509 019c1e5f3c1700345ec3fd881cf52e046259e5f4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1647977		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	1578660	CN	A	2005-02-09	BRISTOL MYERS SQUIBB CO.		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	ROBERT A. WAX
	Attorney Docket Number	03822.000060.

	1	Peng Chen et al., "Enhancement for Dissolution of Poorly Water Soluble Drug by Micronization," 10 Chemistry Bulletin 766-771 (2007).	☒
	2	Second Office Action in Chinese Application No. 201180011229.X (issued Oct. 31, 2014).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-01-16
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Robert A. Wax
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	January 16, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: AF

PETITION UNDER 37 C.F.R. § 1.136(a)

Sir:

Applicants petition the Commissioner for Patents to extend the time for response to the final Office Action dated July 18, 2014, from October 18, 2014 to January 18, 2015. The fee for the extension is submitted herewith. Any deficiency in this fee should be charged, and any overpayment credited, to Deposit Account No. 50-3939.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Robert A. Wax
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	January 16, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of these documents are provided.

This Information Disclosure Statement is, in part, to submit documents listed in a second Office Action that was issued in a corresponding Chinese application. Copies of the Chinese Office Action and its English language translation are provided.

The concise explanation of relevance for CN 1578660 may be found in its provided English language abstract, in its corresponding U.S. Patent No. 6,967,208 B2 (already of record), and/or in the aforementioned English language translation of the Chinese Office Action.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun
Attorney Docket Number:	03822.000060.

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of Appeal	1401	1	800	800
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 3 months with $0 paid	1253	1	1400	1400
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**2380**

Electronic Acknowledgement Receipt

EFS ID:	21231590
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	16-JAN-2015
Filing Date:	10-OCT-2012
Time Stamp:	14:59:03
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2380
RAM confirmation Number	1306
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notice of Appeal Filed	NoticeofAppeal03822000060.PDF	211977 34f0c04fbc0967aa5895bf14d796e89f24f11c25	no	2
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	541839 811d1a69c9c9e202eea1269918e10e1418f60379	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
3	Non Patent Literature	ChenwithTranslation03822000060.pdf	2618694 dfb3d7fbd3e02468a080687007f62bad1aac1cae	no	22
Warnings:					
Information:					
4	Extension of Time	Pet11360382200060.pdf	80770 127684da7a1ada80df7c07eef9aa02183821a3bc	no	2
Warnings:					
Information:					
5	Transmittal Letter	IDSTRANS0382200060.pdf	55005 ea0c09744c86474ae25af2bb6ae3f0cf97a9c98d	no	2
Warnings:					
Information:					
6	Foreign Reference	Ref1.pdf	17717087 da2e3004949452ad2d5cc5f7dc70d37969706ed1	no	351
Warnings:					
Information:					
7	Non Patent Literature	IDSDocSecondChineseOfficeAction03822000060.PDF	1323442 8618ba01894aebd164dbe76e942cfb4a9007c325	no	9

Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	34235 8e4c1f548c2fab7f764faf466ddec83a97d6e6f4	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	22583049	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/31 (02-14)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

NOTICE OF APPEAL FROM THE EXAMINER TO THE PATENT TRIAL AND APPEAL BOARD

Docket Number (Optional): 03822.000060.

I hereby certify that this correspondence is being facsimile transmitted to the USPTO EFS-Web transmitted to the USPTO, or or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on January 16, 2015

Signature /Jason M. Okun/

Typed or printed name Jason M. Okun

In re Application of: JATIN PATEL ET AL.

Application Number	Filed
13/579,796	2012-10-10

For APIXABAN FORMULATIONS

Art Unit	Examiner
1615	ROBERT A. WAX

Applicant hereby **appeals** to the Patent Trial and Appeal Board from the last decision of the examiner.

The fee for this Notice of Appeal is (37 CFR 41.20(b)(1)) $ 800

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: $

☐ A check in the amount of the fee is enclosed.

☑ Payment by credit card. ~~Form PTO-2038 is attached.~~

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 50-3939 .

☑ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☑ attorney or agent of record. Registration number 48,512.

☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34.

/Jason M. Okun/
Signature

Jason M. Okun
Typed or printed name

212-218-2100
Telephone number

January 16, 2015
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 41.31. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	ROBERT A. WAX
	Attorney Docket Number	03822.000060.

	1	Third Party Observations in European Application No. 11707284.3 (filed Jan. 16, 2015).	☐
	2	International Standard – ISO 13320-1, First Edition, Particle Size Analysis – Laser Diffraction Methods, pp. 1-34 (Nov. 1999).	☐
	3	Nor Hafizah Hj Annuar et al., "Effects of Sample Conditions on Multi-Particle Size Analysis Using Laser Diffraction Technique," Scientia Bruneiana, pp. 19-26 (2010).	☐
	4	Zoran Stojanovic et al., "Determination of Particle Size Distributions by Laser Diffraction," 21 Technics – New Materials 11-20 (2012).	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-02-02
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Robert A. Wax
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	February 2, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of these documents are provided.

This Information Disclosure Statement is to submit a copy of Third Party Observations (Observations pursuant to Article 115 EPC) filed on January 16, 2015 in the corresponding European application, as well as documents listed therein.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Yolanda Sharper
Attorney Docket Number:	03822.000060.

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	21370192
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	02-FEB-2015
Filing Date:	10-OCT-2012
Time Stamp:	16:12:43
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	2576
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	IDSRef1.pdf	7961257 5d4d29918297febd5991d88f5a11e53d33c88883	no	66
Warnings:					
Information:					
2	Non Patent Literature	IDSRef2.pdf	4281558 9be52794c4de5a874a8064c0e5592562d27898a3	no	40
Warnings:					
Information:					
3	Non Patent Literature	IDSRef3.pdf	421723 50bfdca17772f04989d0865244e0bcb4ecaeef61	no	9
Warnings:					
Information:					
4	Non Patent Literature	IDSRef4.pdf	5998739 f54218ab9baccaaabd76e9971b771f096b5630ae	no	10
Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060USA600.pdf	541877 c8e974895dd6b95a288387aed586c08ec3a12879	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
6	Transmittal Letter	IDSTRANS03822000060USA600.pdf	54691 784a16021d070354e608993eb426f4a66a471806	no	2
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	30762 ead146755fa356cec90d50db7c5603867acaedd2	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	19290607

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New Applications Under 35 U.S.C. 111
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National Stage of an International Application under 35 U.S.C. 371
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New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	13579796	Filing Date	2012-10-10	Docket Number (if applicable)	03822.000060.	Art Unit	1615
First Named Inventor	Jatin Patel			Examiner Name	Robert A. Wax		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 503939

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-06-16
Name	Jason M. Okun	Registration Number	48512

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

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4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Robert A. Wax
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	June 16, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: RCE

SUBMISSION UNDER 37 C.F.R. § 1.114
AND PETITION FOR EXTENSION OF TIME

Sir:

Applicants petition the Commissioner for Patents to extend the time to June 16, 2015. The fee for the extension is submitted herewith. Any deficiency in the fee in connection with this Submission should be charged, and any overpayment credited, to Deposit Account No. 50-3939.

In response to the final Office Action dated July 18, 2014, please amend the above-captioned application as follows and consider the following remarks.

CLAIMS

A complete listing of all the claims appears below; this listing replaces all earlier amendments and listings of the claims.

1. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of crystalline apixaban particles and a pharmaceutically acceptable diluent or carrier,

~~wherein the apixaban is in particulate and crystalline form, and~~

wherein the crystalline apixaban particles ~~in the pharmaceutical composition~~ have a D_{90} equal to or less than about 89 μm.

2. (Cancelled)

3. (Currently Amended) The ~~A~~ composition as defined in claim 1, wherein said composition comprises Form N-1 of apixaban.

4. (Cancelled)

5. (Currently Amended) The ~~A~~ composition as defined in claim 1, wherein the D_{90} is equal to or less than 85 μm.

6. (Currently Amended) The ~~A~~ composition as defined in claim 1, wherein the D_{90} is equal to or less than 50 μm.

7. (Currently Amended) The ~~A~~ composition as defined in claim 1, wherein the D_{90} is equal to or less than 30 μm.

8. (Currently Amended) The ~~A~~ composition as defined in claim 1, wherein the D_{90} is equal to or less than 25 μm.

9-10. (Cancelled)

11. (Currently Amended) The ~~A~~ composition as defined in claim 1, further comprising:

from 1% to 2 % by weight of a surfactant.

12. (Currently Amended) The ~~A~~ composition as defined in claim 11, wherein the surfactant is sodium lauryl sulfate.

13. (Withdrawn) A method for the treatment or prophylaxis of a thromboembolic disorder, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition as defined in claim 1.

14-15. (Cancelled)

16. (Withdrawn) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials prior to granulation;

(2) granulating the raw materials from the step (1) using a wet or dry granulation process;

(3) blending the granules obtained in the step (2) with extragranular raw materials;

(4) compressing the blend from the step (3) into tablets; and

(5) film coating the tablets from the step (4).

17. (Withdrawn) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials with apixaban of controlled particle size to form a mix;

(2) adding intragranular portions of a binder, a disintegrant and at least one filler to the mix from the step (1) to form a blend;

(3) granulating the materials from the step (2) using a dry granulation process or a wet granulation process,

wherein the dry granulation process comprises:

delumping an intragranular lubricant using a screen or mill;

adding the intragranular lubricant to the blend from the step (2) and blending to form a lubricated blend;

compacting the lubricated blend to ribbons of density in a range of 1.1 to 1.2 g/cc and sizing the compacted ribbons using a roller compactor, and

wherein the wet granulation process comprises:

wet granulating the blend from the step (2) using water to a target end point and, optionally, sizing the wet-granules by passing through a screen or mill;

removing the water from the granulation by drying in a convection oven or a fluid-bed dryer; and

sizing the dried granules by passing through a screen or mill;

(4) blending the granules obtained in the step (3) and an extragranular disintegrant in a blender;

(5) delumping an extragranular lubricant using a screen or mill and blending with granules from the step (4);

(6) compressing the blend from the step (5) into tablets; and

(7) film coating the tablets from the step (6).

18. (Withdrawn) A process of manufacturing apixaban tablets according to claim 17, wherein the dry granulation process is used.

19-25. (Cancelled)

26. (New) The composition as defined in claim 1, wherein at least 77 wt% of apixaban dissolves within 30 minutes in a pH 6.8 phosphate buffer containing 0.05% sodium lauryl sulfate.

27. (New) The composition as defined in claim 1, wherein the pharmaceutical composition comprises from about 2.5 mg to about 5 mg of apixaban.

28. (New) The composition as defined in claim 1, wherein the pharmaceutical composition comprises 2.5 mg of apixaban.

29. (New) The composition as defined in claim 1, wherein the pharmaceutical composition comprises 5 mg of apixaban.

30. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 1.

31. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 27.

32. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 28.

33. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 29.

REMARKS

The claims are 1, 3, 5-8, 11-13, 16-18, and 26-33, with claim 1 being independent. Claims 13 and 16-18 have been withdrawn from consideration as being directed to non-elected subject matter. Claim 1 has been amended for clarification. Support, if needed, may be found throughout the specification. Claims 3, 5-8, 11, and 12 have been amended to improve their form. New claims 26-33 have been added. Support for claim 26 may be found, *inter alia*, in the specification at paragraphs [0013] and [0038], as well as in the examples. Support for claims 27-33 may be found, *inter alia*, in the specification at paragraph [0027] and in the Examples. No new matter has been added. Reconsideration of the claims is respectfully requested.

Claims 1, 3, and 5-8 remain rejected under 35 U.S.C. § 102(a) as being allegedly anticipated by U.S. Patent Application Publication No. 2006/0160841 A1 (Wei). Claims 1, 3, 5-8, and 11 remain rejected under 35 U.S.C. § 103(a) as being allegedly obvious from WO 2010/003811 A1 (Hafner). Claims 1, 3, 5-8, 11, and 12 remain rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Wei or Hafner in view of U.S. Patent Application Publication No. 2012/0087978 A1 (Nause). Claims 1, 3, 5-8, 11, and 12 also remain rejected under 35 U.S.C. § 103(a) as being allegedly obvious from Hafner in view of U.S. Patent Application Publication No. 2009/0285887 A1 (Abu-Baker). The grounds of rejection are respectfully traversed.

Prior to addressing the merits of rejection, Applicants would like to discuss briefly some of the features of the presently claimed invention. That invention, in pertinent part, is related to a pharmaceutical composition comprising a therapeutically effective

amount of crystalline apixaban particles and a pharmaceutically acceptable diluent or carrier. Moreover, these crystalline apixaban particles have a D_{90} equal to or less than about 89 μm.

Wei is related to a process for transforming one apixaban polymorph to another apixaban polymorph. This reference, however, does not teach any pharmaceutical composition, much less one that includes a therapeutically effective amount of crystalline apixaban particles and a pharmaceutically acceptable diluent or carrier. Wei is not concerned with any such composition. Instead, this reference teaches a slurry containing apixaban particles, which is not a pharmaceutical composition that includes a therapeutically effective amount of crystalline apixaban particles.

In addition, Wei does not teach including only crystalline apixaban particles with a D_{90} equal to or less than about 89 μm in a pharmaceutical composition. In fact, based on the disclosure in Wei at paragraph [0020] regarding thermodynamic stability, a polymorph with a D_{90} above 100 μm can be more thermodynamically stable.

Moreover, Wei is silent as to the particle size of crystalline apixaban having any effect on plasma profiles, and does not disclose or suggest that when the D_{90} equal to or less than about 89 μm, consistent *in-vivo* dissolution in humans (at physiologic pH) can be achieved.

As mentioned previously by Applicants, it was surprisingly determined that the size of crystalline apixaban particles affects plasma profiles. Nonetheless, the Office Action takes a position that these results are not surprising, at least in part due to an alleged

teaching in Hafner that "controlling crystallization, crystal purity and crystal size/shape enables optimization of the dissolution rate and maximizes benefits such as bioavailability". Applicants respectfully disagree.

Hafner does not teach that optimization of the dissolution rate of apixaban by controlling the particle size of apixaban crystals would improve its bioavailability. Instead, this reference contains a general statement that "[c]ontrol of crystal size and shape [of a pharmaceutical-grade crystalline product] enables the optimization of the dissolution rate and this may maximize the benefit while minimizing the side effects" (page 1, lines 17-19). It is clear that Hafner does not link control of crystalline particle size with benefits for all drug substances, much less for apixaban, and with respect to bioavailability of apixaban in particular.

Applicants respectfully submit that in assessing parameters that can affect absorption of a drug substance such as apixaban, a skilled artisan would have looked at the Biopharmaceutical Classification System (BCS) classification of this drug. The BCS classifies drugs into four classes according to their solubility and permeability properties:

- BCS class I drugs have a high permeability and high solubility.
- BCS class II drugs have a high permeability and low solubility. Their bioavailability is limited by their dissolution rate.
- BCS class III drugs show low permeability and high solubility. Their absorption is limited by the permeation rate, but not by the dissolution rate.

- BCS class IV drugs have a low permeability and a low solubility. These drugs have a poor bioavailability.

Depending on the classification, drug absorption may be expected to range from heavily dependent on the formulation and manufacturing method (e.g., class II drugs) to mostly dependent on the drug permeability properties (e.g., class III drugs). A drug will be considered to have a high BCS permeability if more than 90% of the orally administered dose is absorbed in the small intestine.

A drug will be considered a drug that has a high BCS solubility if the dose/solubility ratio is 250 mL or less. Apixaban is recognized as a BCS class III drug.[1] To that end, as noted in the specification at paragraphs [0005] and [0011], apixaban is a high solubility drug as defined by the BCS.

Therefore, as also noted in the specification, due to its BCS classification, absorption of apixaban after oral administration would not have been reasonably expected to be limited by its dissolution rate. Thus, a skilled artisan would not have reasonably expected exposure to be dependent on the dissolution rate of apixaban. Consequently, there would have been no reason to control crystalline apixaban particle size as claimed, much less reasonably expect that when D_{90} of these particles exceeds 89 μm, consistent exposure may be not achieved.

As demonstrated in Figs. 3 and 4 and in Table 6, the use of crystalline apixaban particles with a D_{90} equal to or less than about 89 μm resulted in consistent *in-*

[1] See, e.g., http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202155Orig1s000ClinPharmR.pdf (p. 28) ("Apixaban is a BCS class III (high solubility, low permeability) drug.")

vivo dissolution in humans (at physiologic pH). Specifically, Figs. 3 and 4 show the dissolution rate at 30 minutes of 2.5 mg and 5 mg apixaban tablets plotted against the apixaban particle size (D_{90}). Taken together, the *in-vitro in vivo* relationship that has been established based on data of Table 6 and the *in vitro* data of Figs. 3 and 4 leverage the *in vitro-in vivo* relationship that is used in the application to demonstrate the link between crystalline apixaban particle size and exposure.

In order to assist the Office in understanding better the data provided in the application, the attached Annex provides a scheme illustrating the two-step approach that is disclosed in the application at paragraphs [0036], [0037], and [0038], as well as in Figs. 1-4, to demonstrate the surprising and unexpected impact of apixaban particle size on *in vivo* exposure.

Step 1

The observed relationship between *in vivo* systemic exposure (as reflected by C_{max} and AUC values) and *in vitro* dissolution rate is provided in Table 6 of the application. The point to note with these data is that while the oral bioavailability for all of the tablets (A), (B), and (C) (having dissolution rates at 30 minutes of 86, 77, and 89%, respectively) was found to be comparable to that from a solution (in view of the AUC values meeting the bioequivalence criteria), it was determined that the rate of absorption, as defined by C_{max}, was lower for the slower dissolving tablet (77% at 30 min) when strict bioequivalence criteria were applied (as indicated by the lower boundary of the 90% confidence interval of ratio of geometric mean, which was 0.788 for C_{max}) (paragraph [0037]). This indicates that with a dissolution rate of 77% at 30 minutes the C_{max} is lower

than the reference, and this is also an indication that any dissolution slower than 77% at 30 minutes would result in an even lower C_{max}. Thus, while a dissolution rate of 77% at 30 minutes may have been considered an acceptable dissolution rate in terms of the resulting AUC (as the AUC comparison met bioequivalence criteria), it is nonetheless clear that the tablets with the 77% dissolution rate at 30 min were found to produce the lowest AUC values (compare the AUC values for the three tablets). A skilled artisan would therefore understand that upon a further decrease in dissolution rate, the AUC values would also fail to meet bioequivalence criteria.

Step 2

Figs. 3 and 4 depict the observation that the dissolution rate of crystalline apixaban is affected by its particle size. Dissolution rates increase with decreasing particle sizes (paragraph [0038]).

Bringing steps 1 and 2 together

Having found the *in vivo-in vitro* relationship between exposure (as reflected by C_{max} and AUC values) and dissolution rate in step 1, the observation that a dissolution rate of 77% at 30 minutes did not meet bioequivalence criteria in terms of C_{max} was applied to Figs. 3 and 4 to establish the particle size that would be suitable when it comes to providing an *in vivo* exposure that meets bioequivalence criteria both in terms of AUC and C_{max}. Looking at the data for 2.5 mg tablets (Fig. 3) and 5 mg tablets (Fig. 4) collectively, the first data point that gave a dissolution rate at 30 minutes of just above 77%

in Fig. 3 was taken as the threshold for the particle size (this was the data point for tablets made with apixaban drug substance having a D_{90} of 89 microns).

Fig. 3 further establishes that for tablets made with larger particles (having a D_{90} of 120 microns), the dissolution rate at 30 minutes would be lower than 77%. As indicated above, given the observed bioequivalence failure in terms of C_{max} for the tablets having a dissolution rate of 77% at 30 minutes, any such tablet having a dissolution rate lower than 77% at 30 minutes would be expected to have an even further reduced C_{max} and thus provide an unacceptable exposure. This can be deduced from the observed *in vitro-in vivo* relationship between exposure and dissolution rate: with a dissolution rate below 77% at 30 minutes, it is likely that the AUC values would also fail to meet bioequivalence criteria.

Thus, Applicants respectfully submit that the data in the application demonstrate that the claimed pharmaceutical composition that comprises crystalline apixaban provide *in vivo* exposures bioequivalent to that from an apixaban solution, provided that the apixaban particles have a particle size within the claimed range. The same data also show that with particle sizes above the claimed range, the resulting *in vivo* exposures are expected not to meet bioequivalence criteria when compared to the apixaban solution.

That is, the data provided in the application demonstrate that contrary to what a skilled artisan would have reasonably expected prior to the present invention based on apixaban's BCS classification, absorption of apixaban does depends on its dissolution rate. Therefore, nothing in the cited art discloses or suggests controlling D_{90} of crystalline

apixaban particles in a pharmaceutical composition as claimed to provide consistent exposure.

Nause cannot cure the deficiencies of Wei and Hafner. Nause teaches, *inter alia*, amorphous dispersions of apixaban. Solid amorphous dispersions are clearly different from the crystalline apixaban particles recited in the present claims. Thus, Nause also does not disclose or suggest a pharmaceutical composition in which there is a therapeutically effective amount of crystalline apixaban particles that have a D_{90} equal to or less than about 89 μm.

Lastly, Abu-Baker also cannot provide the teaching missing in the other cited references as discussed above at least because it also fails to disclose or suggest crystalline apixaban particles having a D_{90} equal to or less than about 89 μm, much less a pharmaceutical composition that includes a therapeutically effect amount of these particles. Applicants respectfully submit that Abu-Baker does not teach a D_{90} of any active substance.

Abu-Baker is directed to a modified-release pharmaceutical formulation. Specifically, Abu-Baker describes so-called mini-tablets having a diameter of less than 5 mm and comprising a therapeutically effective amount of a Factor Xa inhibitor within a polymer matrix. These mini-tablets are made by compressing granules having a particle size D_{50} (median particle size) between 50-300 μm. Thus, both the granules and the mini-tablets do not comprise only an active substance, but also include at least a polymer. Therefore, the size of the mini-tablets or the size of the granules is not the particle size of

the active substance in Abu-Baker. Therefore, Abu-Baker fails to teach compositions wherein a factor Xa inhibitor has a defined particle size.

Moreover, the two specific Factor Xa inhibitors with which Abu-Baker is concerned are not apixaban. Therefore, a skilled artisan would not have looked to this reference for guidance with respect to apixaban particles.

Accordingly, Applicants respectfully submit that the cited documents, whether considered separately or in any permissible combination, do not disclose or suggest the claimed invention and do not render it unpatentable.

Wherefore, withdrawal of the outstanding rejections and allowance of the claims is respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
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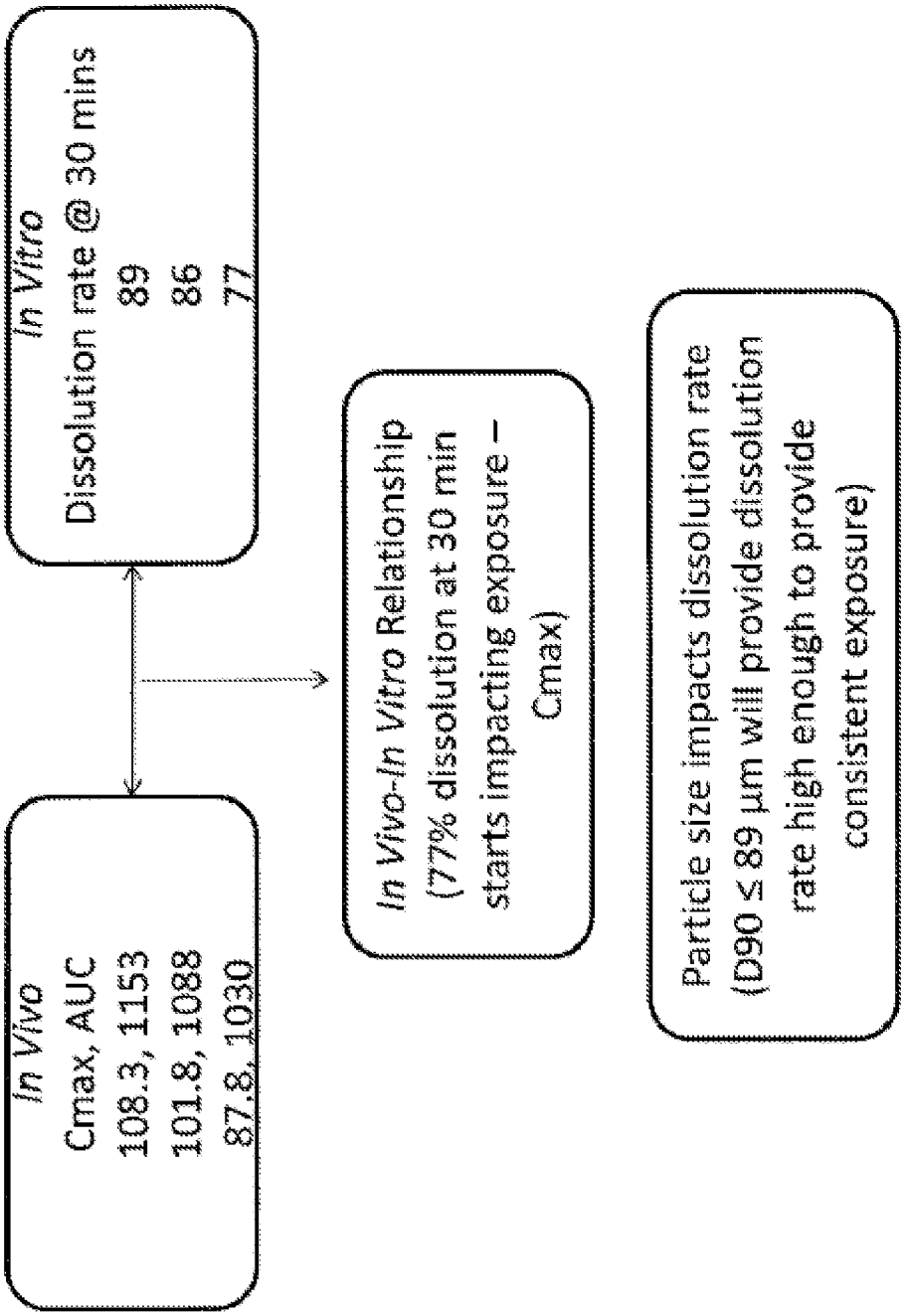
ANNEX


In Vitro
Dissolution rate @ 30 mins
89
86
77
In Vivo
Cmax, AUC
108.3, 1153
101.8, 1088
87.8, 1030
In Vivo-In Vitro Relationship
(77% dissolution at 30 min
starts impacting exposure –
Cmax)
Particle size impacts dissolution rate
(D90 ≤ 89 µm will provide dissolution
rate high enough to provide
consistent exposure)

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

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	1	2010-502762	JP	A	2010-01-28	GLAXO GROUP LTD.		☐
	2	2005-507889	JP	A	2005-03-24	BRISTOL MYERS SQUIBB COMPANY		☐
	3	2008-537750	JP	A	2008-09-25	NOVARTIS AG		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	ROBERT A. WAX
	Attorney Docket Number	03822.000060.

	4	2008-514712	JP	A	2008-05-08	BRISTOL MYERS SQUIBB COMPANY		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Official Action in Mexican Application No. MX/a/2012/009244 (dated Feb. 10, 2015).	☒
	2	Notification of Reasons for Refusal in Japanese Patent Application No. 2012-555127 (notified Feb. 24, 2015).	☒
	3	Hiroshi Nakagawa et al., "Formulation of Insoluble Drug," 24(11) JJSHP 15-22 (1988).	☒
	4	Hideo Yamada, Pharmaceutics I: Drug Compounding/Formulation, Chapter 2: Pharmaceutical Preparation Method, pp. 62-76 (Asakura Publishing Co., Ltd., 1995).	☒
	5	Heiichirou Toubata, Granulation Handbook, Application of Pelletization, pp. 438-439 (Japan Powder Industry Association, 1975).	☒
	6	Akinobu Ohtsuka et al., Pharmaceutics, Chapter 4 : Unit Operation of Powder Preparation, pp.104-105 (Hirokawa Publishing Co., Ltd., 1976).	☒
	7	Office Action in Russian Application No. 2012140690 (dated Feb. 12, 2015).	☒
	8	Dressman et al., "The BCS: Where Do We Go from Here?" Pharmaceutical Technology, pp. 68-76 (Jul. 2001).	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2012-10-10
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	Art Unit	1615
	Examiner Name	ROBERT A. WAX
	Attorney Docket Number	03822.000060.

	9	Third Party Observations in European Application No. 11707284.3 (dated May 19, 2015).	☐
	10	Notification Concerning the Date of Oral Proceedings in European Application No. 11707284.3 (dated May 12, 2015).	☐
	11	Notification Concerning the Date of Oral Proceedings in European Application No. 11707284.3 (dated May 27, 2015).	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-06-16
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Robert A. Wax
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1615
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	June 16, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of these documents are provided.

This Information Disclosure Statement is, in part, to submit copies of Third Party Observations and other papers from a corresponding European application, as well as copies of Office Actions issued in corresponding Mexican, Japanese, and Russian applications, along with their English language translations. Also submitted are Japanese

language documents listed in the aforementioned Japanese Office Action. The remaining documents listed in these Office Actions are already of record.

The concise explanation of relevance for the following Japanese patent publications may be found, *inter alia*, in their provided English language abstracts, in the aforementioned Japanese Office Action, and/or in their related English language publications (all of which are already of record) as listed in the table below:

Japanese Patent Publication	**Related English Language Publication**
JP 2010-502762	U.S. Patent Application Publication No. 2009/0285887 A1
JP 2005-507889	U.S. Patent No. 6,967,208 B2
JP 2008-537750	WO 2006/108643 A2
JP 2008-514712	U.S. Patent No. 7,396,932 B2

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Amy Steensen
Attorney Docket Number:	03822.000060.

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 3 months with $0 paid	1253	1	1400	1400
Miscellaneous:				
Request for Continued Examination	1801	1	1200	1200
		Total in USD ($)		**2600**

Electronic Acknowledgement Receipt

EFS ID:	22649580
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	16-JUN-2015
Filing Date:	10-OCT-2012
Time Stamp:	19:51:22
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2600
RAM confirmation Number	6286
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	Ref1.pdf	6424312 2b120f43dc0381aaf0d9b3fb98f901f9bc92eaa1	no	19
Warnings:					
Information:					
2	Foreign Reference	Ref3.pdf	16155467 2306e6f2a01251c3eb026de1fc73ea2288e32866	no	33
Warnings:					
Information:					
3	Foreign Reference	Ref4.pdf	19674680 596709d0f53aa116a64cb4ce8ec50387363c3660	no	42
Warnings:					
Information:					
4	Request for Continued Examination (RCE)	RCE03822000060.PDF	697904 16ffaacb38dbdafe82534f3a58c1ac5f1d06b3c9	no	3
Warnings:					
Information:					
5	Non Patent Literature	TranslationofMexicanOfficeAction03822000060.pdf	606207 0adc8bbcb41c829a7caeac784d4a8ba40eb17d09	no	32
Warnings:					
Information:					
6	Non Patent Literature	NotificationofReasonsforRefusalinJapanesePatentApp201255512703822000060.pdf	560532 b75a3c9197ff184a931c2f1b6eb6b8f0526e21f5	no	9
Warnings:					
Information:					
7	Non Patent Literature	JJSHPEnglishTranslation.PDF	6561768 536d9491cf84074120d199fae4d39ee3af8ab530	no	17
Warnings:					
Information:					

8	Non Patent Literature	JPRef5EnglishTranslation.pdf	14942100 9895da946551b37a67c2e20953ecffd3f405f056	no	32
Warnings:					
Information:					
9	Non Patent Literature	GranulationHandbookEnglishTranslation.PDF	3265350 b85d16ce6bbbc69c87fa201f14715708d8dabd3f	no	4
Warnings:					
Information:					
10	Non Patent Literature	PharmaceuticsEnglishTranslation.pdf	2115545 d45059d6a9d3d0c30f7c8ebaf26c3b38e8f38676	no	7
Warnings:					
Information:					
11	Non Patent Literature	RussianOA.PDF	1452972 38f4bef4379fa7d7682a28e50fd207f039a67486	no	11
Warnings:					
Information:					
12	Non Patent Literature	Dressman.PDF	4396704 fc598c1b7a137e9164f0e01f3e0e152c8feefa67	no	5
Warnings:					
Information:					
13	Non Patent Literature	ThirdPartyObservations.PDF	4768556 66ae2bcb3d891962363ba139caa4afc436101b58	no	10
Warnings:					
Information:					
14		SubmissionUnder1114andEOT03822000060.pdf	201312 e815da792e38a481961ff7b9d315c25548bd980e	yes	17

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment Submitted/Entered with Filing of CPA/RCE	1	1
Claims	2	7
Applicant Arguments/Remarks Made in an Amendment	8	17

Warnings:

Information:

15	Foreign Reference	JP2005507889_Part1.pdf	21719654 048d4be1ee0970f75b6f0095c3d2f23942cf2879	no	305
Warnings:					
Information:					
16	Foreign Reference	JP2005507889_Part2.pdf	15822235 94a28a63bf32afb09541a4e43fc4c13540314dca	no	224
Warnings:					
Information:					
17	Foreign Reference	JP2005507889_Part3.pdf	17220070 b2e997603e2dcb2c60906c5d937feaa02e55388f	no	220
Warnings:					
Information:					
18	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	542446 b3bfc9a0366ccf6058da00be49cb43fef3f49237	no	5
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
19	Transmittal Letter	IDSTRANS03822000060.pdf	106299 42bcfa97e7386a1c0028db46e711ccbf631304de	no	3
Warnings:					
Information:					
20	Non Patent Literature	NotificationReOralProceedings.pdf	164904 b51d2ca66b5cd91ec58628cf391631a1ad0699a1	no	4
Warnings:					
Information:					
21	Non Patent Literature	NotificationReOralProceedings2.pdf	23877 a61749cfe69979f18931d8ae581618a13a8bbce1	no	1
Warnings:					
Information:					
22	Fee Worksheet (SB06)	fee-info.pdf	32713 89fc037aadfc8587d538225b4645ec8ffcb09db5	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	137455607		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/579,796	Filing Date 10/10/2012	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **06/16/2015**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 20	Minus	** 23	= 0	X $80 =	0
Independent (37 CFR 1.16(h))	* 1	Minus	***3	= 0	X $420 =	0
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	0

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))						
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/LINDA HUMES/

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20060069258	A1	2006-03-30	SHAPIRO ET AL.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

	1	Official Action in Israeli Application No. 221064 (dated May 10, 2015).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-07-07
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	22840290
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	07-JUL-2015
Filing Date:	10-OCT-2012
Time Stamp:	16:13:45
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	Eng_FormTranslationofOfficeaction-1.pdf	4670563 9a3c72bef4b16047282f35ceaeac9742164532a8	no	5

Warnings:	
Information:	

2	Transmittal Letter	IDSTRANS03822000060.pdf	54241 7d12a5445b1c240fecaa7f58be156e2a7b204eda	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	541703 b2b35c23601e61d000fb6900e69842e905cd37b5	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	5266507	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	July 7, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a.

This Information Disclosure Statement is, in part, to submit a copy of an Office Action issued in a corresponding Israeli application, along with its English language translation. Applicants note that US 2006/0069258 A1 is a pre-grant publication of U.S. Patent No. 7,396,932 B2, which is already of record in the present application. All other documents listed in the Israeli Office Actions are also already of record.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

	1	Technical Report No. EDM 36-2015 in Peruvian Application No. 001362-2012 (dated Jul. 9, 2015).	☒
	2	Opposition to Peruvian Application No. 001362-2012 (dated Jun. 20, 2013).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-07-31
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	23079581
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	31-JUL-2015
Filing Date:	10-OCT-2012
Time Stamp:	14:29:07
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDSTRANS03822000060.pdf	53588 3f1687881fcf2aabddb9e2dfeae9e67df6ae90e5	no	2

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.pdf	541598 919ad3c43c1a2149bac85d6fdaf1b5d2aabd528e	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
3	Non Patent Literature	IDSDoc1.pdf	1340981 aaadb40b6c1f51b242d5f04c97b1c23eb0c4df29	no	21
Warnings:					
Information:					
4	Non Patent Literature	IDSDoc2.pdf	2610438 1863117213211fbc90e397991eecb9878e6150a6f	no	37
Warnings:					
Information:					
			Total Files Size (in bytes):	4546605	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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New International Application Filed with the USPTO as a Receiving Office

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03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	July 31, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a.

This Information Disclosure Statement is to submit a copy of an Office Action (Technical Report No. EDM 36-2015) issued in a corresponding Peruvian application, along with its English language translation. Also submitted is a copy of an Opposition filed in the aforementioned Peruvian application, which is referenced in the

Office Action, with its English language translation. The documents listed in the Peruvian Office Action and in the Opposition paper are already of record.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 08/13/2015

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER
FRAZIER, BARBARA S

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
08/13/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 13/579,796	Applicant(s) PATEL ET AL.	
	Examiner BARBARA FRAZIER	Art Unit 1611	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2015*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5)☒ Claim(s) *1,3,5-8,11-13,16-18 and 26-33* is/are pending in the application.

5a) Of the above claim(s) *13 and 16-18* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3,5-8,11,12 and 26-33* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *See Continuation Sheet*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

Continuation of Attachment(s) 2). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/27/14,11/13/14,11/18/14,1/16/15,2/2/15,6/16/15,7/7/15,7/31/15.

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 June 2015 has been entered.

Status of Claims

3. Claims 1, 3, 5-8, 11-13, 16-18, and 26-33 are pending in this application.

4. Addition of new claims 26-33 is acknowledged.

5. Claims 13 and 16-18 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 January 2014.

6. Claims 1, 3, 5-8, 11, 12, and 26-33 are examined.

Examiner's Remarks

7. Applicants' arguments, filed 16 June 2015, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

8. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under pre-AIA 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

11. Claims 1, 3, 5-8, 11, 12, and 26-33 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Nause et al. (“Nause”, US 2012/0087978, previously cited, priority date 16 June 2009) in view of Wei et al. ("Wei", US 2006/0160841, previously cited).

Regarding claims 1, 5-8, 27, 29-31, and 33, Nause teaches a factor Xa inhibitor dosage form comprising apixaban in a solubility-improved form (abstract). The solubility-improved forms include crystalline forms, such as a crystalline highly soluble form (paragraphs [0010], [0149]; claim 6). Desired dosages (which constitute therapeutically effective amounts) may be determined by the skilled artisan and range, for example, from 1 mg/day to 100 mg/day (paragraph [0255]). The core may include a wide variety of additives and excipients that enhance the performance of the dosage form or that promote stability, tableting or processing (paragraph [0066]). A tablet

comprising 5 mg apixaban and pharmaceutically diluents/carriers is exemplified (Example 7, Table 8).

While Nause teaches its solubility-improving forms of apixaban comprise crystalline forms, Nause does not specifically teach the size of the crystalline apixaban.

Wei generally teaches that it is well known in the pharmaceutical industry that the bioavailability of a sparingly soluble organic compound is often enhanced when the compound is very pure and the molecules of the compound have a small, uniform particle size, high surface area, and short dissolution time (paragraph [0003]). Wei teaches a robust crystallization that process that can produce small and uniform crystals with high purity, high stability, and high surface area, without the necessity of post-crystallization milling, thus producing apixaban particles which are crystalline and have a D_{90} of less than about 20 microns (paragraph [0011]; Examples 1-3).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine Wei with Nause and utilize the crystalline apixaban particles of Wei in the composition of Nause; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because the crystalline apixaban particles of Wei provide the benefits of small, uniform particle size, high surface area, and short dissolution time, as well as improved solubility, as taught by Wei, and Nause teaches that its compositions may comprise a crystalline highly soluble form.

Regarding claim 3, Wei teaches that the crystalline apixaban particles are in the N-1 form (Examples 1-3).

Regarding claims 11 and 12, Nause teaches a surfactant such as sodium lauryl sulfate may be added (paragraph [0066]); a composition comprising 2% sodium lauryl sulfate is exemplified (Example 7, Table 8).

Regarding claim 26, it is noted that, since the crystalline apixaban particles of Wei have the same limitations as those of the claimed invention, one skilled in the art would reasonably expect said particles to possess the same dissolution properties, absent evidence to the contrary.

Regarding claims 28 and 32, Nause teaches desired dosages may be determined by the skilled artisan and range, for example, from 1 mg/day to 100 mg/day (paragraph [0255]). This range encompasses that of the claimed invention; one skilled in the art would be motivated to manipulate the dosage from within said ranges by routine experimentation, in order to optimize the efficacy of the resultant composition. Nause further teaches that specific dosage regimens should be adjusted over time according to the individual need and the professional judgment of the person administering or supervising the administration of the compositions, and may also be adjusted based on parameters such as toxic effects and/or laboratory values (paragraph [0255]), and thus the determination of the particular dosage would be within the purview of the skilled artisan.

Response to Arguments

12. Applicant's arguments filed 16 June 2015 have been fully considered but they are not persuasive.

Applicant's arguments directed to the teachings of Wei alone and Hafner are moot in light of the new rejection (see paragraph 11, above).

In response to Applicant's arguments regarding apixaban's BCS classification, it is noted that said arguments are inconsistent with the clear teachings of Nause and Wei. Nause teaches that in most cases apixaban is sufficiently insoluble in aqueous media that a surfactant such as SLS may be added to raise the solubility of the drug (paragraph [0055]), and Wei teaches that bioavailability of a sparingly soluble organic compound is often enhanced when the compound is very pure and the molecules of the compound have a small, uniform particle size, high surface area, and short dissolution time (paragraph [0003]), exemplifying apixaban (Examples 1-3). Therefore, while Applicant's arguments have been considered, they are not sufficient to overcome the teachings of the cited prior art, and the rejection is maintained.

In response to Applicant's arguments directed to data presented in the specification, it is noted that said data appears to be consistent with what is already known in the pharmaceutical industry, i.e., that bioavailability is often enhanced when the compound is very pure and the molecules of the compound have a **small, uniform particle size**, high surface area, and **short dissolution time**, as taught by Wei (paragraph [0003]), and therefore Applicant's results are neither surprising nor unexpected.

Therefore, it is the Examiner's position that the claims are rendered obvious.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Friday 9am-2:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bethany Barham can be reached on (571)272-6175. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BARBARA FRAZIER/
Examiner, Art Unit 1611

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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Receipt date: 11/18/2014	Application Number	13579796 13579796 - GAU: 1611
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	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

/B.F./	1	Summons to attend oral proceedings pursuant to Rule 115(1) EPC in European Application No. 11707284.3 (dated Nov. 14, 2014).	☐

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	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

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☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

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Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2014-11-18
Name/Print	Jason M. Okun	Registration Number	48,512

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

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	1	2010-502762	JP	A	2010-01-28	GLAXO GROUP LTD.		☐
	2	2005-507889	JP	A	2005-03-24	BRISTOL MYERS SQUIBB COMPANY		☐
	3	2008-537750	JP	A	2008-09-25	NOVARTIS AG		☐

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Receipt date: 06/16/2015	Application Number	13579796	13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-10-10	
(Not for submission under 37 CFR 1.99)	First Named Inventor	JATIN PATEL ET AL.	
	Art Unit	1615	
	Examiner Name	ROBERT A. WAX	
	Attorney Docket Number	03822.000060.	

	4	2008-514712	JP	A	2008-05-08	BRISTOL MYERS SQUIBB COMPANY		☐

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	1	Official Action in Mexican Application No. MX/a/2012/009244 (dated Feb. 10, 2015).	☒
	2	Notification of Reasons for Refusal in Japanese Patent Application No. 2012-555127 (notified Feb. 24, 2015).	☒
	3	Hiroshi Nakagawa et al., "Formulation of Insoluble Drug," 24(11) JJSHP 15-22 (1988).	☒
	4	Hideo Yamada, Pharmaceutics I: Drug Compounding/Formulation, Chapter 2: Pharmaceutical Preparation Method, pp. 62-76 (Asakura Publishing Co., Ltd., 1995).	☒
	5	Heiichirou Toubata, Granulation Handbook, Application of Pelletization, pp. 438-439 (Japan Powder Industry Association, 1975).	☒
	6	Akinobu Ohtsuka et al., Pharmaceutics, Chapter 4 : Unit Operation of Powder Preparation, pp.104-105 (Hirokawa Publishing Co., Ltd., 1976).	☒
	7	Office Action in Russian Application No. 2012140690 (dated Feb. 12, 2015).	☒
	8	Dressman et al., "The BCS: Where Do We Go from Here?" Pharmaceutical Technology, pp. 68-76 (Jul. 2001).	☐

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	First Named Inventor	JATIN PATEL ET AL.	
	Art Unit	1615	
	Examiner Name	ROBERT A. WAX	
	Attorney Docket Number	03822.000060.	

	9	Third Party Observations in European Application No. 11707284.3 (dated May 19, 2015).	☐
	10	Notification Concerning the Date of Oral Proceedings in European Application No. 11707284.3 (dated May 12, 2015).	☐
	11	Notification Concerning the Date of Oral Proceedings in European Application No. 11707284.3 (dated May 27, 2015).	☐

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Examiner Signature	/Barbara Frazier/	Date Considered	08/09/2015

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Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-06-16
Name/Print	Jason M. Okun	Registration Number	48,512

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Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

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Receipt date: 07/07/2015	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

/B.F./	1	Official Action in Israeli Application No. 221064 (dated May 10, 2015).	☒

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	Examiner Name	BARBARA S. FRAZIER
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Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-07-07
Name/Print	Jason M. Okun	Registration Number	48,512

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

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Receipt date: 07/31/2015	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

/B.F./	1	Technical Report No. EDM 36-2015 in Peruvian Application No. 001362-2012 (dated Jul. 9, 2015).	☒
/B.F./	2	Opposition to Peruvian Application No. 001362-2012 (dated Jun. 20, 2013).	☒

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Examiner Signature	/Barbara Frazier/	Date Considered	08/09/2015

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Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	BETHANY P. BARHAM
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.F./

Receipt date: 08/27/2014	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	BETHANY P. BARHAM
	Attorney Docket Number	03822.000060.

	1	Third Party Observations in European Application No. 11707284.3 (dated July 30, 2014).	☐
	2	Third Party Observations in European Application No. 11707284.3 (dated July 15, 2014).	☐
	3	Third Party Observations in European Application No. 11707284.3 (dated August 18, 2014).	☐
	4	European Pharmacopoeia 6.0; Section 2.9.31 - "Particle Size Analysis by Laser Light Diffraction", pp. 311-314 (July 2007).	☐
	5	European Pharmacopoeia 7.0; Section 2.9.31 - "Particle Size Analysis by Laser Light Diffraction", pp. 295-299 (July 2010).	☐

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Examiner Signature	/Barbara Frazier/	Date Considered	08/09/2015

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Filing Date	2012-10-10
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Receipt date: 11/13/2014	Application Number	13579796 13579796 - GAU: 1611
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/B.F./	1	Resolution Nº 61405 in Colombian Application No. 12.152.138 (dated Oct. 14, 2014).	☒

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
/B.F./	1	1578660	CN	A	2005-02-09	BRISTOL MYERS SQUIBB CO.		☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

Receipt date: 01/16/2015	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2011-02-24
(Not for submission under 37 CFR 1.99)	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	ROBERT A. WAX
	Attorney Docket Number	03822.000060.

/B.F./	1	Peng Chen et al., "Enhancement for Dissolution of Poorly Water Soluble Drug by Micronization," 10 Chemistry Bulletin 766-771 (2007).	☒
/B.F./	2	Second Office Action in Chinese Application No. 201180011229.X (issued Oct. 31, 2014).	☒

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EXAMINER SIGNATURE

Examiner Signature	/Barbara Frazier/	Date Considered	08/09/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Receipt date: 01/16/2015	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	ROBERT A. WAX
	Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-01-16
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13579796	PATEL ET AL.
	Examiner	Art Unit
	BETHANY BARHAM	1615

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East (see attached search notes)	07/16/14	BB
Palm Inventors Search (all inventors)	07/16/14	BB
EAST search updated	8/10/15	BSF
Inventor search updated	8/10/15	BSF

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/B.F./ Examiner.Art Unit 1611	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	13/579796.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:19
S2	3	"20060016841".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:20
S3	2	"20060160841".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:21
S4	3	"20120087978".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:27
S5	2	S4 and mg	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:31
S6	3	WO-2010003811-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:33
S7	2	S5 and (sulfate or SLS)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:34
S8	2	(S3 or S4) and (tablet or capsule)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:51
S9	2	S4 and crystal$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/08 15:52
S10	3	"20060069258".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/09 21:41
S11	2	"6967208".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2015/08/09 21:52

EAST Search History (Interference)

< This search history is empty>

8/ 10/ 2015 9:53:39 AM
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2011-02-24
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1615
Examiner Name	ROBERT A. WAX
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

Receipt date: 02/02/2015	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2011-02-24
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1615
	Examiner Name	ROBERT A. WAX
	Attorney Docket Number	03822.000060.

/B.F./	1	Third Party Observations in European Application No. 11707284.3 (filed Jan. 16, 2015).	☐
/B.F./	2	International Standard – ISO 13320-1, First Edition, Particle Size Analysis – Laser Diffraction Methods, pp. 1-34 (Nov. 1999).	☐
/B.F./	3	Nor Hafizah Hj Annuar et al., "Effects of Sample Conditions on Multi-Particle Size Analysis Using Laser Diffraction Technique," Scientia Bruneiana, pp. 19-26 (2010).	☐
/B.F./	4	Zoran Stojanovic et al., "Determination of Particle Size Distributions by Laser Diffraction," 21 Technics – New Materials 11-20 (2012).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Barbara Frazier/	Date Considered	08/09/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Receipt date: 02/02/2015	Application Number	13579796	13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2011-02-24	
	First Named Inventor	JATIN PATEL ET AL.	
	Art Unit	1615	
	Examiner Name	ROBERT A. WAX	
	Attorney Docket Number	03822.000060.	

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☐ A certification statement is not submitted herewith.

SIGNATURE

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Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-02-02
Name/Print	Jason M. Okun	Registration Number	48,512

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 09/17/2015

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER
FRAZIER, BARBARA S

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
09/17/2015	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/579,796	PATEL ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

All participants (applicant, applicant's representative, PTO personnel):

(1) *BARBARA FRAZIER*.

(2) *Jason Okun*.

(3) *Barry Jacobsen*.

(4) *Jatin Patel*.

Date of Interview: *15 September 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1,3,5-8,11,12 and 26-33*.

Identification of prior art discussed: *Nause; Wei*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicants discussed different properties observed with claimed invention, including dissolution rate, and stated the position that one skilled in the art would not have expected particle size to have made a difference in in vivo data, since apixaban is a BCS Class III drug (highly soluble) Applicants stated the dosage form of Nause is directed controlled release, while the claimed invention is directed to immediate release, noting dissolution property recited in claim 26. Applicants discussed Wei is directed to making specific polymorphs, rather than therapeutic properties of apixaban. Examiner suggested incorporating claim 26 into claim 1 to further define the claimed composition. Applicants will consider making amendments and/or further arguments with the next response. An agreement was not reached with respect to the claims.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/BARBARA FRAZIER/ Examiner, Art Unit 1611	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

	1	Third Party Observations on European Application No. 11707284.3 (dated July 24, 2015).	☐
	2	U.S. Pharmacopoeia (USP) 38, Chapter 429, "Light Diffraction Measurement of Particle Size," pp. 294-299 (May 2015) (Annex 1).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-09-18
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	23532527
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	18-SEP-2015
Filing Date:	10-OCT-2012
Time Stamp:	12:05:27
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	IDSDoc1.pdf	534036 a2cab5aed082ab5741650b33695b61302dfccc75	no	10

Warnings:	
Information:	

2	Non Patent Literature	IDSDoc2.pdf	525119 316495772c6e5d4f8f99b5ac87ac97c9bd1d8b89	no	6
Warnings:					
Information:					
3	Transmittal Letter	IDSTRANS03822000060.pdf	54040 54884fced59cef445519253258cc14bd6d43f337	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.pdf	541759 0c7152cc3e3db0451f87e97ce06ea4aa2c34782f	no	4
Warnings:					
Information:					

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

Total Files Size (in bytes):	1654954

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	September 18, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a.

This Information Disclosure Statement is to submit copies of Third Party Observations and an Annex thereto from the corresponding allowed European application.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

	1	Resolution No. 39058 in Colombian Application No. 12.152.138 (published Aug. 4, 2015).	☒
	2	Resolution No. 64634 in Colombian Application No. 14.268.266 (published Sep. 22, 2015).	☒

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2015-10-29
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	October 29, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of these documents are provided.

This Information Disclosure Statement is to submit copies of Resolutions (Office Actions) from the corresponding Colombian applications. The English language translations of these Resolutions are also submitted. Applicants note that D1-D6 listed in

Resolution No. 39058 correspond to D1-D6 listed in Resolution No. 64634 and are all already of record.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Acknowledgement Receipt

EFS ID:	23929095
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	29-OCT-2015
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Application Type:	U.S. National Stage under 35 USC 371

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.pdf	541579 df2b8c8fb43e2444bac2f823778aca5daa389a3e	no	4

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2	Non Patent Literature	IDSDoc1.pdf	9792836 f04192d30d678cd1b1d2cf548968c6255ecbb764	no	28
Warnings:					
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3	Non Patent Literature	IDSDoc2.pdf	11535896 acd832f0659ab254018d12b380e73256fa6275b2	no	32
Warnings:					
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4	Transmittal Letter	IDSTRANS03822000060.pdf	54243 33baf7c5468bc92fa8cd9c93a766ac02c00f5818	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	21924554		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	November 30, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT, STATEMENT OF THE SUBSTANCE OF THE INTERVIEW
AND PETITION FOR EXTENSION OF TIME

Sir:

Applicants petition the Commissioner for Patents to extend the time for response to the Office Action dated August 13, 2015, to December 13, 2015. The fee for the extension is submitted herewith. Any deficiency in this fee should be charged, and any overpayment credited, to Deposit Account No. 50-3939.

In response to the Office Action dated August 13, 2015, please amend the above-captioned application as follows and consider the following remarks.

CLAIMS

A complete listing of all the claims appears below; this listing replaces all earlier amendments and listings of the claims.

1. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of crystalline apixaban particles and a pharmaceutically acceptable diluent or carrier,

wherein the crystalline apixaban particles have a D_{90} equal to or less than about 89 μm, and

wherein at least 77 wt% of apixaban dissolves within 30 minutes in a pH 6.8 phosphate buffer containing 0.05% sodium lauryl sulfate.

2. (Cancelled)

3. (Previously Presented) The composition as defined in claim 1, wherein said composition comprises Form N-1 of apixaban.

4. (Cancelled)

5. (Previously Presented) The composition as defined in claim 1, wherein the D_{90} is equal to or less than 85 μm.

6. (Previously Presented) The composition as defined in claim 1, wherein the D_{90} is equal to or less than 50 μm.

7. (Previously Presented) The composition as defined in claim 1, wherein the D_{90} is equal to or less than 30 μm.

8. (Previously Presented) The composition as defined in claim 1, wherein the D_{90} is equal to or less than 25 μm.

9-10. (Cancelled)

11. (Previously Presented) The composition as defined in claim 1, further comprising:

from 1% to 2 % by weight of a surfactant.

12. (Previously Presented) The composition as defined in claim 11, wherein the surfactant is sodium lauryl sulfate.

13. (Withdrawn) A method for the treatment or prophylaxis of a thromboembolic disorder, comprising administering to a patient in need of such treatment or prophylaxis a therapeutically effective amount of a composition as defined in claim 1.

14-15. (Cancelled)

16. (Withdrawn) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials prior to granulation;

(2) granulating the raw materials from the step (1) using a wet or dry granulation process;

(3) blending the granules obtained in the step (2) with extragranular raw materials;

(4) compressing the blend from the step (3) into tablets; and

(5) film coating the tablets from the step (4).

17. (Withdrawn) A process of manufacturing apixaban tablets having a composition as defined in claim 1, comprising the steps of:

(1) blending raw materials with apixaban of controlled particle size to form a mix;

(2) adding intragranular portions of a binder, a disintegrant and at least one filler to the mix from the step (1) to form a blend;

(3) granulating the materials from the step (2) using a dry granulation process or a wet granulation process,

wherein the dry granulation process comprises:

delumping an intragranular lubricant using a screen or mill;

adding the intragranular lubricant to the blend from the step (2) and blending to form a lubricated blend;

compacting the lubricated blend to ribbons of density in a range of 1.1 to 1.2 g/cc and sizing the compacted ribbons using a roller compactor, and

wherein the wet granulation process comprises:

wet granulating the blend from the step (2) using water to a target end point and, optionally, sizing the wet-granules by passing through a screen or mill;

removing the water from the granulation by drying in a convection oven or a fluid-bed dryer; and

sizing the dried granules by passing through a screen or mill;

(4) blending the granules obtained in the step (3) and an extragranular disintegrant in a blender;

(5) delumping an extragranular lubricant using a screen or mill and blending with granules from the step (4);

(6) compressing the blend from the step (5) into tablets; and

(7) film coating the tablets from the step (6).

18. (Withdrawn) A process of manufacturing apixaban tablets according to claim 17, wherein the dry granulation process is used.

19-26. (Cancelled)

27. (Previously Presented) The composition as defined in claim 1, wherein the pharmaceutical composition comprises from about 2.5 mg to about 5 mg of apixaban.

28. (Previously Presented) The composition as defined in claim 1, wherein the pharmaceutical composition comprises 2.5 mg of apixaban.

29. (Previously Presented) The composition as defined in claim 1, wherein the pharmaceutical composition comprises 5 mg of apixaban.

30. (Previously Presented) A tablet or capsule comprising the pharmaceutical composition as defined in claim 1.

31. (Previously Presented) A tablet or capsule comprising the pharmaceutical composition as defined in claim 27.

32. (Previously Presented) A tablet or capsule comprising the pharmaceutical composition as defined in claim 28.

33. (Previously Presented) A tablet or capsule comprising the pharmaceutical composition as defined in claim 29.

34. (New) A pharmaceutical composition comprising a therapeutically effective amount of apixaban and a pharmaceutically acceptable diluent or carrier,

wherein apixaban comprises crystalline apixaban particles,

wherein the crystalline apixaban particles have a D_{90} equal to or less than about 89 μm, and

wherein, as measured using a USP Apparatus 2 at a paddle rotation speed of 75 rpm in 900 mL of a dissolution medium at 37 °C, at least 77 wt% of apixaban in the pharmaceutical composition dissolves within 30 minutes in the dissolution medium, and the dissolution medium is 0.05 M sodium phosphate at a pH 6.8 containing 0.05% sodium lauryl sulfate.

35. (New) The composition as defined in claim 34, wherein said composition comprises Form N-1 of apixaban.

36. (New) The composition as defined in claim 34, wherein the D_{90} is equal to or less than 85 μm.

37. (New) The composition as defined in claim 34, wherein the D_{90} is equal to or less than 50 μm.

38. (New) The composition as defined in claim 34, wherein the D_{90} is equal to or less than 30 μm.

39. (New) The composition as defined in claim 34, wherein the D_{90} is equal to or less than 25 μm.

40. (New) The composition as defined in claim 34, further comprising: from 1% to 2 % by weight of a surfactant.

41. (New) The composition as defined in claim 40, wherein the surfactant is sodium lauryl sulfate.

42. (New) The composition as defined in claim 34, wherein the pharmaceutical composition comprises from about 2.5 mg to about 5 mg of apixaban.

43. (New) The composition as defined in claim 34, wherein the pharmaceutical composition comprises 2.5 mg of apixaban.

44. (New) The composition as defined in claim 34, wherein the pharmaceutical composition comprises 5 mg of apixaban.

45. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 34.

46. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 42.

47. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 43.

48. (New) A tablet or capsule comprising the pharmaceutical composition as defined in claim 44.

STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

Applicants and their undersigned attorney, as well as Dr. Jatin Patel, would like to thank the Examiner for the courtesies extended during an in-person interview conducted on September 15, 2015. During this in-person interview, the outstanding rejection over U.S. Patent Application Publication No. 2012/0087978 A1 (Nause) in view of U.S. Patent Application Publication No. 2006/0160841 A1 (Wei) was discussed. Applicants' attorney pointed out, *inter alia*, that because apixaban is a BCS class III drug, a skilled arttisan would not have expected its particle size to have made a difference with respect to its *in vivo* absorption. The data presented in the application, however, shows otherwise.

Applicants also pointed out that Nause is directed to controlled release dosage forms, which are difference from a composition of the present invention, as is evident from, for example, the rate of dissolution recited in claim 26. The Examiner acknowledged this difference and suggested incorporating claim 26 into claim 1 to further define the claimed composition.

With respect to Wei, Applicants reiterated that this reference does not teach or suggest a pharmaceutical composition, much less such a composition that includes apixaban of a specific particle size. At best, Wei teaches how to form polymophs of a certain desired form, but sheds no light on why any specific particle size of apixaban would be desired.

REMARKS

The claims are 1, 3, 5-8, 11-13, 16-18, and 27-48, with claims 1 and 34 being independent. Claims 13 and 16-18 have been withdrawn from consideration as being directed to non-elected subject matter. Claim 26 has been cancelled without prejudice or disclaimer and its features have been included in claim 1. New claims 34-48 have been added. Support for claim 34 may be found, for example, in claim 1 and in the specification at paragraph [0030], as well as in Tables 5 and 6. Support for claims 35-48 may be found in claims 3, 5-8, 11, 12, and 27-33, respectively. No new matter has been added. Reconsideration of the claims is respectfully requested.

Claims 1, 3, 5-8, 11, 12, and 26-33 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious from U.S. Patent Application Publication No. 2012/0087978 A1 (Nause) in view of U.S. Patent Application Publication No. 2006/0160841 A1 (Wei). The rejection is respectfully traversed.

Prior to addressing the merits of rejection, Applicants would like to discuss briefly some of the features of the presently claimed embodiments of the invention. Those embodiments, in pertinent part, are related to a pharmaceutical composition comprising crystalline apixaban particles that have a D_{90} equal to or less than about 89 μm. At least 77 wt% of apixaban in this composition dissolves within 30 minutes in a pH 6.8 phosphate buffer containing 0.05% sodium lauryl sulfate.

Nause is related to a controlled release dosage form of apixaban that preferably "releases in vivo or in vitro 70 wt % of apixaban over 2 hours or more after administration of the dosage form to an aqueous environment of use" (paragraph [0006]). As pointed out during the aforementioned in-person interview, this is considerably

different from a pharmaceutical composition of the present invention, which is such that "at least 77 wt% of apixaban dissolves within 30 minutes in a pH 6.8 phosphate buffer containing 0.05% sodium lauryl sulfate", and which Nause does not disclose or suggest. In fact, Nause specifically differentiates its controlled release dosage form from the type of composition that is claimed, which, according to the teachings in Nause, would have been considered to be an immediate release composition:

> The present invention provides a controlled release dosage form comprising apixaban in a solubility-improved form. As used herein, by "immediate release" is meant that at least 70 wt % of a compound initially present in the dosage form is released within one hour or less following introduction to a use environment. By "controlled release" is meant that apixaban is released at a rate that is slower than immediate release i.e., less than 70 wt % of apixaban is released by (within) one hour following introduction to a use environment. Paragraph [0032].

In addition, Nause teaches achieving its goal by providing a solid amorphous dispersion, which is clearly different from a composition that includes crystalline apixaban particles recited in the present claims. Thus, Nause not only fails to disclose or suggest a pharmaceutical composition with crystalline apixaban particles that have a D_{90} equal to or less than about 89 μm, but Nause also is not at all relevant with respect to the claimed type of formulations that contain crystalline apixaban and, consequently, is not relevant with respect to the present invention.

Wei is related to a process for transforming one polymorph to another polymorph. This reference, however, does not teach any pharmaceutical composition, much less one that includes crystalline apixaban particles with the claimed parameters and a pharmaceutically acceptable diluent or carrier, which results in at least 77 wt% of

apixaban dissolving within 30 minutes in a pH 6.8 phosphate buffer containing 0.05% sodium lauryl sulfate. In fact, Wei is not concerned with any such composition. This reference teaches a slurry containing apixaban particles, which is not a pharmaceutical composition.

In essence, while Wei teaches how to transform a first polymoph into a second polymorph, this reference sheds no light on which one of these two polymorps, if any, or even a combination of polymorps, would have been desired for apixaban. In particular, Wei states:

> The process is useful for transforming a first polymorph (including solvate) of a chemical material into a second polymorph (including solvate) of the same chemical material. **The second polymorph can be thermodynamically more stable or thermodynamically less stable than the first polymorph.** In addition, the first polymorph can be in a solvate form, including hydrate form and the second polymorph can be in an anhydrous form. Paragraph [0020].

Wei provides no reason for selecting crystalline apixaban with a D_{90} equal to or less than about 89 μm for use in a pharmaceutical composition. Wei merely teaches how to produce a specific crystalline form.

As mentioned during the in-person interview, the general statement at paragraph [0003] of Wei regarding improvement of bioavailability of a sparingly soluble compound by providing small, uniform particle sizes, to which the Office Action refers, would not have been deemed by a skilled artisan to be applicable to apixaban, because apixaban is a highly soluble drug in accordance with the Biopharmaceutical Classification System (BCS) system. To that end, Applicants respectfully submit that in assessing parameters that can affect absorption of a drug substance such as apixaban, a skilled artisan

would have looked at the BCS classification of this drug. The BCS classifies drugs into four classes according to their solubility and permeability properties:

- BCS class I drugs have a high permeability and high solubility.
- BCS class II drugs have a high permeability and low solubility. Their bioavailability is limited by their dissolution rate.
- BCS class III drugs show low permeability and high solubility. Their absorption is limited by the permeation rate, but not by the dissolution rate.
- BCS class IV drugs have a low permeability and a low solubility. These drugs have a poor bioavailability.

Depending on the classification, drug absorption may be expected to range from heavily dependent on the formulation and manufacturing method (e.g., class II drugs) to mostly dependent on the drug permeability properties (e.g., class III drugs). A drug will be considered to have a high BCS permeability if more than 90% of the orally administered dose is absorbed in the small intestine.

A drug will be considered a drug that has a high BCS solubility if the dose/solubility ratio is 250 mL or less. Apixaban is recognized as a BCS class III drug.[1] Thus, as noted in the specification at paragraphs [0005] and [0011] and mentioned above, apixaban is a high solubility drug as defined by the BCS.

[1] See, e.g., http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202155Orig1s000ClinPharmR.pdf (p. 28) ("Apixaban is a BCS class III (high solubility, low permeability) drug.")

Accordingly, as also noted in the specification, due to its BCS classification, absorption of apixaban after oral administration would not have been reasonably expected to be limited by its dissolution rate. Thus, a skilled artisan would not have reasonably expected exposure to be dependent on the dissolution rate of apixaban. That is, even if assumed, *arguendo*, that a skilled artisan would have understood that the dissolution rate of apixaban could be increased by decreasing particle size, such an increase in dissolution rate would not have been expected to impact absorption of apixaban, because apixaban is a BCS class III highly soluble drug – absorption of such a drug is deemed to be mostly dependent on its permeability properties, rather than its dissolution rate. Consequently, Applicants respectfully submit that there would have been no reason to control crystalline apixaban particle size for achieving consistent exposure. Additionally, in view of the BCS classification of apixaban, there clearly would not have been a reasonable expectation that when D_{90} of these particles exceeds about 89 μm, consistent exposure may be not achieved (see specification, paragraph [0006]).

The criticality of the claimed D_{90} threshold is supported by *in-vivo* and *in-vitro* data provided in the present application. As demonstrated in Figs. 3 and 4 and in Table 6, the use of crystalline apixaban particles with a D_{90} equal to or less than about 89 μm resulted in consistent *in-vivo* dissolution in humans (at physiologic pH). Specifically, Figs. 3 and 4 show the dissolution rate at 30 minutes of 2.5 mg and 5 mg apixaban tablets plotted against the apixaban particle size (D_{90}). Taken together, the *in-vitro in vivo* relationship that has been established based on data of Table 6 and the *in vitro* data of Figs. 3 and 4 leverage the *in vitro-in vivo* relationship that is used in the application to demonstrate the link between crystalline apixaban particle size and exposure.

In order to assist the Office in understanding better the data provided in the application, the attached Annex provides a scheme illustrating the two-step approach that is disclosed in the application at paragraphs [0036], [0037], and [0038], as well as in Figs. 1-4, to demonstrate the surprising and unexpected impact of apixaban particle size on *in vivo* exposure.

Step 1

The observed relationship between *in vivo* systemic exposure (as reflected by C_{max} and AUC values) and *in vitro* dissolution rate is provided in Table 6 of the application. The point to note with these data is that while the oral bioavailability for all of the tablets (A), (B), and (C) (having dissolution rates at 30 minutes of 86, 77, and 89%, respectively) was found to be comparable to that from a solution (in view of the AUC values meeting the bioequivalence criteria), it was determined that the rate of absorption, as defined by C_{max}, was lower for the slower dissolving tablet (77% at 30 min) when strict bioequivalence criteria were applied (as indicated by the lower boundary of the 90% confidence interval of ratio of geometric mean, which was 0.788 for C_{max}) (paragraph [0037]). This indicates that with a dissolution rate of 77% at 30 minutes the C_{max} is lower than the reference, and this is also an indication that any dissolution slower than 77% at 30 minutes would result in an even lower C_{max}. Thus, while a dissolution rate of 77% at 30 minutes may have been considered an acceptable dissolution rate in terms of the resulting AUC (as the AUC comparison met bioequivalence criteria), it is nonetheless clear that the tablets with the 77% dissolution rate at 30 min were found to produce the lowest AUC values (compare the AUC values for the three tablets). A skilled artisan would therefore

understand that upon a further decrease in dissolution rate, the AUC values would also fail to meet bioequivalence criteria.

Step 2

Figs. 3 and 4 depict the observation that the dissolution rate of crystalline apixaban is affected by its particle size. Dissolution rates increase with decreasing particle sizes (paragraph [0038]).

Bringing steps 1 and 2 together

Having found the *in vivo-in vitro* relationship between exposure (as reflected by C_{max} and AUC values) and dissolution rate in step 1, the observation that a dissolution rate of 77% at 30 minutes did not meet bioequivalence criteria in terms of C_{max} can be used based on Figs. 3 and 4 to establish the particle size that would be suitable when it comes to providing an *in vivo* exposure that meets bioequivalence criteria both in terms of AUC and C_{max}. Looking at the data for 2.5 mg tablets (Fig. 3) and 5 mg tablets (Fig. 4) collectively, the first data point that gave a dissolution rate at 30 minutes of just above 77% in Fig. 3 was taken as the threshold for the particle size (this was the data point for tablets made with apixaban drug substance having a D_{90} of 89 μm).

Fig. 3 further establishes that for tablets made with larger particles (having a D_{90} of 120 μm), the dissolution rate at 30 minutes would be lower than 77%. As indicated above, given the observed bioequivalence failure in terms of C_{max} for the tablets having a dissolution rate of 77% at 30 minutes, any such tablet having a dissolution rate lower than 77% at 30 minutes would be expected to have an even further reduced C_{max} and thus provide an unacceptable exposure. This can be deduced from the observed *in vitro-in vivo*

relationship between exposure and dissolution rate: with a dissolution rate below 77% at 30 minutes, it is likely that the AUC values would also fail to meet bioequivalence criteria.

Thus, Applicants respectfully submit that the data in the application demonstrate that the claimed pharmaceutical composition provides *in vivo* exposures bioequivalent to that from an apixaban solution, provided that the apixaban particles have a particle size within the claimed range. The same data also show that with particle sizes above those that are claimed, the resulting *in vivo* exposures are expected not to meet bioequivalence criteria when compared to the apixaban solution.

To summarize, the data presented in the application demonstrate that contrary to what a skilled artisan would have reasonably expected prior to the present invention based on apixaban's BCS classification, the inventors found that absorption of apixaban does depends on its dissolution rate. Nothing in the cited art discloses or suggests controlling D_{90} of crystalline apixaban particles in a pharmaceutical composition as claimed to provide consistent exposure.

Accordingly, Applicants respectfully submit that the cited documents, whether considered separately or in any permissible combination, do not disclose or suggest the claimed invention and do not render it unpatentable.

Wherefore, withdrawal of the outstanding rejection and allowance of the claims is respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
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New York, New York 10104-3800
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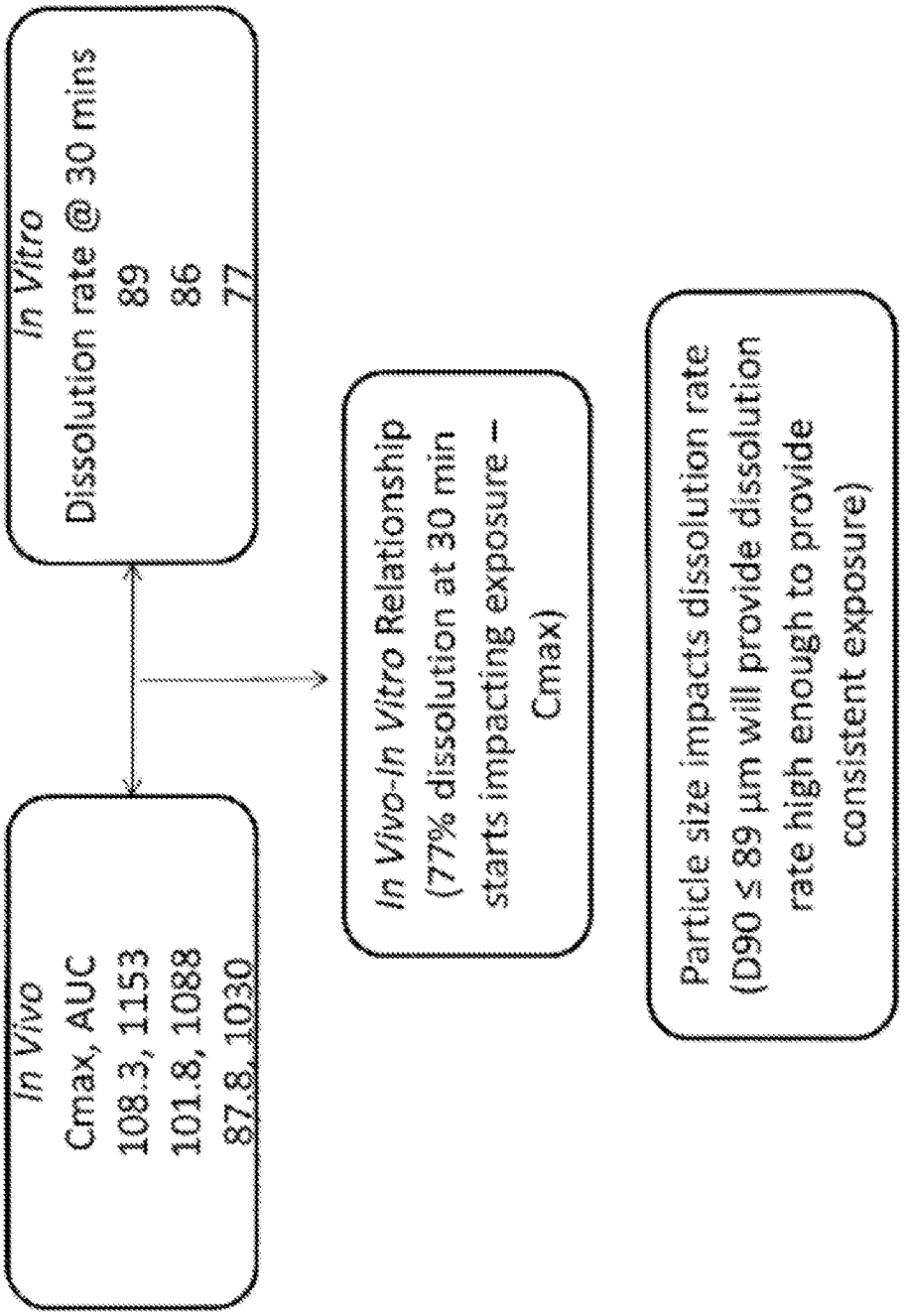
ANNEX


In Vivo
Cmax, AUC
108.3, 1153
101.8, 1088
87.8, 1030
In Vitro
Dissolution rate @ 30 mins
89
86
77
In Vivo-In Vitro Relationship
(77% dissolution at 30 min
starts impacting exposure –
Cmax)
Particle size impacts dissolution rate
(D90 ≤ 89 µm will provide dissolution
rate high enough to provide
consistent exposure)

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun
Attorney Docket Number:	03822.000060.

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1615	14	80	1120
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	200	200
Miscellaneous:				
			Total in USD ($)	**1320**

Electronic Acknowledgement Receipt

EFS ID:	24208537
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	30-NOV-2015
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Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1320
RAM confirmation Number	1350
Deposit Account	503939
Authorized User	NGUY, DAVID

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		AMDSUBINTVWEXT03822000060.pdf	280232 92af613dcea96466cc0c5f8e72ce6f0c5b6922f1	yes	20

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	9
Applicant summary of interview with examiner	10	10
Applicant Arguments/Remarks Made in an Amendment	11	20

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	32443 a865730481e0851ac10b8431c2aabcc4528c66ce	no	2

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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/579,796	Filing Date 10/10/2012	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	11/30/2015	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 34	Minus	** 23	= 11	X $80 =	880
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**880**

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE
/CAROL BARNES/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

	1	Third Office Action in Chinese Application No. 201180011229.X (notified Dec. 11, 2015).	X

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2016-01-22
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	24701689
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	22-JAN-2016
Filing Date:	10-OCT-2012
Time Stamp:	15:45:31
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	IDSTRANS03822000060.pdf	55095 99b4e6e830732ba3821d05e1233a5a4297fcd0e4	no	3

Warnings:	
Information:	

2	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	541640 9f9463a9b1567e3ff0e30cc92960d7ebc5536567	no	4

Warnings:

Information:

A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.

3	Non Patent Literature	TranslationofOA303822000060.pdf	3229463 e632c868a74195dd035b787949cbb862ec5a7045	no	12

Warnings:

Information:

Total Files Size (in bytes):	3826198

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	January 22, 2016

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of that document is provided.

This Information Disclosure Statement is to submit a copy of an Office Action issued in a corresponding Chinese application and its English language translation. The documents D2 and D3 listed in this Chinese Office Action are already of record.

STATEMENT UNDER 37 C.F.R. § 1.704(d)

Each item of information contained in the Information Disclosure Statement:

(i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

(ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

5514 7590 03/04/2016

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER
FRAZIER, BARBARA S

ART UNIT	PAPER NUMBER
1611	

DATE MAILED: 03/04/2016

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

TITLE OF INVENTION: APIXABAN FORMULATIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/06/2016

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

5514 7590 03/04/2016
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

TITLE OF INVENTION: APIXABAN FORMULATIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/06/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
FRAZIER, BARBARA S	1611	424-464000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 03/04/2016

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

DATE MAILED: 03/04/2016

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 13/579,796	Applicant(s) PATEL ET AL.	
	Examiner BARBARA FRAZIER	Art Unit 1611	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Response filed 30 November 2015*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1,3,5-8,11,12,27-29,34-44 and 49-64*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 10/29/15,1/22/16
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *2/24/16* .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/B. F./
Examiner, Art Unit 1611

DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Jason Okun on 24 February 2016.

The application has been amended as follows:

IN THE CLAIMS:

Claim 1, line 1, after "A" please insert --solid--.

Please cancel claim 13.

Please cancel claims 16-18.

Please cancel claims 30-33.

Claim 34, line 1, after "A" please insert --solid--.

Please cancel claims 45-48.

Please add new claims 49-64:

49. (New) The composition as defined in claim 1, which is a tablet.

50. (New) The composition as defined in claim 1, which is a capsule.

51. (New) The composition as defined in claim 27, which is a tablet.

52. (New) The composition as defined in claim 27, which is a capsule.

53. (New) The composition as defined in claim 28, which is a tablet.

54. (New) The composition as defined in claim 28, which is a capsule.

55. (New) The composition as defined in claim 29, which is a tablet.

56. (New) The composition as defined in claim 29, which is a capsule.

57. (New) The composition as defined in claim 34, which is a tablet.

58. (New) The composition as defined in claim 34, which is a capsule.

59. (New) The composition as defined in claim 42, which is a tablet.

60. (New) The composition as defined in claim 42, which is a capsule.

61. (New) The composition as defined in claim 43, which is a tablet.

62. (New) The composition as defined in claim 43, which is a capsule.

63. (New) The composition as defined in claim 44, which is a tablet.

64. (New) The composition as defined in claim 44, which is a capsule.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the closest prior art of record is Nause et al. ("Nause", US 2012/0087978) in view of Wei et al. ("Wei", US 20060160841). The inventions of Nause and Wei are delineated in the previous Office action (see pages 4-6 of Office action mailed 13 August 2015, incorporated herein by reference). However, Applicant's data in the specification demonstrates the criticality of the particular size range claimed, wherein the crystalline apixaban particles have a D90 equal to or less than about 89 µm, and the resulting dissolution property, wherein at least 77wt% of apixaban dissolves within 30 minutes in a pH 6.8 phosphate buffer containing 0.05% sodium lauryl sulfate, for establishing bioequivalence of solid apixaban formulations with a solution (see paragraphs [0035]-[0038] of the specification). It is also noted that Nause teaches 'controlled release' formulations of apixaban, which Nause distinguishes from 'immediate release'

formulations having similar dissolution rates to those of the claimed invention (see Nause, paragraph [0032]). Therefore, it would not have been obvious to a person having ordinary skill in the art at the time the invention was made to formulate solid apixaban pharmaceutical formulations according to the specific limitations of size and dissolution claimed, with the results of unexpectedly improved bioequivalence within said ranges as demonstrated in the specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Friday 9am-2:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Bethany Barham can be reached on (571)272-6175. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BETHANY BARHAM/
Supervisory Patent Examiner, Art Unit 1611

/B. F./
Examiner, Art Unit 1611

Examiner-Initiated Interview Summary	Application No.	Applicant(s)	
	13/579,796	PATEL ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

All participants (applicant, applicant's representative, PTO personnel):

(1) *BARBARA FRAZIER*. (3)_____.

(2) *Jason Okun*. (4)_____.

Date of Interview: *24 February 2016*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1,3,5-8,11-13,16-18 and 27-48*.

Identification of prior art discussed: *Nause; Wei*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner contacted Applicant's representative ("Applicant") to discuss allowable subject matter. Examiner noted data in the specification demonstrated criticality of the particular size range claimed in independent claims 1 and 34 for the solid pharmaceutical formulations tested, and suggested Applicant amend claims 1 and 34 to specify a solid pharmaceutical formulation to be commensurate in scope with the data. Applicant further suggested canceling withdrawn claims 13 and 16-18 and separating the limitations of "tablet" and "capsule" into separate dependent claims, as outlined in the attacted Examiner's Amendment. Applicant authorized said changes by Examiner's Amendment.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/BARBARA FRAZIER/ Examiner, Art Unit 1611	

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

/B.F./	1	Third Party Observations on European Application No. 11707284.3 (dated July 24, 2015).	☐
/B.F./	2	U.S. Pharmacopoeia (USP) 38, Chapter 429, "Light Diffraction Measurement of Particle Size," pp. 294-299 (May 2015) (Annex 1).	☐

If you wish to add additional non-patent literature document citation information please click the Add button **Add**

EXAMINER SIGNATURE

Examiner Signature	/Barbara Frazier/	Date Considered	03/02/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13579796	PATEL ET AL.
	Examiner	**Art Unit**
	BARBARA FRAZIER	1611

CPC							
Symbol						**Type**	**Version**
A61K		9	/	2018		F	2013-01-01
A61K		31	/	437		A	2013-01-01
A61K		31	/	4412		A	2013-01-01
A61K		9	/	2054		I	2013-01-01
A61K		9	/	2095		I	2013-01-01
A61K		31	/	4545		I	2013-01-01
A61K		9	/	2013		I	2013-01-01
			/				
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CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
			/					
			/					

/BARBARA FRAZIER/ Examiner.Art Unit 1611	3/1/16	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	38	
/BETHANY BARHAM/ Supervisory Patent Examiner.Art Unit 1611	03/02/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
13579796	PATEL ET AL.
Examiner	**Art Unit**
BARBARA FRAZIER	1611

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
424	464

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
424	451	489			
514	303				

INTERNATIONAL CLASSIFICATION														
CLAIMED						NON-CLAIMED								
A	6	1	K	9 / 20 (2006.0)										
A	6	1	K	31 / 4545 (2006.0)										

/BARBARA FRAZIER/ Examiner.Art Unit 1611	3/1/16	**Total Claims Allowed:** 38
(Assistant Examiner)	(Date)	
/BETHANY BARHAM/ Supervisory Patent Examiner.Art Unit 1611	03/02/2016	O.G. Print Claim(s): 1 / O.G. Print Figure: 3
(Primary Examiner)	(Date)	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13579796	PATEL ET AL.
	Examiner	**Art Unit**
	BARBARA FRAZIER	1611

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	39	33	59										
2	3	18	40	34	60										
3	5	19	41	35	61										
4	6	20	42	36	62										
5	7	21	43	37	63										
6	8	22	44	38	64										
7	11	23	49												
8	12	24	50												
9	27	25	51												
10	28	26	52												
11	29	27	53												
12	34	28	54												
13	35	29	55												
14	36	30	56												
15	37	31	57												
16	38	32	58												

/BARBARA FRAZIER/ Examiner.Art Unit 1611	3/1/16	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	38	
/BETHANY BARHAM/ Supervisory Patent Examiner.Art Unit 1611	03/02/2016	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13579796	PATEL ET AL.
	Examiner	Art Unit
	BETHANY BARHAM	1615

CPC- SEARCHED		
Symbol	Date	Examiner
A61K 31/4545; 9/2013; 9/2018; 9/2054 (see history)	3/1/16	BSF

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
East (see attached search notes)	07/16/14	BB
Palm Inventors Search (all inventors)	07/16/14	BB
EAST search updated	8/10/15	BSF
Inventor search updated	8/10/15	BSF
EAST search updated	3/1/16	BSF
Inventor search updated	3/1/16	BSF

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61K	31/4545; 9/2013; 9/2018; 9/2054 (see history)	3/1/16	BSF

/B.F./ Examiner.Art Unit 1611	

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BIB DATA SHEET

CONFIRMATION NO. 2947

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/579,796	10/10/2012	424	1611	03822.000060.

APPLICANTS

INVENTORS

Jatin Patel, West Windsor, NJ;
Charles Frost, Yardley, PA;
Jingpin Jia, Belle Mead, NJ;
Chandra Vemavarapu, Hillsborough, NJ;

**** CONTINUING DATA ***************************

This application is a 371 of PCT/US11/25994 02/24/2011
which claims benefit of 61/308,056 02/25/2010

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

11/09/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /BARBARA S FRAZIER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		NJ	4	~~23~~ 38	2

ADDRESS

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800
UNITED STATES

TITLE

APIXABAN FORMULATIONS

FILING FEE RECEIVED	FEES: Authority has been given in Paper	☐ All Fees
2550	No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	WO-2008031782-$.did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 16:35
L2	9740	A61K31/4545.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 17:16
L3	960	apixaban	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 17:16
L4	87	2 and 3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 17:16
L5	44	3 near5 crystallin$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 17:17
L6	21	4 and 5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 17:17
L8	3231	A61K9/2013.cpc. and A61K9/2018.cpc. and A61K9/2054.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 17:21
L9	56	2 and 8	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/03/01 17:21
S43	2	"20060160841".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/22 16:47
S44	0	S43 and apixaban	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/22 16:47
S45	3	"20120087978".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/22 16:53
S46	3	"20060029258".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 13:43

S47	3	"20060069258".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 13:43
S48	3	"20120087978".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 13:47
S49	2	"20060160841".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 13:53
S50	3	("2006/0160841").URPN.	USPAT	ADJ	ON	2016/02/23 13:55
S51	0	"11235327".app.	USPAT	ADJ	ON	2016/02/23 13:56
S52	0	"11/235327".app.	USPAT	ADJ	ON	2016/02/23 13:56
S53	0	11/235327.app.	USPAT	ADJ	ON	2016/02/23 13:57
S54	1	11/235327.app.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 13:57
S55	114470	(immediate or fast or immediately or quickly) near3 (release or released or releasing)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 14:02
S56	954	apixaban	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 14:02
S57	6	S55 near20 S56	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2016/02/23 14:02

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L10	2145	A61K31/4545.cpc.	US-PGPUB; USPAT	ADJ	ON	2016/03/01 17:22
L11	33	10 and apixaban	US-PGPUB; USPAT	ADJ	ON	2016/03/01 17:22
L12	620	A61K9/2013.cpc. and A61K9/2018.cpc. and A61K9/2054.cpc.	US-PGPUB; USPAT	ADJ	ON	2016/03/01 17:24
L13	6	10 and 12	US-PGPUB; USPAT	ADJ	ON	2016/03/01 17:24

3/ 1/ 2016 5:25:01 PM
C:\ Users\ bfrazier\ Documents\ EAST\ Workspaces\ 13579796.wsp

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Receipt date: 01/22/2016	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date	2012-10-10
(Not for submission under 37 CFR 1.99)	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

/B.F./	1	Third Office Action in Chinese Application No. 201180011229.X (notified Dec. 11, 2015).	X

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Examiner Signature	/Barbara Frazier/	Date Considered	03/01/2016

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
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Receipt date: 10/29/2015	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

/B.F./	1	Resolution No. 39058 in Colombian Application No. 12.152.138 (published Aug. 4, 2015).	☒
/B.F./	2	Resolution No. 64634 in Colombian Application No. 14.268.266 (published Sep. 22, 2015).	☒

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 03/14/2016

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/14/2016	PAPER

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P.O. Box 1450
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www.uspto.gov

Application No. : 13579796
Applicant : Patel
Filing Date : 10/10/2012
Date Mailed : 03/14/2016

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

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/Shirley Winslow/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 13579796

IDENTIFICATION OF SPECIFICATION/DRAWING INCONSISTENCIES

☐ On Page of the specification there is a brief description of FIG. , but the drawings filed do not include a drawing with that designation. Applicant must respond either by supplying the omitted drawing or by amending the specification to remove all references to that drawing.

☐ The drawings filed include FIG. , but the specification's brief description of the drawings does not describe a drawing with that designation. Applicant must respond either by amending the specification to add a brief description of that drawing or by correcting the drawings to remove the drawing in question.

☒ Drawings are present in the application and are referred to in the detailed description of the invention, but the specification does not contain a brief description of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(8).

☐ Page of the specification refers to FIG. , but no drawing with that designation is described in the brief description of the drawings and no drawing with that designation is present in the application. Applicant must respond either by amending the specification to remove all references to that drawing, or by supplying that drawing and amending the specification to add a brief description of it.

☐ In the reissue application, FIG. , is labeled as “New” but is not described in the reissue specification’s brief description of the drawings. Applicant must respond by amending the reissue specification’s brief description of the drawings to add a brief description of the new drawing.

☐ OTHER:

☐ COMMENTS:

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

	1	Office Action in Russian Application No. 2012140690 (dated Dec. 18, 2015).	X

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2016-03-17
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Amy Steensen
Attorney Docket Number:	03822.000060.

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	25223845
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	17-MAR-2016
Filing Date:	10-OCT-2012
Time Stamp:	15:06:26
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	1508
Deposit Account	503939
Authorized User	NGUY, DAVID

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	NoticetoFileCorrectedApplicationPapers03822000060.PDF	104832 c915d244f149e183624f82b70ae6a2f8ef8755fb	no	3
Warnings:					
Information:					
2	Transmittal Letter	IDSTRANS03822000060.pdf	54072 ea7fc501d865bd1902d72eadcd74f55ab4b888c5	no	2
Warnings:					
Information:					
3	Non Patent Literature	RussianOfficeAction03822000060.PDF	291525 bc8db46c2cb3600d6e08d5205a04538cf4c1ce43	no	7
Warnings:					
Information:					
4		RESPtoNOTICEtoFILECORRECTEDAPPLNPAPERS03822000060.pdf	77890 420072feaf2e4d0b38032113e356d71b368cc7a7	yes	3

Multipart Description/PDF files in .zip description

Document Description	Start	End
Post Allowance Communication - Incoming	1	1
Specification	2	2
Post Allowance Communication - Incoming	3	3

Warnings:					
Information:					
5	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.PDF	541633 e4f651ef3d255d96fa2485b16a9d4c1bd09d7577	no	4
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Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
6	Fee Worksheet (SB06)	fee-info.pdf	30555 7faa911f00c374ba0d7940d439ba569ef128aff0	no	2
Warnings:					
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 03/14/2016

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/14/2016	PAPER

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The time period for reply, if any, is set in the attached communication.

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Commissioner for Patents
United States Patent and Trademark Office
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Application No. : 13579796
Applicant : Patel
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NOTICE TO FILE CORRECTED APPLICATION PAPERS

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This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Shirley Winslow/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 13579796

IDENTIFICATION OF SPECIFICATION/DRAWING INCONSISTENCIES

☐ On Page of the specification there is a brief description of FIG. , but the drawings filed do not include a drawing with that designation. Applicant must respond either by supplying the omitted drawing or by amending the specification to remove all references to that drawing.

☐ The drawings filed include FIG. , but the specification's brief description of the drawings does not describe a drawing with that designation. Applicant must respond either by amending the specification to add a brief description of that drawing or by correcting the drawings to remove the drawing in question.

☒ Drawings are present in the application and are referred to in the detailed description of the invention, but the specification does not contain a brief description of the drawings as required by 37 CFR 1.74 and 37 CFR 1.77(b)(8).

☐ Page of the specification refers to FIG. , but no drawing with that designation is described in the brief description of the drawings and no drawing with that designation is present in the application. Applicant must respond either by amending the specification to remove all references to that drawing, or by supplying that drawing and amending the specification to add a brief description of it.

☐ In the reissue application, FIG. , is labeled as “New” but is not described in the reissue specification’s brief description of the drawings. Applicant must respond by amending the reissue specification’s brief description of the drawings to add a brief description of the new drawing.

☐ OTHER:

☐ COMMENTS:

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	March 17, 2016

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the document listed on the concurrently submitted Form PTO/SB/08a. A copy of that document is provided.

This Information Disclosure Statement is to submit a copy of an Office Action issued in a corresponding Russian application.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	March 17, 2016

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Sir:

In response to the Notice to File Corrected Application Papers dated March 14, 2016, please amend the application as follows. A copy of the Notice is submitted herewith, as required.

SPECIFICATION

Please insert the following at page 5, line 27, immediately before the "DETAILED DESCRIPTION OF THE INVENTION" section:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a scatter plot of individual dose-normalized AUC(INF) values for solutions (CV185001, CV185006, and CV185007) and tablets (CV185001 and CV185024).

Figure 2 is scatter plot of individual dose-normalized C_{max} values for solutions (CV185001, CV185006, and CV185007) and tablets (CV185001 and CV185024).

Figure 3 is a plot of dissolution rates of 2.5 mg apixaban tablets using drug substance of different particle size.

Figure 4 is a plot of dissolution rates of 5 mg apixaban tablets using drug substance of different particle size.

REMARKS

The Notice to File Corrected Application Papers indicates that the specification does not contain a brief description of the drawings. In response, the specification has been amended in accordance with 37 C.F.R. § 1.121 to provide the brief description of the drawings. Support for this amendment, if needed, may be found, *inter alia*, in the captions of the drawings. No new matter has been added.

Expedient processing of this paper is respectfully requested.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our address given below.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 03/22/2016

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER
FRAZIER, BARBARA S

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/22/2016	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Rule 312 Communication	Application No. 13/579,796	Applicant(s)
	Examiner	Art Unit

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

1. ☒ The amendment filed on *17 March 2016* under 37 CFR 1.312 has been considered, and has been:

   a) ☒ entered.

   b) ☐ entered as directed to matters of form not affecting the scope of the invention.

   c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
   Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

   d) ☐ disapproved. See explanation below.

   e) ☐ entered in part. See explanation below.

MN
Publishing Division

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	13579796
	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

	1	Extended European Search Report in European Application No. 15190823.3 (Feb. 3, 2016).	
	2	Technical Report No. EDM 008-2016/A in Peruvian Application No. 001362-2012 (Mar. 7, 2016).	X

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2016-03-24
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

03822.000060. PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Barbara S. Frazier
JATIN PATEL ET AL.	)	
	:	Group Art Unit: 1611
Application No.: 13/579,796	)	
	:	Confirmation No.: 2947
Int'l Appln No. PCT/US2011/025994	)	
	:	
Filed: February 24, 2011	)	
	:	
For: APIXABAN FORMULATIONS	)	March 24, 2016

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is directed to the documents listed on the concurrently submitted Form PTO/SB/08a. Copies of those documents are provided.

This Information Disclosure Statement is to submit copies of an Extended European Search Report issued in a corresponding European application and of Technical Report No. EDM 008-2016/A issued in a corresponding Peruvian application. The documents listed in the European Search Report and in the Peruvian Technical Report are

already of record. In that connection, it is Applicants' understanding that "US 2010/003811" listed as "D2" in the Peruvian Technical Report is a typographical error and should instead be "WO 2010/003811". This is reflected in the provided English language translation of the Technical Report.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a written confirmation be returned indicating that such information has been considered.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Jason M. Okun/
Jason M. Okun
Attorney for Applicants
Registration No. 48,512

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun
Attorney Docket Number:	03822.000060.

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	25292276
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	24-MAR-2016
Filing Date:	10-OCT-2012
Time Stamp:	12:32:27
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	25973
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	IDS03822000060.pdf	541606 5f51983808dcbd91e430cddad5491604768d1486	no	4
Warnings:					
Information:					
A U.S. Patent Number Citation or a U.S. Publication Number Citation is required in the Information Disclosure Statement (IDS) form for autoloading of data into USPTO systems. You may remove the form to add the required data in order to correct the Informational Message if you are citing U.S. References. If you chose not to include U.S. References, the image of the form will be processed and be made available within the Image File Wrapper (IFW) system. However, no data will be extracted from this form. Any additional data such as Foreign Patent Documents or Non Patent Literature will be manually reviewed and keyed into USPTO systems.					
2	Non Patent Literature	IDSDoc1.pdf	323524 702b798ac0c8b61def0dc3e0ad72718cfadf57bf	no	11
Warnings:					
Information:					
3	Transmittal Letter	IDSTRANS03822000060.pdf	55074 a2ea49c732d2326fd37477a6e3bdbce2ce93175a	no	2
Warnings:					
Information:					
4	Non Patent Literature	IDSDoc2.pdf	4681744 e72349e1f36c7a75e6ff768b7f565b2ed81765d2	no	13
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	30518 a76a4a439044d95d7fe7d854f487c4fb17e418b1	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	5632466		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 03/25/2016

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER
FRAZIER, BARBARA S

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/25/2016	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Corrected Notice of Allowability	Application No. 13/579,796	Applicant(s) PATEL ET AL.	
	Examiner BARBARA FRAZIER	Art Unit 1611	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *IDS filed 17 March 2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1,3,5-8,11,12,27-29,34-44 and 49-64*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 3/17/16
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/B. F./ Examiner, Art Unit 1611	/BETHANY BARHAM/ Supervisory Patent Examiner, Art Unit 1611

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

Receipt date: 03/17/2016	Application Number	13579796 13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-10-10
	First Named Inventor	JATIN PATEL ET AL.
	Art Unit	1611
	Examiner Name	BARBARA S. FRAZIER
	Attorney Docket Number	03822.000060.

/B.F./	1	Office Action in Russian Application No. 2012140690 (dated Dec. 18, 2015).	X

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Barbara Frazier/	Date Considered	03/22/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

Receipt date: 03/17/2016	Application Number	13579796	13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-10-10	
	First Named Inventor	JATIN PATEL ET AL.	
	Art Unit	1611	
	Examiner Name	BARBARA S. FRAZIER	
	Attorney Docket Number	03822.000060.	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jason M. Okun/	Date (YYYY-MM-DD)	2016-03-17
Name/Print	Jason M. Okun	Registration Number	48,512

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13579796
Filing Date	2012-10-10
First Named Inventor	JATIN PATEL ET AL.
Art Unit	1611
Examiner Name	BARBARA S. FRAZIER
Attorney Docket Number	03822.000060.

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

Receipt date: 03/24/2016	Application Number	13579796	13579796 - GAU: 1611
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99**)	Filing Date	2012-10-10	
	First Named Inventor	JATIN PATEL ET AL.	
	Art Unit	1611	
	Examiner Name	BARBARA S. FRAZIER	
	Attorney Docket Number	03822.000060.	

/B.F./	1	Extended European Search Report in European Application No. 15190823.3 (Feb. 3, 2016).	
/B.F./	2	Technical Report No. EDM 008-2016/A in Peruvian Application No. 001362-2012 (Mar. 7, 2016).	X

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Barbara Frazier/	Date Considered	03/26/2016

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2012-10-10	
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Name/Print	Jason M. Okun	Registration Number	48,512

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

5514 7590 03/30/2016

FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/30/2016	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Corrected Notice of Allowability	**Application No.** 13/579,796	**Applicant(s)** PATEL ET AL.	
	Examiner BARBARA FRAZIER	**Art Unit** 1611	**AIA (First Inventor to File) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *IDS filed 24 March 2016*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1,3,5-8,11,12,27-29,34-44 and 49-64*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 3/24/16
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/B. F./ Examiner, Art Unit 1611	/BETHANY BARHAM/ Supervisory Patent Examiner, Art Unit 1611

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

5514 7590 03/04/2016
FITZPATRICK CELLA HARPER & SCINTO
1290 Avenue of the Americas
NEW YORK, NY 10104-3800

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	10/10/2012	Jatin Patel	03822.000060.	2947

TITLE OF INVENTION: APIXABAN FORMULATIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/06/2016

EXAMINER	ART UNIT	CLASS-SUBCLASS
FRAZIER, BARBARA S	1611	424-464000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Fitzpatrick, Cella, Harper & Scinto
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE	(B) RESIDENCE: (CITY and STATE OR COUNTRY)
Bristol-Myers Squibb Company	Princeton, NJ
Pfizer Inc.	New York, NY

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☒ Payment by credit card. ~~Form PTO-2038 is attached~~.
- ☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-3939 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Jason M. Okun/ Date March 30, 2016

Typed or printed name Jason M. Okun Registration No. 48,512

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	13579796
Filing Date:	10-Oct-2012
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Filer:	Jason M. Okun/Amy Steensen
Attorney Docket Number:	03822.000060.

Filed as Large Entity

Filing Fees for U.S. National Stage under 35 USC 371

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	25348488
Application Number:	13579796
International Application Number:	
Confirmation Number:	2947
Title of Invention:	APIXABAN FORMULATIONS
First Named Inventor/Applicant Name:	Jatin Patel
Customer Number:	5514
Filer:	Jason M. Okun/DAVID NGUY
Filer Authorized By:	Jason M. Okun
Attorney Docket Number:	03822.000060.
Receipt Date:	30-MAR-2016
Filing Date:	10-OCT-2012
Time Stamp:	18:07:48
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$960
RAM confirmation Number	5244
Deposit Account	503939
Authorized User	NGUY, DAVID

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

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1	Issue Fee Payment (PTO-85B)	IssueFee03822000060.pdf	156395 b65dfe6d01ec0b0ab23cc6bf311e557f9d908309	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30494 a0957daddc5cb0ef97c3199a98095c03a6677c87	no	2
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/579,796	05/03/2016	9326945	03822.000060.	2947

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

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