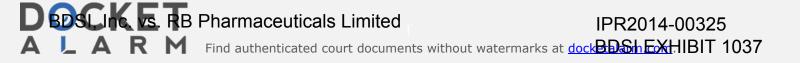
	ed States Patent	and Trademark Office	UNITED STATES DEPAR United States Patent and Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 22: www.uspto.gov	FOR PATENTS
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/964,975	08/12/2013	Garry L. Myers	2333-2 CON II	8904
23869 7590 11/07/2013 Hoffmann & Baron LLP 6900 Jericho Turnpike			EXAMINER	
			EPPS -SMITH, JANET L	
Syosset, NY 11	.791		ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			11/07/2013	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.



	Application No. 13/964,975		Applicant(s) MYERS ET AL.	
Office Action Summary	Examiner Janet Epps-Smith	Art Unit 1633	AIA (First Inventor to Fil Status No	
The MAILING DATE of this communication Period for Reply				
 A SHORTENED STATUTORY PERIOD FOR REWHICHEVER IS LONGER, FROM THE MAILING Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory per Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the maximum datent term adjustment. See 37 CFR 1.704(b). 	A DATE OF THIS COMMUNE (1.136(a). In no event, however, may a iod will apply and will expire SIX (6) MOI tute, cause the application to become A	ICATION. reply be timely filed NTHS from the mailing date BANDONED (35 U.S.C. § 1	of this communication. 33).	
Status 1 M - Responsive to communication(a) filed on Q	07 2012			
 Responsive to communication(s) filed on <u>9-</u> A declaration(s)/affidavit(s) under 37 CFR 				
	his action is non-final.	<u> </u>		
3) An election was made by the applicant in re		rement set forth dur	ing the interview on	
; the restriction requirement and elect	• •			
 4) ☐ Since this application is in condition for allow closed in accordance with the practice under 	wance except for formal mat	ters, prosecution as		
Disposition of Claims				
5) Claim(s) <u>1-24</u> is/are pending in the applicati	on.			
5a) Of the above claim(s) is/are with				
6) Claim(s) is/are allowed.				
7) Claim(s) $1-24$ is/are rejected.				
8) Claim(s) is/are objected to.				
9) Claim(s) are subject to restriction and	d/or election requirement.			
* If any claims have been determined allowable, you may b	e eligible to benefit from the Pa	tent Prosecution Hig	hway program at a	
participating intellectual property office for the correspondin	g application. For more informa	tion, please see		
http://www.uspto.gov/patents/init_events/pph/index.jsp or se	end an inquiry to PPHfeedback	@uspto.gov.		
Application Papers				
10) The specification is objected to by the Exam	iner			
11) The drawing(s) filed on is/are: a) \Box a		by the Examiner		
Applicant may not request that any objection to t		-	5(a)	
Replacement drawing sheet(s) including the con				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for fore	ign 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 docum				
2. Certified copies of the priority docum				
3. Copies of the certified copies of the p		n received in this Na	ational Stage	
application from the International Bur				
* See the attached detailed Office action for a lis	t of the certified copies not rece	eived.		
Attachment(s)				
1) 🔀 Notice of References Cited (PTO-892)	3) 🔲 Interview	Summary (PTO-413)		
2) Information Disclosure Statement(s) (PTO/SB/08)	Paper No	(s)/Mail Date		
OCKET				
	documente without wate	arke at decketale	com	
IN IN Find authenticated court of	documents without waterma	arks at <u>docketalarm</u>	<u>.com</u> .	

DETAILED ACTION

1. The prior Office Action mailed 10/29/2013 is now vacated. The previous Office Action *improperly indicated* that the instant application was Under Accelerated Examination, and limited Applicants to a 1-month response time with no extensions of time available. The instant Office Action grants Applicants a 3-month response time with extensions of time available.

2. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Claim Rejections - 35 USC § 103

3. 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.

4. Claims 1-24 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable

over Oksche et al. (US2010/0087470A1 or WO 2008025791 A1; citations given from

the PGPUB).

RM

5. Independent claims 1 and 7 recite the following:

1. An orally dissolving film formulation comprising from about 2 to about 16 mg of buprenorphine and from about 0.5 to about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.6 ng/ml and about 5.7 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of between about 41 pg/ml to about 324 pg/ml for naloxone.

Application/Control Number: 13/964,975 Art Unit: 1633

between about 40 pg/ml to about 405 pg/ml for naloxone.

7. An orally dissolving film formulation comprising from about 2 to about 16 mg of buprenorphine and from about 0.5 to about 4 mg of naloxone, wherein said formulation provides an in vivo plasma profile having a mean C_{max} of between about 0.7 ng/ml and about 6.9 ng/ml for buprenorphine and an in vivo plasma profile having a mean C_{max} of

6. Oksche et al. discloses the following embodiments, see the following paragraphs: [0039] As regards the dosage amount, the pharmaceutical compositions in accordance with the present invention will typically comprise between approximately 0.1 mg and approximately 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof such as buprenorphine hydrochloride. Preferred dosage amounts will be in the range of between approximately 0.4 mg and approximately 12 mg or between approximately 2 mg and approximately 8 mg buprenorphine or a pharmaceutically acceptable salt thereof.

[0040] The oral pharmaceutical dosage forms in accordance with the invention may have the further characteristic of providing a C_{max} of approximately 1.5 to 2.5 ng/ml in the case of a dose of 4 mg buprenorphine hydrochloride being administered. A preferred C_{max} in the case of a dose of 4 mg of buprenorphine hydrochloride being administered being administered being administered may be approximately between 1.7 ng/ml to 2 ng/ml.

[0041] In the case of a dose of 8 mg buprenorphine hydrochloride being administered, the C_{max} may be approximately between 2.5 and 3.5 ng/ml. In a preferred embodiment the C_{max} may be approximately between 2.75 ng/ml and 3.25 ng/ml in the case of a dose of 8 mg buprenorphine hydrochloride being administered.

Find authenticated court documents without watermarks at docketalarm.com.

[0042] In case of a dose of 16 mg buprenorphine hydrochloride being administered, the C_{max} may preferably be in the range of approximately 5 to 7 ng/ml. In a preferred embodiment the C_{max} may be between 5.5 and 6.5 ng/ml if 16 mg of buprenorphine hydrochloride are administered.

[0043] The AUC₀₋₄₈ (i.e. the Area under the Curve for 48 hours after administration) may in the case of administration of 4 mg of buprenorphine hydrochloride be in the range of approximately 10 to 15 hours.times.ng/ml. In a preferred embodiment the AUC₀₋₄₈ may be approximately 12 to 13 hours.times.ng/ml. In the case of 8 mg buprenorphine hydrochloride being administered the AUC₀₋₄₈ may be approximately in the range of 15 to 25 hours X ng/ml. In a preferred embodiment the AUC₀₋₄₈ in this case may be between approximately 20 to 22 hours.times.ng/ml. In the case of 16 mg buprenorphine hydrochloride being administered, the AUC₀₋₄₈ may be in the range of 25 to 40 hours X ng/ml. In a preferred embodiment the AUC₀₋₄₈ may be in the range of 25

[0050] A particularly preferred antagonist is naloxone. Of the naloxone salts, naloxone hydrochloride dihydrate may be particularly preferable in combination with buprenorphine hydrochloride.

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.