AO 120 (Rev. 08/10)

TO:	**Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313–1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the **U.S. District Court for the District of New Jersey** on the following:
____ Trademarks or **X** Patents. (____ the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
3:15–cv–03107–MAS–LHG	5/1/2015	TRENTON, NJ

PLAINTIFF	DEFENDANT
SANOFI–AVENTIS U.S. LLC	ACTAVIS LLC

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 US 8,927,592 B2	JAN. 6, 2015	AVENTIS PHARMA SA
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ___ Amendment ___ Answer ___ Cross Bill ___ Other Pleading

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
William T. Walsh	s/ Karen McGonigle	5/1/2015

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

AO 120 (Rev. 08/10)

TO:	**Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313–1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

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____ Trademarks or **X** Patents. (____ the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
3:15–cv–02521–MAS–LHG	4/6/2015	TRENTON, NJ
PLAINTIFF SANOFI–AVENTIS U.S. LLC		DEFENDANT BPI LABS, LLC

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 US 8,927,592 B2	Jan. 6, 2015	Aventis Parma SA
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ___ Amendment ___ Answer ___ Cross Bill ___ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
William T. Walsh	s/ Karen McGonigle	4/6/2015

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

AO 120 (Rev. 08/10)

TO:	**Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313–1450**	**REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK**

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____ Trademarks or **X** Patents. (____ the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
3:15–cv–02522–MAS–LHG	4/6/2015	TRENTON, NJ

PLAINTIFF	DEFENDANT
SANOFI–AVENTIS U.S. LLC	DR. REDDYS LABORATORIES, INC.

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 US 8,927,592 B2	Jan. 6, 2015	Aventis Parma SA
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ___ Amendment ___ Answer ___ Cross Bill ___ Other Pleading

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
William T. Walsh	s/ Karen McGonigle	4/6/2015

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

AO 120 (Rev. 08/10)

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____ Trademarks or **X** Patents. (____ the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
3:15–cv–02523–MAS–LHG	4/6/2015	TRENTON, NJ
PLAINTIFF SANOFI–AVENTIS U.S. LLC		DEFENDANT GLENMARK GENERICS INC.

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 US 8,927,592 B2	Jan. 6, 2015	Aventis Parma SA
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DATE INCLUDED	INCLUDED BY ___ Amendment ___ Answer ___ Cross Bill ___ Other Pleading

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DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
William T. Walsh	s/ Karen McGonigle	4/6/2015

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AO 120 (Rev. 08/10)

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____ Trademarks or **X** Patents. (____ the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
3:15–cv–02631–MAS–LHG	4/13/2015	TRENTON, NJ
PLAINTIFF SANOFI–AVENTIS U.S. LLC		DEFENDANT FRESENIUS KABI USA, LLC

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 US 8,927,592 B2	Jan. 6, 2015	Aventis Parma SA
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ___ Amendment ___ Answer ___ Cross Bill ___ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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DECISION/JUDGEMENT

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William T. Walsh	s/ Karen McGonigle	4/13/2015

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____ Trademarks or **X** Patents. (____ the patent action involves 35 U.S.C. § 292.)

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
3:15–cv–01836–MAS–LHG	3/11/2015	TRENTON, NJ

PLAINTIFF	DEFENDANT
SANOFI–AVENTIS U.S. LLC	BRECKENRIDGE PHARMACEUTICAL, INC.

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 8,927,592	1/6/2015	Aventis Pharma S.A.
2		
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ___ Amendment ___ Answer ___ Cross Bill ___ Other Pleading

PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
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DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
William T. Walsh	s/ Karen McGonigle	3/11/2015

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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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/456,720	01/06/2015	8927592	FR2009/121 US CNT	1083

5487 7590 12/17/2014

ANDREA Q. RYAN
SANOFI
55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

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.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Sunil GUPTA, Chester Springs, PA;

Amendments to the Specification

Change(s) applied to document, /K.W./ 12/3/2014

Replace the paragraph at page 5, line 11 with the following rewritten paragraph:

Figure 4 graphically depicts the proportion of patients with changes in ECOG performance status from baseline during treatment (safety population). The "Improved" column represents PS2 at baseline changed to 0 or 1 during treatment. The "stable" column represents no change, and the "Worse" column represents PS2 at baseline and changed to ≥ 3, or 0 or 1 at baseline changed to ≥ 2 during treatment.

Replace the paragraph at page 5, line 24 with the following rewritten paragraph:

Figure 5 graphically depicts the proportion of patients with changes from baseline in the Present Pain Intensity score during treatment (ITT). The "Improved" column represents patients in which the PPI score during treatment was lower versus baseline. The "Stable" column represents no change, and the "Worse" column represents patients with >1 unit increase in PPI score during treatment versus baseline.

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)

5487 7590 11/14/2014
ANDREA Q. RYAN
SANOFI
55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

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.
13/456,720	04/26/2012	Sunil GUPTA	FR2009/121 US CNT	1083

TITLE OF INVENTION: NOVEL ANTITUMORAL USE OF CABAZITAXEL

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	02/17/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
ANDERSON, JAMES D	1629	514-449000

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 Kelly L. Bender
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: Aventis Pharma SA

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Antony, France

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 18-1982 (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 /Kelly L. Bender/ Date November 20, 2014

Typed or printed name Kelly L. Bender Registration No. 52,610

Electronic Patent Application Fee Transmittal

Application Number:	13456720
Filing Date:	26-Apr-2012
Title of Invention:	NOVEL ANTITUMORAL USE OF CABAZITAXEL
First Named Inventor/Applicant Name:	Sunil GUPTA
Filer:	Kelly L. Bender/Brian Pritchett
Attorney Docket Number:	FR2009/121 US CNT

Filed as Large Entity

Utility under 35 USC 111(a) 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:				
Utility Appl Issue Fee	1501	1	960	960
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	20750442
Application Number:	13456720
International Application Number:	
Confirmation Number:	1083
Title of Invention:	NOVEL ANTITUMORAL USE OF CABAZITAXEL
First Named Inventor/Applicant Name:	Sunil GUPTA
Customer Number:	5487
Filer:	Kelly L. Bender/Brian Pritchett
Filer Authorized By:	Kelly L. Bender
Attorney Docket Number:	FR2009/121 US CNT
Receipt Date:	20-NOV-2014
Filing Date:	26-APR-2012
Time Stamp:	11:37:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$960
RAM confirmation Number	10114
Deposit Account	181982
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Miscellaneous Incoming Letter	FR2009-121USCNT_20141120_COT.pdf	111479 7d4eb12a82b4d85c36faff7153a3d5fc81f83e89	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	FR2009-121USCNT_20141120_IFD.pdf	96479 6cf5742e9cfc497042961755409c15f91fd9fea4	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31975 4d6d6e62a7cf2b77ace15d24efa690e074fa83a7	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	239933		

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
GUPTA, et al.

Examiner:
James D. Anderson

Application No.:
13/456,720

Art Unit:
1629

Filed:
April 26, 2012

Title: **NOVEL ANTITUMORAL USE OF CABAZITAXEL**

CERTIFICATE OF EFS-WEB TRANSMISSION
I hereby certify that the correspondence below is being transmitted via the USPTO's electronic filing system in accordance with 1.6(a)(4), on

November 20, 2014
Date of Deposit

/Brian Pritchett/
Signature

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

Attached are the following documents:

			Number of Pages
☐	Application Data Sheet		
☐	Declaration		
☐	Drawings		
☐	Extension of Time		
☐	Information Disclosure Statement and Form 1449		
☐	Response to		
☐	Specification, Claims and Abstract	Specification	
		Claims	
		Abstract	
☐	Transmittal Letter:		
☒	Other *(specify):* ISSUE FEE		1
☐	Other *(specify):*		
☐	Other *(specify):*		

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

5487 7590 11/14/2014

ANDREA Q. RYAN
SANOFI
55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

EXAMINER
ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 11/14/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/456,720	04/26/2012	Sunil GUPTA	FR2009/121 US CNT	1083

TITLE OF INVENTION: NOVEL ANTITUMORAL USE OF CABAZITAXEL

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	02/17/2015

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

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ANDREA Q. RYAN
SANOFI
55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

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.
13/456,720	04/26/2012	Sunil GUPTA	FR2009/121 US CNT	1083

TITLE OF INVENTION: NOVEL ANTITUMORAL USE OF CABAZITAXEL

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	02/17/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
ANDERSON, JAMES D	1629	514-449000

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. _____

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/456,720	04/26/2012	Sunil GUPTA	FR2009/121 US CNT	1083

5487 7590 11/14/2014

ANDREA Q. RYAN
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MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 11/14/2014

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:

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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.
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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 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. 13/456,720	Applicant(s) GUPTA, SUNIL	
	Examiner JAMES D. ANDERSON	Art Unit 1629	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 *RCE filed 11/4/2014*.
   ☐ 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 *1,4,6-10,13-17,19,24,34,35 and 37-50*. 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 11/4/2014
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 _____.

/JAMES D ANDERSON/
Primary Examiner, Art Unit 1629

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

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

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 allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). 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, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/4/2014 has been entered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/4/2014 was filed after the mailing date of the Notice of Allowance on 8/4/2014. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The claims are the same as presented when previously allowed on 8/4/2014. See Claims filed 7/16/2014 and Notice of Allowance mailed 8/4/2014. The material cited in the Information Disclosure Statement filed 11/4/2014 has been considered by the Examiner and does not affect the allowability of the claims.

As previously discussed (Notice of Allowance mailed 8/4/2014), the examiner is persuaded by Applicants' arguments and factual evidence that it is surprising and unexpected that the claimed combination of cabazitaxel and a corticoid are clinically effective in the treatment of prostate cancer that has progressed during or after treatment with docetaxel. Specifically, the 37 CFR 1.132 Declaration of Dr. S artor filed 7/16/2014 provides convincing evidence that while the art was full of promising early clinical results, these failed to predict whether therapies would ultimately provide a clinically meaningful benefit to the desired patient populations and that mCRPC was known to be a particularly challenging and unpredictable indication.

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.

Conclusion

Claims 1, 4, 6-10, 13-17, 19, 24, 34, 35, and 37-50 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST (Telework Mondays and Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. 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.

/JAMES D ANDERSON/
Primary Examiner, Art Unit 1629

November 6, 2014

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NEWS 19	JUN 10	MEDLINE on STN Now Updated Daily
NEWS 20	AUG 18	Latest Version of Emtree Introduces 811 New Terms
NEWS 21	JUL 1	CHEMCATS (Chemical Catalogs Online) on STN Enhanced with New Search and Display Fields and More Frequent Updates
NEWS 22	JUL 24	Batch search results for DGENE, USGENE and PCTGEN now available for 30 days
NEWS 23	JUL 28	Latest release of new STN now available, expands global patent coverage and enhances search capabilities
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NEWS 26	OCT 23	CPC Thesaurus based on official CPC Scheme
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=> s cabazitaxel/cn
L1 1 CABAZITAXEL/CN

=> d l1

L1 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2014 ACS on STN
RN 183133-96-2 REGISTRY

ED Entered STN: 14 Nov 1996
CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)
OTHER CA INDEX NAMES:
CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, 12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, [2aR-[2aα,4β,4aβ,6β,9α(αR*,.beta.S*),11α,12α,12aα,12bα]]-
OTHER NAMES:
CN **Cabazitaxel**
CN Jevtana
CN TXD 258
CN XRP 6258
FS STEREOSEARCH
DR 890654-44-1
MF C45 H57 N O14
CI COM
SR CA
LC STN Files: ADISINSIGHT, BIOSIS, CA, CAPLUS, CASREACT, CBNB, CHEMCATS, CHEMLIST, EMBASE, IMSPATENTS, IMSRESEARCH, IPA, TOXCENTER, USAN, USPAT2, USPATFULL

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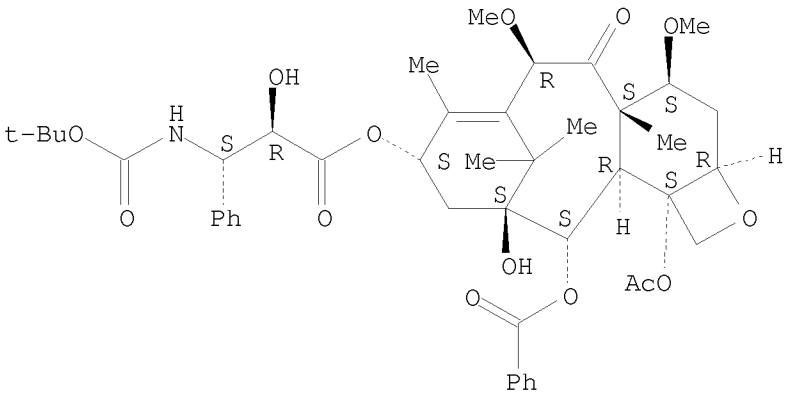

PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT

363 REFERENCES IN FILE CA (1907 TO DATE)
11 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
372 REFERENCES IN FILE CAPLUS (1907 TO DATE)

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L3 32 L1 OR L2

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E1 THROUGH E41 ASSIGNED

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E2            1     CABAZITAXEL HYDRATE/BI
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E4            1     CABAZITAXEL/BI
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E6            1     TXD 258/BI
E7            1     XRP 6258/BI
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E41           1     890654-44-1/BI


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            (1393818-87-5/RN)
          1402820-62-5/BI
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  (1453809-58-9/RN)
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  (1453809-59-0/RN)
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  (1453809-60-3/RN)
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  (1453809-63-6/RN)
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  (1453809-64-7/RN)
1610883-90-3/BI
  (1610883-90-3/RN)
1613293-82-5/BI
  (1613293-82-5/RN)
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  (1613293-83-6/RN)
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1613316-40-7/BI
  (1613316-40-7/RN)
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183133-96-2/BI
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L4   QUE ("CABAZITAXEL DIHYDRATE"/BI OR "CABAZITAXEL HYDRATE"/BI OR "CABAZITAXE
         L MONOHYDRATE"/BI OR CABAZITAXEL/BI OR JEVTANA/BI OR "TXD 258"/BI OR "
         XRP 6258"/BI OR 1345729-91-0/BI OR 1393818-87-5/BI OR 1402820-62-5/BI
         OR 1402820-63-6/BI OR 1402820-64-7/BI OR 1402820-65-8/BI OR 1402820-68
         -1/BI OR 1426815-65-7/BI OR 1426815-66-8/BI OR 1426815-67-9/BI OR 1430
         721-70-2/BI OR 1438897-79-0/BI OR 1443430-50-9/BI OR 1453809-54-5/BI O
         R 1453809-55-6/BI OR 1453809-56-7/BI OR 1453809-57-8/BI OR 1453809-58-
         9/BI OR 1453809-59-0/BI OR 1453809-60-3/BI OR 1453809-61-4/BI OR 14538
         09-62-5/BI OR 1453809-63-6/BI OR 1453809-64-7/BI OR 1610883-90-3/BI OR
          1613293-82-5/BI OR 1613293-83-6/BI OR 1613316-39-4/BI OR 1613316-40-7
         /BI OR 1616603-95-2/BI OR 1620556-85-5/BI OR 1622919-97-4/BI OR 183133
         -96-2/BI OR 890654-44-1/BI)

=> file hcaplus; del sel y
COST IN U.S. DOLLARS                            SINCE FILE      TOTAL
                                                     ENTRY    SESSION
FULL ESTIMATED COST                                 24.55      24.79

FILE 'HCAPLUS' ENTERED AT 13:50:48 ON 06 NOV 2014
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FILE COVERS 1907 - 6 Nov 2014 VOL 161 ISS 20
FILE LAST UPDATED: 5 Nov 2014 (20141105/ED)
REVISED CLASS FIELDS (/NCL) LAST RELOADED:  Sep 2014
USPTO MANUAL OF CLASSIFICATIONS THESAURUS ISSUE DATE:  Sep 2014

HCAplus includes complete International Patent Classification (IPC)
reclassification data for the fourth quarter of 2014.

HCAplus now includes the comprehensive Cooperative Patent Classification
(CPC).  See HELP CPC for details.

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http://www.cas.org/legal/infopolicy

This file contains CAS Registry Numbers for easy and accurate
substance identification.



=> s l4(L)((pac or pkt or dma or bac or thu)/rl or (treat? or cure? or curi? or
?therap? or pharm? or ?drug))
          397 "CABAZITAXEL"/BI
        41427 "DIHYDRATE"/BI
          777 "DIHYDRATES"/BI
        41823 "DIHYDRATE"/BI
                (("DIHYDRATE" OR "DIHYDRATES")/BI)
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     1 "CABAZITAXEL DIHYDRATE"/BI
         (("CABAZITAXEL"(W)"DIHYDRATE")/BI)
   397 "CABAZITAXEL"/BI
130148 "HYDRATE"/BI
 41610 "HYDRATES"/BI
151095 "HYDRATE"/BI
         (("HYDRATE" OR "HYDRATES")/BI)
     3 "CABAZITAXEL HYDRATE"/BI
         (("CABAZITAXEL"(W)"HYDRATE")/BI)
   397 "CABAZITAXEL"/BI
 44283 "MONOHYDRATE"/BI
   961 "MONOHYDRATES"/BI
 44853 "MONOHYDRATE"/BI
         (("MONOHYDRATE" OR "MONOHYDRATES")/BI)
     1 "CABAZITAXEL MONOHYDRATE"/BI
         (("CABAZITAXEL"(W)"MONOHYDRATE")/BI)
   397 CABAZITAXEL/BI
    16 JEVTANA/BI
    67 "TXD"/BI
     1 "TXDS"/BI
    68 "TXD"/BI
         (("TXD" OR "TXDS")/BI)
 20732 "258"/BI
     7 "TXD 258"/BI
         (("TXD"(W)"258")/BI)
    93 "XRP"/BI
    10 "XRPS"/BI
    98 "XRP"/BI
         (("XRP" OR "XRPS")/BI)
   237 "6258"/BI
     4 "XRP 6258"/BI
         (("XRP"(W)"6258")/BI)
     1 1345729-91-0/BI
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     1 1402820-65-8/BI
     1 1402820-68-1/BI
     2 1426815-65-7/BI
     1 1426815-66-8/BI
     2 1426815-67-9/BI
     2 1430721-70-2/BI
     2 1438897-79-0/BI
     3 1443430-50-9/BI
     1 1453809-54-5/BI
     2 1453809-55-6/BI
     2 1453809-56-7/BI
     2 1453809-57-8/BI
     1 1453809-58-9/BI
     1 1453809-59-0/BI
     1 1453809-60-3/BI
     1 1453809-61-4/BI
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     0 1610883-90-3/BI
     3 1613293-82-5/BI
     1 1613293-83-6/BI
     1 1613316-39-4/BI
     1 1613316-40-7/BI
     1 1616603-95-2/BI
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             1 1620556-85-5/BI
             1 1622919-97-4/BI
           372 183133-96-2/BI
             0 890654-44-1/BI
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        113460 PKT/RL
       1025550 DMA/RL
                 (PAC/RL)
       1019430 BAC/RL
       1967161 THU/RL
       5503465 TREAT?
        223504 CURE?
        294980 CURI?
       1296329 ?THERAP?
            11 ?THREAP?
            11 ?THREAP?
       1296334 ?THERAP?
                 (?THERAP? OR ?THREAP?)
       1337547 PHARM?
       1413052 ?DRUG
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               OR CURI? OR ?THERAP? OR PHARM? OR ?DRUG))

=> s l5 and (ad<20091029 or pd<20091029 or prd<20091029)
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      31877925 PD<20091029
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       6807411 PRD<20091029
                 (PRD<20091029)
L6          27 L5 AND (AD<20091029 OR PD<20091029 OR PRD<20091029)

=> s l6 and prostate
        108615 PROSTATE
          1873 PROSTATES
        108741 PROSTATE
                 (PROSTATE OR PROSTATES)
L7           9 L6 AND PROSTATE

=> file medline; del sel y
COST IN U.S. DOLLARS                            SINCE FILE      TOTAL
                                                   ENTRY    SESSION
FULL ESTIMATED COST                                 9.69      34.48

FILE 'MEDLINE' ENTERED AT 13:52:19 ON 06 NOV 2014

 FILE LAST UPDATED: 5 Nov 2014 (20141105/UP).  FILE COVERS 1946 TO DATE.

 MEDLINE(R) is a registered trademark of the U.S. National Library of
 Medicine (NLM).

 Effective June 2014, MEDLINE is now updated daily - seven days
 per week.  Alerts running on a frequency of Every Update will now
 be delivered seven times per week.  See NEWS for further information.

 The 2014 MEDLINE reload was completed on January 26, 2014.
 See HELP RLOAD for details on new search capabilities introduced
 with the reload.

 This file contains CAS Registry Numbers for easy and accurate
 substance identification.
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 See HELP RANGE before carrying out any RANGE search.


=> s l4 and prostate
           343 "CABAZITAXEL"/BI
          4027 "DIHYDRATE"/BI
            46 "DIHYDRATES"/BI
          4058 "DIHYDRATE"/BI
                 (("DIHYDRATE" OR "DIHYDRATES")/BI)
             0 "CABAZITAXEL DIHYDRATE"/BI
                 (("CABAZITAXEL"(W)"DIHYDRATE")/BI)
           343 "CABAZITAXEL"/BI
          7819 "HYDRATE"/BI
          1363 "HYDRATES"/BI
          8616 "HYDRATE"/BI
                 (("HYDRATE" OR "HYDRATES")/BI)
             0 "CABAZITAXEL HYDRATE"/BI
                 (("CABAZITAXEL"(W)"HYDRATE")/BI)
           343 "CABAZITAXEL"/BI
          5539 "MONOHYDRATE"/BI
            69 "MONOHYDRATES"/BI
          5581 "MONOHYDRATE"/BI
                 (("MONOHYDRATE" OR "MONOHYDRATES")/BI)
             0 "CABAZITAXEL MONOHYDRATE"/BI
                 (("CABAZITAXEL"(W)"MONOHYDRATE")/BI)
           343 CABAZITAXEL/BI
            15 JEVTANA/BI
            17 "TXD"/BI
         13333 "258"/BI
             1 "TXD 258"/BI
                 (("TXD"(W)"258")/BI)
            30 "XRP"/BI
             2 "XRPS"/BI
            30 "XRP"/BI
                 (("XRP" OR "XRPS")/BI)
           126 "6258"/BI
             1 "XRP 6258"/BI
                 (("XRP"(W)"6258")/BI)
             0 1345729-91-0/BI
             0 1393818-87-5/BI
             0 1402820-62-5/BI
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             0 1402820-64-7/BI
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             0 1402820-68-1/BI
             0 1426815-65-7/BI
             0 1426815-66-8/BI
             0 1426815-67-9/BI
             0 1430721-70-2/BI
             0 1438897-79-0/BI
             0 1443430-50-9/BI
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             0 1453809-59-0/BI
             0 1453809-60-3/BI
             0 1453809-61-4/BI
             0 1453809-62-5/BI
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             0 1453809-63-6/BI
             0 1453809-64-7/BI
             0 1610883-90-3/BI
             0 1613293-82-5/BI
             0 1613293-83-6/BI
             0 1613316-39-4/BI
             0 1613316-40-7/BI
             0 1616603-95-2/BI
             0 1620556-85-5/BI
             0 1622919-97-4/BI
             0 183133-96-2/BI
             0 890654-44-1/BI
        136546 PROSTATE
          3014 PROSTATES
        136723 PROSTATE
                 (PROSTATE OR PROSTATES)
L8         315 L4 AND PROSTATE

=> s l8 and py<2010
      19501611 PY<2010
L9           1 L8 AND PY<2010

=> file biosis
COST IN U.S. DOLLARS                            SINCE FILE      TOTAL
                                                     ENTRY    SESSION
FULL ESTIMATED COST                                   0.47      34.95

FILE 'BIOSIS' ENTERED AT 13:52:34 ON 06 NOV 2014
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FILE COVERS 1926 TO DATE.
CAS REGISTRY NUMBERS AND CHEMICAL NAMES (CNs) PRESENT
FROM JANUARY 1926 TO DATE.

RECORDS LAST ADDED: 5 November 2014 (20141105/ED)

BIOSIS has been augmented with 1.8 million archival records from 1926
through 1968.  These records have been re-indexed to match current
BIOSIS indexing.

=> s l8 and py<2010
           209 "CABAZITAXEL"/BI
          3094 "DIHYDRATE"/BI
            33 "DIHYDRATES"/BI
          3110 "DIHYDRATE"/BI
                 (("DIHYDRATE" OR "DIHYDRATES")/BI)
             0 "CABAZITAXEL DIHYDRATE"/BI
                 (("CABAZITAXEL"(W)"DIHYDRATE")/BI)
           209 "CABAZITAXEL"/BI
         10696 "HYDRATE"/BI
          2013 "HYDRATES"/BI
         12231 "HYDRATE"/BI
                 (("HYDRATE" OR "HYDRATES")/BI)
             0 "CABAZITAXEL HYDRATE"/BI
                 (("CABAZITAXEL"(W)"HYDRATE")/BI)
           209 "CABAZITAXEL"/BI
          4915 "MONOHYDRATE"/BI
            57 "MONOHYDRATES"/BI
          4952 "MONOHYDRATE"/BI
                 (("MONOHYDRATE" OR "MONOHYDRATES")/BI)
             0 "CABAZITAXEL MONOHYDRATE"/BI
                 (("CABAZITAXEL"(W)"MONOHYDRATE")/BI)
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          209 CABAZITAXEL/BI
           12 JEVTANA/BI
           28 "TXD"/BI
         9908 "258"/BI
            0 "TXD 258"/BI
                (("TXD"(W)"258")/BI)
           35 "XRP"/BI
            4 "XRPS"/BI
           36 "XRP"/BI
                (("XRP" OR "XRPS")/BI)
          292 "6258"/BI
            0 "XRP 6258"/BI
                (("XRP"(W)"6258")/BI)
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            0 1393818-87-5/BI
            0 1402820-62-5/BI
            0 1402820-63-6/BI
            0 1402820-64-7/BI
            0 1402820-65-8/BI
            0 1402820-68-1/BI
            0 1426815-65-7/BI
            0 1426815-66-8/BI
            0 1426815-67-9/BI
            0 1430721-70-2/BI
            0 1438897-79-0/BI
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            0 1453809-54-5/BI
            0 1453809-55-6/BI
            0 1453809-56-7/BI
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            0 1613316-40-7/BI
            0 1616603-95-2/BI
            0 1620556-85-5/BI
            0 1622919-97-4/BI
            1 183133-96-2/BI
            0 890654-44-1/BI
       150606 PROSTATE
         2900 PROSTATES
       151005 PROSTATE
                (PROSTATE OR PROSTATES)
     20337066 PY<2010
L10         0 L8 AND PY<2010

=> file embase; del sel y
COST IN U.S. DOLLARS                          SINCE FILE      TOTAL
                                                   ENTRY    SESSION
FULL ESTIMATED COST                                 1.08      36.03

FILE 'EMBASE' ENTERED AT 13:52:46 ON 06 NOV 2014
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FILE COVERS: Embase-originated material 1947 to 6 Nov 2014 (20141106/ED)
Unique MEDLINE content 1948 to present
Emtree thesaurus last updated September 2014

This file contains CAS Registry Numbers for easy and accurate substance identification.

Effective July 28, 2013, the content in Embase Alert (EMBAL) is strictly complementary to that in Embase (EMBASE). EMBAL contains, at any given time, approximately 100,000 novel records not yet available in Embase. Search both databases for the most timely and comprehensive results. See NEWS for details.

NOTICE: Because of an extremely large update on October 31, 2014, consisting mostly of conference records, Embase SDIs running on November 6 may retrieve more records than usual. See NEWS for further information.

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=> s l4 and prostate
          1009 "CABAZITAXEL"/BI
          3499 "DIHYDRATE"/BI
            44 "DIHYDRATES"/BI
          3527 "DIHYDRATE"/BI
                 (("DIHYDRATE" OR "DIHYDRATES")/BI)
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                 (("CABAZITAXEL"(W)"DIHYDRATE")/BI)
          1009 "CABAZITAXEL"/BI
         12618 "HYDRATE"/BI
          1361 "HYDRATES"/BI
         13514 "HYDRATE"/BI
                 (("HYDRATE" OR "HYDRATES")/BI)
             0 "CABAZITAXEL HYDRATE"/BI
                 (("CABAZITAXEL"(W)"HYDRATE")/BI)
          1009 "CABAZITAXEL"/BI
          5476 "MONOHYDRATE"/BI
            75 "MONOHYDRATES"/BI
          5526 "MONOHYDRATE"/BI
                 (("MONOHYDRATE" OR "MONOHYDRATES")/BI)
             0 "CABAZITAXEL MONOHYDRATE"/BI
                 (("CABAZITAXEL"(W)"MONOHYDRATE")/BI)
          1009 CABAZITAXEL/BI
           136 JEVTANA/BI
            50 "TXD"/BI
         14841 "258"/BI
            23 "TXD 258"/BI
                 (("TXD"(W)"258")/BI)
           125 "XRP"/BI
             2 "XRPS"/BI
           125 "XRP"/BI
                 (("XRP" OR "XRPS")/BI)
           217 "6258"/BI
            47 "XRP 6258"/BI
                 (("XRP"(W)"6258")/BI)
             0 1345729-91-0/BI
             0 1393818-87-5/BI
             0 1402820-62-5/BI
             0 1402820-63-6/BI
             0 1402820-64-7/BI
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             0 1402820-65-8/BI
             0 1402820-68-1/BI
             0 1426815-65-7/BI
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             0 1443430-50-9/BI
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             0 1620556-85-5/BI
             0 1622919-97-4/BI
           677 183133-96-2/BI
             0 890654-44-1/BI
        234991 PROSTATE
          4110 PROSTATES
        235088 PROSTATE
                  (PROSTATE OR PROSTATES)
L11        928 L4 AND PROSTATE

=> s l11 and py<2010
      23256196 PY<2010
L12         11 L11 AND PY<2010

=> d his

     (FILE 'HOME' ENTERED AT 13:49:42 ON 06 NOV 2014)

     FILE 'REGISTRY' ENTERED AT 13:50:04 ON 06 NOV 2014
L1            1 S CABAZITAXEL/CN
L2           31 S 183133-96-2/CRN
L3           32 S L1 OR L2
                SELECT CHEM L3 1-
L4              QUE E1-E41

     FILE 'HCAPLUS' ENTERED AT 13:50:48 ON 06 NOV 2014
                DEL SEL Y
L5          400 S L4(L)((PAC OR PKT OR DMA OR BAC OR THU)/RL OR (TREAT? OR CURE
L6           27 S L5 AND (AD<20091029 OR PD<20091029 OR PRD<20091029)
L7            9 S L6 AND PROSTATE

     FILE 'MEDLINE' ENTERED AT 13:52:19 ON 06 NOV 2014
                DEL SEL Y
L8          315 S L4 AND PROSTATE
L9            1 S L8 AND PY<2010

     FILE 'BIOSIS' ENTERED AT 13:52:34 ON 06 NOV 2014
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L10           0 S L8 AND PY<2010

     FILE 'EMBASE' ENTERED AT 13:52:46 ON 06 NOV 2014
                DEL SEL Y
L11         928 S L4 AND PROSTATE
L12          11 S L11 AND PY<2010

=> dup rem l7 l9 l10 l12
L10 HAS NO ANSWERS
COST IN U.S. DOLLARS                                SINCE FILE      TOTAL
                                                         ENTRY    SESSION
FULL ESTIMATED COST                                       2.19      38.22

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FILE 'EMBASE' ENTERED AT 13:53:12 ON 06 NOV 2014
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PROCESSING COMPLETED FOR L7
PROCESSING COMPLETED FOR L9
PROCESSING COMPLETED FOR L10
PROCESSING COMPLETED FOR L12
L13          19 DUP REM L7 L9 L10 L12 (2 DUPLICATES REMOVED)

=> d l13 1-19 ibib abs hitstr

L13  ANSWER 1 OF 19  HCAPLUS  COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER:         2012:467402  HCAPLUS
DOCUMENT NUMBER:          156:412029
TITLE:                    Estrogen receptor ligands and methods of use thereof
INVENTOR(S):              Dalton, James T.; Steiner, Mitchell S.; Morton, Ronald
                          A.
PATENT ASSIGNEE(S):       GTx, Inc., USA
SOURCE:                   U.S. Pat. Appl. Publ., 69pp., Cont.-in-part of
                          PCT/US2010/025032.
                          CODEN: USXXCO
DOCUMENT TYPE:            Patent
LANGUAGE:                 English
FAMILY ACC. NUM. COUNT:   13
PATENT INFORMATION:

     PATENT NO.           KIND  DATE        APPLICATION NO.          DATE
     ---------------      ----  --------    ---------------------    --------
     US 20120077845        A1   20120329    US 2011-13215679         20110823 <--
     JP 2008156239         A    20080710    JP 2006-343474           20061220 <--
     WO 2010096801         A1   20100826    WO 2010-US25032          20100223 <--
         W:  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
         RW: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU,
             IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI,
             SK, SM, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE,
             SN, TD, TG, BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG,
             ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM
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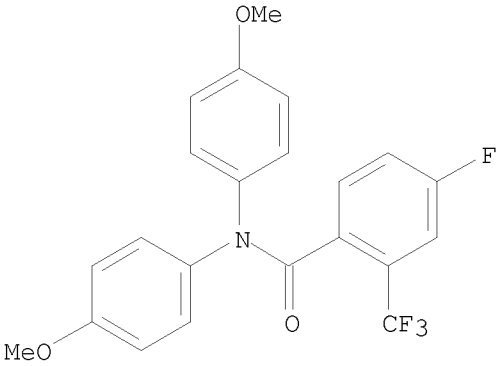
AU 2011226856 A1 20111013 AU 2011-226856 20110923 <--
AU 2011226856 B2 20120927
CA 2845890 A1 20130328 CA 2012-2845890 20120823
WO 2013043304 A1 20130328 WO 2012-US52141 20120823
WO 2013043304 A9 20140424
W: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, 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, QA, RO, RS, RU, RW, 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
RW: AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, RU, TJ, TM
AU 2012312902 A1 20130523 AU 2012-312902 20120823
IL 231070 A 20140430 IL 2012-231070 20120823
KR 2014064906 A 20140528 KR 2014-7007549 20120823
EP 2747562 A1 20140702 EP 2012-834287 20120823
R: AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR
CN 103957706 A 20140730 CN 2012-80051979 20120823
JP 2014524479 T 20140922 JP 2014-527312 20120823
PRIORITY APPLN. INFO.: US 2009-61154707 P 20090223 <--
US 2009-61168983 P 20090414 <--
US 2009-61261669 P 20091116
WO 2010-US25032 A2 20100223
US 2010-61380113 P 20100903
AU 2006-318400 A3 20061128 <--
US 2006-604897 T0 20061128 <--
US 2011-13215679 A 20110823
WO 2012-US52141 W 20120823
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
OTHER SOURCE(S): CASREACT 156:412029; MARPAT 156:412029

GI



AB The present invention relates to methods for reducing testosterone levels by reduction of LH or independent of LH levels in a male subject and methods of treating, suppressing, reducing the incidence, reducing the severity, or inhibiting **prostate** cancer, advanced **prostate** cancer, and castration-resistant **prostate** cancer (CRPC) and palliative treatment of

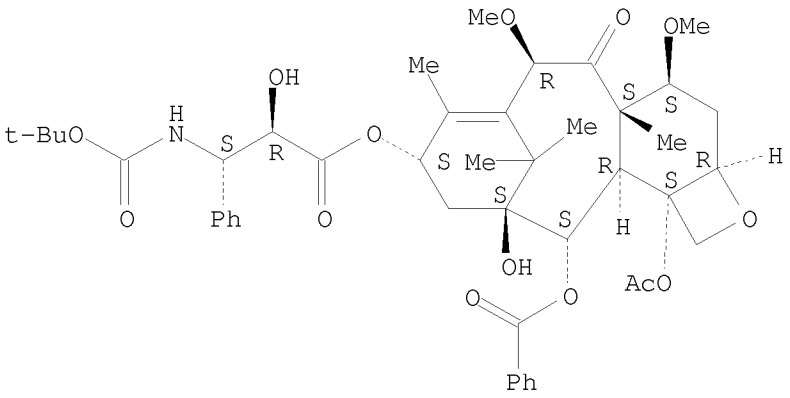
prostate cancer, advanced **prostate** cancer and castration-resistant **prostate** cancer (CRPC). The compds. of this invention suppress free or total testosterone levels to castrate levels which may be used to treat **prostate** cancer, advanced **prostate** cancer, and CRPC without causing bone loss, decreased bone mineral d., increased risk of bone fractures, increased body fat, hot flashes and/or gynecomastia.

IT **183133-96-2, Cabazitaxel**
RL: **THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(**treatment** of castration-resistant **prostate** cancer that continues to progress or worsen despite continued **treatment** with addnl. drugs)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



L13 ANSWER 2 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2010:437266 HCAPLUS
DOCUMENT NUMBER: 152:446754
TITLE: Resistance expression signature-based methods for predicting or monitoring whether a patient affected by a cancer is responsive to a treatment with a molecule of the taxoid family
INVENTOR(S): Chauchereau, Anne; Al Nakouzi, Nader
PATENT ASSIGNEE(S): Institut Gustave Roussy, Fr.; INSERM (Institut National de la Sante et de la Recherche Medicale)
SOURCE: PCT Int. Appl., 73pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 2
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2010037859	A2	20100408	WO 2009-EP62851	20091002 <--
WO 2010037859	A3	20100603		

W: 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, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW
RW: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU,
IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI,
SK, SM, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE,
SN, TD, TG, BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG,
ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AP, EA, EP, OA
EP 2177630 A1 20100421 EP 2008-305634 20081002 <--
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU,
IE, IS, IT, LI, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI,
SK, TR, AL, BA, MK, RS
EP 2356256 A2 20110817 EP 2009-783708 20091002 <--
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU,
IE, IS, IT, LI, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE,
SI, SK, SM, TR
US 20110177970 A1 20110721 US 2011-13121975 20110331 <--
PRIORITY APPLN. INFO.: EP 2008-305634 A 20081002 <--
WO 2009-EP62851 W 20091002 <--
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT

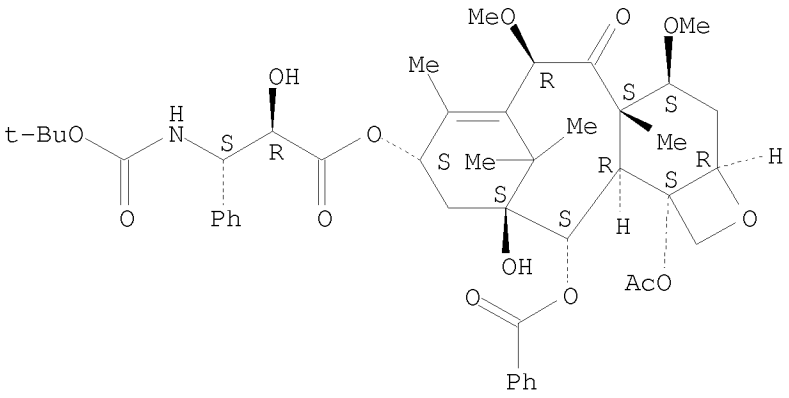
AB The invention discloses in vitro methods for predicting or monitoring whether a patient affected by a cancer is responsive to a treatment with a mol. of the taxoid family based on a resistance expression signature, as well as kits for performing the methods and methods for screening or identifying a compound suitable for improving the treatment of a cancer with a mol. of the taxoid family or for reducing the resistance development during the treatment of a cancer with the mol. of the taxoid family.

IT **183133-96-2**
RL: BSU (Biological study, unclassified); **PAC (Pharmacological activity)**; **THU (Therapeutic use)**; BIOL (Biological study);
USES (Uses)
(signature-based methods for predicting or monitoring taxoid antitumor responsiveness)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



L13 ANSWER 3 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN

ACCESSION NUMBER: 2010:498376 HCAPLUS
DOCUMENT NUMBER: 152:493436
TITLE: Gene expression markers for prediction of the response of a tumor to taxane therapy
INVENTOR(S): Chauchereau, Anne; Al Nakouzi, Nader
PATENT ASSIGNEE(S): Institut Gustave Roussy, Fr.
SOURCE: Eur. Pat. Appl., 59pp.
CODEN: EPXXDW
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 2
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
EP 2177630	A1	20100421	EP 2008-305634	20081002 <--
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR, AL, BA, MK, RS				
WO 2010037859	A2	20100408	WO 2009-EP62851	20091002 <--
WO 2010037859	A3	20100603		
W: 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, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW				
RW: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AP, EA, EP, OA				
EP 2356256	A2	20110817	EP 2009-783708	20091002 <--
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR				
US 20110177970	A1	20110721	US 2011-13121975	20110331 <--
PRIORITY APPLN. INFO.:			EP 2008-305634 A	20081002 <--
			WO 2009-EP62851 W	20091002 <--

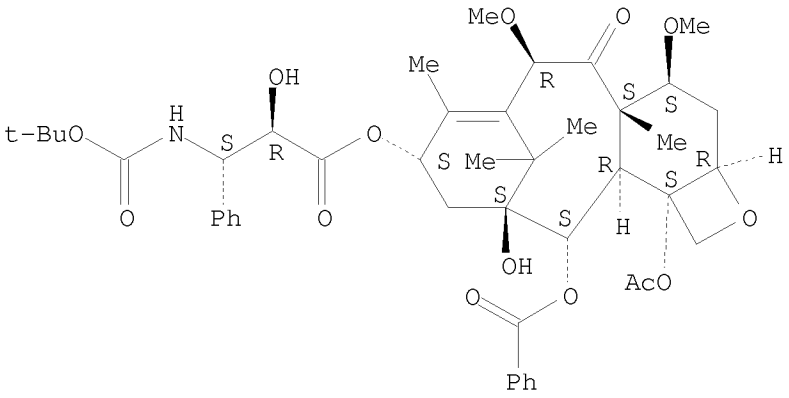
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT

AB Gene expression markers that can be used to predict the response of a tumor to therapy with taxanes are described. These markers can also be used to monitor the effectiveness of the therapy. Markers that show increased expression in a favorable response and markers that show decreased expression are identified. There are 300 genes that are members of known biochem. networks and anal. of expression of one or two members of each network is sufficient to assess the response to the therapy. Changes in expression can also be used in the early identification of the development of resistance to these drugs.

IT **183133-96-2**
RL: **THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(as antitumor agent, predicting tumor response to; gene expression markers for prediction of response of tumor to taxane **therapy**
)

RN 183133-96-2 HCAPLUS
CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 2 THERE ARE 2 CAPLUS RECORDS THAT CITE THIS RECORD (2 CITINGS)
REFERENCE COUNT: 6 THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L13 ANSWER 4 OF 19 EMBASE COPYRIGHT (c) 2014 Elsevier B.V. All rights reserved on STN
ACCESSION NUMBER: 2010014964 EMBASE
TITLE: Cytotoxic compounds in the treatment of castration-resistant **prostate** cancer.
AUTHOR: Lee, Patrick; Aragon-Ching, Jeanny B.
CORPORATE SOURCE: Division of Hematology and Oncology, George Washington University Medical Center, 2150 Pennsylvania Avenue, NW, Washington, DC 20037, United States. jaragonching@mfa.gwu.edu
AUTHOR: Aragon-Ching, J. B. (correspondence)
CORPORATE SOURCE: Division of Hematology and Oncology, George Washington University Medical Center, 2150 Pennsylvania Avenue, NW, Washington, DC 20037, United States. jaragonching@mfa.gwu.edu
SOURCE: Anti-Cancer Agents in Medicinal Chemistry, (2009) Vol. 9, No. 10, pp. 1040-1045.
Refs: 79
ISSN: 1871-5206
DIGITAL OBJECT ID: 10.2174/187152009789734991
PUBLISHER: Bentham Science Publishers B.V., P.O. Box 294, Bussum, 1400 AG, Netherlands.
COUNTRY: Netherlands
DOCUMENT TYPE: Journal; General Review; (Review)
FILE SEGMENT: 016 Cancer
022 Human Genetics
028 Urology and Nephrology
030 Clinical and Experimental Pharmacology
037 Drug Literature Index
038 Adverse Reactions Titles
LANGUAGE: English
SUMMARY LANGUAGE: English
ENTRY DATE: Entered Embase: 1 Mar 2010
Last Updated on Embase: 1 Mar 2010

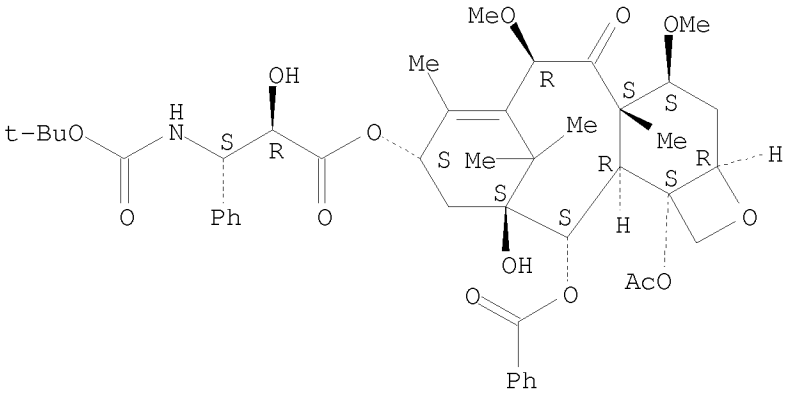
AB **Prostate** cancer is the most common non-cutaneous cancer among men in the United States. Most will be diagnosed at an early stage, but a significant number will still develop metastatic castration resistant disease. Docetaxel has demonstrated improved quality of life and overall

survival in metastatic castration-resistant **prostate** cancer but virtually all patients will ultimately become refractory to taxane therapy. Second-line options are limited and new effective chemotherapeutic agents or combinations are needed in this setting. This review will focus on cytotoxic compounds in clinical investigation either in combination with taxanes in the first or second-line setting and other novel compounds, such as platinums and microtubule-targeting agents that are in active clinical investigation. © 2009 Bentham Science Publishers Ltd.

L13 ANSWER 5 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN DUPLICATE 1
ACCESSION NUMBER: 2009:59403 HCAPLUS
DOCUMENT NUMBER: 151:115508
TITLE: Phase I and Pharmacokinetic Study of XRP6258 (RPR 116258A), a Novel Taxane, Administered as a 1-Hour Infusion Every 3 Weeks in Patients with Advanced Solid Tumors
AUTHOR(S): Mita, Alain C.; Denis, Louis J.; Rowinsky, Eric K.; DeBono, Johann S.; Goetz, Andrew D.; Ochoa, Leonel; Forouzesh, Bahram; Beeram, Muralidhar; Patnaik, Amita; Molpus, Kathleen; Semiond, Dorothee; Besenval, Michele; Tolcher, Anthony W.
CORPORATE SOURCE: Institute for Drug Development, Cancer Therapy and Research Center and University of Texas Health Science Center at San Antonio, San Antonio, TX, USA
SOURCE: Clinical Cancer Research (**2009**), 15(2), 723-730
CODEN: CCREF4; ISSN: 1078-0432
DIGITAL OBJECT ID: 10.1158/1078-0432.CCR-08-0596
PUBLISHER: American Association for Cancer Research
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Purpose: To assess the feasibility of administering XRP6258, a new taxane with a low affinity for the multidrug resistance 1 protein, as a 1-h i.v. infusion every 3 wk. The study also sought to determine the maximum tolerated dose and the recommended dose, to describe the pharmacokinetic (PK) behavior of the compound, and to seek preliminary evidence of anticancer activity. Exptl. Design: Twenty-five patients with advanced solid malignancies were treated with 102 courses of XRP6258 at four dose levels ranging from 10 to 25 mg/m2. Dose escalation was based on the occurrence of dose-limiting toxicity (DLT) at each dose level, provided that PK variables were favorable. The maximum tolerated dose was defined as the dose at which at least two patients developed a DLT at the first course. Results: Neutropenia was the principal DLT, with one patient experiencing febrile neutropenia and two others showing prolonged grade 4 neutropenia at the 25 mg/m2 dose level. Nonhematol. toxicities, including nausea, vomiting, diarrhea, neurotoxicity, and fatigue, were generally mild to moderate in severity. XRP6258 exhibited dose-proportional PK, a triphasic elimination profile, a long terminal half-life (77.3 h), a high clearance (mean CL, 53.5 L/h), and a large volume of distribution (mean Vss, 2,034 L/m2). Objective antitumor activity included partial responses in two patients with metastatic **prostate** carcinoma, one unconfirmed partial response, and two minor responses. Conclusion: The recommended phase II dose of XRP6258 on this schedule is 20 mg/m2. The general tolerability and encouraging antitumor activity in taxane-refractory patients warrant further evaluations of XRP6258.
IT **183133-96-2, XRP 6258**
RL: ADV (Adverse effect, including toxicity); **PAC (Pharmacological activity); PKT (Pharmacokinetics); THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(**pharmacokinetics** of XRP6258 in patients with advanced solid tumors)
RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 105 THERE ARE 105 CAPLUS RECORDS THAT CITE THIS RECORD (108 CITINGS)
REFERENCE COUNT: 21 THERE ARE 21 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L13 ANSWER 6 OF 19 EMBASE COPYRIGHT (c) 2014 Elsevier B.V. All rights reserved on STN
ACCESSION NUMBER: 2009457731 EMBASE
TITLE: Recent Progress and Pitfalls in Testing Novel Agents in Castration-Resistant **Prostate** Cancer.
AUTHOR: Bellmunt, Joaquim (correspondence)
CORPORATE SOURCE: University Hospital del Mar, IMIM, U. Pompeu Fabra, Barcelona, Spain. jbellmunt@imas.imim.es
AUTHOR: Bellmunt, Joaquim (correspondence); Rosenberg, Jonathan E.; Choueiri, Toni K.
CORPORATE SOURCE: Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, United States. jbellmunt@imas.imim.es
SOURCE: European Urology, (October 2009) Vol. 56, No. 4, pp. 606-608.
Refs: 15
ISSN: 0302-2838 CODEN: EUURAV
DIGITAL OBJECT ID: 10.1016/j.eururo.2009.07.015
PUBLISHER: Elsevier, P.O. Box 211, Amsterdam, 1000 AE, Netherlands.
PUBLISHER IDENT.: S 0302-2838(09)00728-3
COUNTRY: Netherlands
DOCUMENT TYPE: Journal; Editorial
FILE SEGMENT: 016 Cancer
028 Urology and Nephrology
037 Drug Literature Index
LANGUAGE: English
ENTRY DATE: Entered Embase: 21 Sep 2009
Last Updated on Embase: 21 Sep 2009

L13 ANSWER 7 OF 19 EMBASE COPYRIGHT (c) 2014 Elsevier B.V. All rights reserved on STN
ACCESSION NUMBER: 2009203301 EMBASE
TITLE: Tubulin-interactive natural products as anticancer agents.

AUTHOR: Kingston, David G. I.
CORPORATE SOURCE: Department of Chemistry, Virginia Polytechnic Institute, State University, Blacksburg, VA 24061-0212. dkingston@vt.edu
AUTHOR: Kingston, D. G. I. (correspondence)
CORPORATE SOURCE: Department of Chemistry, Virginia Polytechnic Institute, State University, Blacksburg, VA 24061-0212. dkingston@vt.edu
SOURCE: Journal of Natural Products, (27 Mar 2009) Vol. 72, No. 3, pp. 507-515.
Refs: 163
ISSN: 0163-3864 CODEN: JNPRDF
DIGITAL OBJECT ID: 10.1021/np800568j
PUBLISHER: American Chemical Society, 2540 Olentangy River Road, P.O. Box 3337, Columbus, OH 43210-3337, United States.
COUNTRY: United States
DOCUMENT TYPE: Journal; General Review; (Review)
FILE SEGMENT: 006 Internal Medicine
016 Cancer
030 Clinical and Experimental Pharmacology
037 Drug Literature Index
038 Adverse Reactions Titles
039 Pharmacy
LANGUAGE: English
SUMMARY LANGUAGE: English
ENTRY DATE: Entered Embase: 8 May 2009
Last Updated on Embase: 8 May 2009

AB This review provides an overview of the discovery, structures, and biological activities of anticancer natural products that act by inhibiting or promoting the assembly of tubulin to microtubules. The emphasis is on providing recent information on those compounds in clinical use or in advanced clinical trials. The vinca alkaloids, the combretastatins, NPI-2358, the halichondrin B analogue eribulin, dolastatin 10, noscapine, hemiasterlin, and rhizoxin are discussed as tubulin polymerization inhibitors, while the taxanes and the epothilones are the major classes of tubulin polymerization promoters presented, with brief treatments of discodermolide, eleutherobin, and laulimalide. The challenges and future directions of tubulin-interactive natural products-based drug discovery programs are also discussed briefly.

L13 ANSWER 8 OF 19 EMBASE COPYRIGHT (c) 2014 Elsevier B.V. All rights reserved on STN
ACCESSION NUMBER: 2009493213 EMBASE
TITLE: New agents in metastatic **prostate** cancer.
AUTHOR: Fizazi, Karim (correspondence); Massard, Christophe
CORPORATE SOURCE: Department of Medicine, University of Paris XI, Villejuif, France.
SOURCE: European Journal of Cancer, (September 2009) Vol. 45, No. SUPPL. 1, pp. 379-380.
Refs: 15
ISSN: 0959-8049 CODEN: EJCAEL
DIGITAL OBJECT ID: 10.1016/S0959-8049(09)70056-5
PUBLISHER: Elsevier Ltd, Langford Lane, Kidlington, Oxford, OX5 1GB, United Kingdom.
PUBLISHER IDENT.: S 0959-8049(09)70056-5
COUNTRY: United Kingdom
DOCUMENT TYPE: Journal; Article
FILE SEGMENT: 006 Internal Medicine
016 Cancer
028 Urology and Nephrology

030 Clinical and Experimental Pharmacology
037 Drug Literature Index
LANGUAGE: English
ENTRY DATE: Entered Embase: 5 Nov 2009
Last Updated on Embase: 5 Nov 2009

L13 ANSWER 9 OF 19 EMBASE COPYRIGHT (c) 2014 Elsevier B.V. All rights reserved on STN
ACCESSION NUMBER: 2009585532 EMBASE
TITLE: Editorial: New therapeutic agents for castration-refractory **prostate** cancer.
AUTHOR: Patten, David (correspondence); Sartor, Oliver
CORPORATE SOURCE: Department of Medicine, Tulane Medical School, New Orleans, LA, United States.
AUTHOR: Sartor, Oliver
CORPORATE SOURCE: Division of Hematology/Oncology, Tulane Medical School, New Orleans, LA, United States.
AUTHOR: Sartor, Oliver
CORPORATE SOURCE: Department of Urology, Tulane Medical School, New Orleans, LA, United States.
SOURCE: Clinical Genitourinary Cancer, (2009) Vol. 7, No. 2, pp. E4-E6.
Refs: 15
ISSN: 1558-7673
DIGITAL OBJECT ID: 10.3816/CGC.2009.n.013
PUBLISHER: Cancer Information Group, LP, 3500 Maple Avenue, Suite 750, Dallas, TX 75219, United States.
PUBLISHER IDENT.: T6323758T2710605
COUNTRY: United States
DOCUMENT TYPE: Journal; Editorial
FILE SEGMENT: 006 Internal Medicine
016 Cancer
028 Urology and Nephrology
037 Drug Literature Index
LANGUAGE: English
ENTRY DATE: Entered Embase: 14 Dec 2009
Last Updated on Embase: 14 Dec 2009

L13 ANSWER 10 OF 19 EMBASE COPYRIGHT (c) 2014 Elsevier B.V. All rights reserved on STN
ACCESSION NUMBER: 2008294234 EMBASE
TITLE: New tubulin targeting agents currently in clinical development.
AUTHOR: Carlson, Robert O., Dr. (correspondence)
CORPORATE SOURCE: Discovery Biology, Myriad Pharmaceuticals Inc., 320 Wakara Way, Salt Lake City, UT 84103, United States. rcarlson@myriad.com
SOURCE: Expert Opinion on Investigational Drugs, (May 2008) Vol. 17, No. 5, pp. 707-722.
Refs: 117
ISSN: 1354-3784 CODEN: EOIDER
DIGITAL OBJECT ID: 10.1517/13543784.17.5.707
COUNTRY: United Kingdom
DOCUMENT TYPE: Journal; General Review; (Review)
FILE SEGMENT: 016 Cancer
030 Clinical and Experimental Pharmacology
037 Drug Literature Index
038 Adverse Reactions Titles
LANGUAGE: English
SUMMARY LANGUAGE: English
ENTRY DATE: Entered Embase: 27 Jun 2008
Last Updated on Embase: 27 Jun 2008

AB Background: The first tubulin targeting agents were approved as cancer chemotherapeutics over 40 years ago and tubulin as an antitumor target continues to attract significant drug discovery and development attention. Mechanism of action as defined by tubulin binding sites and effect on microtubules distinguishes these agents, but the end result is equivalent in that microtubule disruption leads to cell cycle arrest at G2/M phase of the cell cycle and subsequent apoptotic cell death. Objectives: The goal of this review is to describe the state of clinical development of tubulin targeting agents as of early 2008, with descriptions of clinical experience slanted toward the most advanced trials for each agent. Method: Objective information in this review was obtained exclusively from public sources that included journals, scientific meeting abstracts, posters and oral presentations, websites and public presentations from companies. Opinions expressed in this review are exclusively from the author. Results/conclusions: A large number of tubulin targeting agents are currently in clinical development, including microtubule stabilizing and destabilizing compounds acting through all three of the characterized tubulin binding sites. With the approval of ixabepilone for refractory breast cancer, the epothilones appear best positioned to make an impact among the new microtubule stabilizing compounds. There are 17 microtubule destabilizing agents under clinical assessment, with many only in Phase I and results to date include at best modest efficacy signals with no obvious indication trend.

L13 ANSWER 11 OF 19 MEDLINE ® on STN DUPLICATE 2
ACCESSION NUMBER: 2008503223 MEDLINE
DOCUMENT NUMBER: PubMed ID: 18685415
TITLE: Systemic therapy after first-line docetaxel in metastatic castration-resistant **prostate** cancer.
AUTHOR: Beardsley Emma K
CORPORATE SOURCE: BC Cancer Agency, Vancouver, Canada.
AUTHOR: Chi Kim N
SOURCE: Current opinion in supportive and palliative care, **(2008 Sep)** Vol. 2, No. 3, pp. 161-6. Ref: 31
Journal code: 101297402. E-ISSN: 1751-4266. L-ISSN: 1751-4258.
DIGITAL OBJECT ID: 10.1097/SPC.0b013e32830c48a3
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
General Review; (REVIEW)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
ENTRY MONTH: 200810
ENTRY DATE: Entered STN: 8 Aug 2008
Last Updated on STN: 21 Oct 2008
Entered Medline: 20 Oct 2008
OS.CITING REF COUNT: 4 There are 4 MEDLINE records that cite this record
REFERENCE COUNT: 31 There are 31 cited references for this document.
AB PURPOSE OF REVIEW: There is an urgent need for systemic treatment options for patients with castration-resistant **prostate** cancer who have progressed after receiving first-line docetaxel chemotherapy. The purpose of this article is to review recent developments in this area.

RECENT FINDINGS: Retreatment with docetaxel has been employed with evidence of activity in selected populations. Mitoxantrone, the previous first-line standard based on its palliative effect, has also been used with clinical responses observed; however, the symptom benefit in this setting has not been established. Several classes of cytotoxic agents have been tested including platinum agents (satraplatin), epothilones (ixabepilone and patupilone) and taxanes (**XRP-6258**). A number of targeted therapies have also been clinically evaluated including

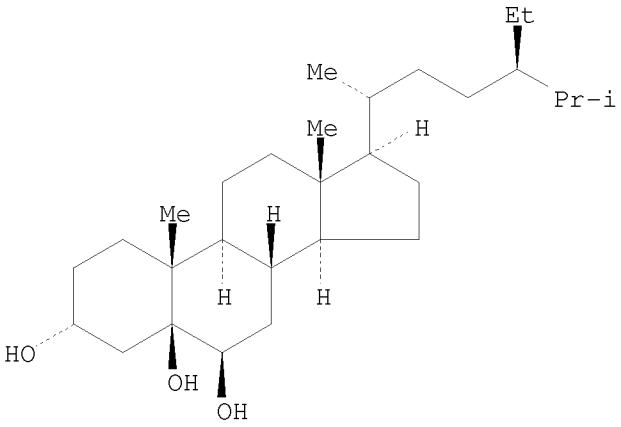
inhibitors of cytoprotective chaperones (OGX-011) and the vascular endothelial growth factor receptor (sorafenib, sunitinib, and cediranib). An area generating great interest has been the development of agents that target the androgen receptor axis more effectively (MDV3100 and abiraterone) with encouraging early phase trial results.

SUMMARY: There is no accepted standard systemic treatment for patients with castration resistant **prostate** cancer and progressive disease after docetaxel. Novel agents are in phase II and III clinical testing in this setting.

L13 ANSWER 12 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2007:619578 HCAPLUS
DOCUMENT NUMBER: 147:46112
TITLE: Treatment of cancer and other diseases
INVENTOR(S): Habib, Nabil
PATENT ASSIGNEE(S): Nabil Habib Lab, Lebanon; Vianova Labs, Inc.
SOURCE: PCT Int. Appl., 86pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2007064691	A1	20070607	WO 2006-US45665	20061130 <--
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, 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, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW				
RW: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM				
CA 2632903	A1	20070607	CA 2006-2632903	20061130 <--
EP 1968607	A1	20080917	EP 2006-844623	20061130 <--
EP 1968607	B1	20140115		
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LI, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR				
US 20090226431	A1	20090910	US 2009-85892	20090306 <--
US 8293726	B2	20121023		

PRIORITY APPLN. INFO.: US 2005-60741725 P 20051202 <--
WO 2006-US45665 W 20061130 <--
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
OTHER SOURCE(S): MARPAT 147:46112
GI



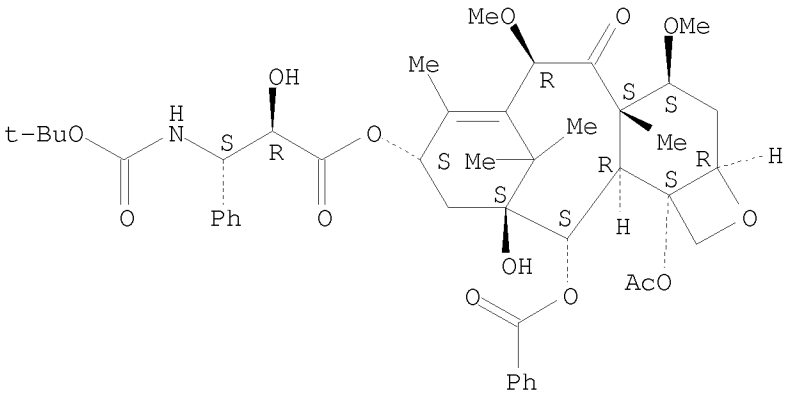
AB The present invention relates to a novel compound (e.g., 24-ethyl-cholestane-3β,5α,6α-triol), its production, its use, and to methods of treating neoplasms and other tumors as well as other diseases including hypercholesterolemia, autoimmune diseases, viral diseases (e.g., hepatitis B, hepatitis C, or HIV), and diabetes.

IT **183133-96-2, TXD 258**
RL: **PAC (Pharmacological activity); THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(**treatment** of cancer and other diseases using ethylcholestane triol and combination with other agents)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 1 THERE ARE 1 CAPLUS RECORDS THAT CITE THIS RECORD (1 CITINGS)

REFERENCE COUNT: 2 THERE ARE 2 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L13 ANSWER 13 OF 19 EMBASE

ACCESSION NUMBER: 2007375639 EMBASE
TITLE: Medical management of advanced **prostate** cancer: A multidisciplinary team approach.
AUTHOR: Molins, Joaquim Bellmunt, Dr. (correspondence)
CORPORATE SOURCE: Hospital Del Mar, Solid Tumor Oncology (GU and GI) Medical Oncology Service, Paseo Maritimo 25-29, Barcelona 08003, Spain. jbellmunt@imas.imim.es
AUTHOR: Gelaberti i Mas, Antoni
CORPORATE SOURCE: Hospital Del Mar, Urology Department, Paseo Maritimo 25-29, Barcelona 08003, Spain. agelabert@imas.imim.es
SOURCE: Expert Review of Anticancer Therapy, (Jul 2007) Vol. 7, No. 7, pp. 977-979.
ISSN: 1473-7140; E-ISSN: 1744-8328 CODEN: ERATBJ
DIGITAL OBJECT ID: 10.1586/14737140.7.7.977
COUNTRY: United Kingdom
DOCUMENT TYPE: Journal; Conference Article; (Conference paper)
FILE SEGMENT: 016 Cancer
017 Public Health, Social Medicine and Epidemiology
028 Urology and Nephrology
037 Drug Literature Index
038 Adverse Reactions Titles
LANGUAGE: English
ENTRY DATE: Entered Embase: 1 Oct 2007
Last Updated on Embase: 1 Oct 2007

L13 ANSWER 14 OF 19 EMBASE
ACCESSION NUMBER: 2008001236 EMBASE
TITLE: How do microtubule-targeted drugs work? An overview.
AUTHOR: Jordan, Mary Ann (correspondence); Kamath, Kathy
CORPORATE SOURCE: Department of Molecular, Cellular, and Developmental Biology, Neuroscience Research Institute, University of California Santa Barbara, Santa Barbara, CA 93106, United States. jordan@lifesci.ucsb.edu
SOURCE: Current Cancer Drug Targets, (Dec 2007) Vol. 7, No. 8, pp. 730-742.
Refs: 168
ISSN: 1568-0096 CODEN: CCDTB9
DIGITAL OBJECT ID: 10.2174/156800907783220417
COUNTRY: Netherlands
DOCUMENT TYPE: Journal; General Review; (Review)
FILE SEGMENT: 015 Chest Diseases, Thoracic Surgery and Tuberculosis
016 Cancer
025 Hematology
030 Clinical and Experimental Pharmacology
037 Drug Literature Index
LANGUAGE: English
SUMMARY LANGUAGE: English
ENTRY DATE: Entered Embase: 4 Feb 2008
Last Updated on Embase: 4 Feb 2008
AB The importance of microtubules in mitosis makes them a superb target for a group of highly successful, chemically diverse anticancer drugs. Knowledge of the mechanistic differences among the many drugs of this class is vital to understanding their tissue and cell specificity, the development of resistance, the design of novel improved drugs, optimal scheduling of treatment, and potential synergistic combinations. This overview covers microtubule assembly dynamics, the exquisite regulation of microtubule dynamics in cells by endogenous regulators, the important role of microtubule dynamics in mitosis, the diversity and number of microtubule-targeted drugs undergoing clinical development, the antimitotic mechanisms of microtubule-targeted drugs with emphasis on suppression of microtubule dynamics by vinblastine and taxol, the role of

drug uptake and retention in the efficacy of microtubule-targeted drugs, and the anti-angiogenic and vascular-disrupting mechanisms of microtubule targeted drugs. In view of the success of this class of drugs, it has been argued that microtubules represent the single best cancer target identified to date, and it seems likely that drugs in this class will continue to remain an important chemotherapeutic class of drugs even as more selective chemotherapeutic approaches are developed. © 2007 Bentham Science Publishers Ltd.

L13 ANSWER 15 OF 19 EMBASE COPYRIGHT (c) 2014 Elsevier B.V. All rights reserved on STN

ACCESSION NUMBER: 2006519050 EMBASE
TITLE: Development of new cancer therapeutic agents targeting mitosis.
AUTHOR: Miglarese, Mark R., Dr. (correspondence)
CORPORATE SOURCE: Array BioPharma, Inc., 3200 Walnut Street, Boulder, CO 80301, United States. mark.miglarese@arraybiopharma.com
AUTHOR: Carlson, Robert O.
CORPORATE SOURCE: Myriad Pharmaceuticals, 320 Wakara Way, Salt Lake City, UT 84103, United States. rcarlson@myriad.com
SOURCE: Expert Opinion on Investigational Drugs, (Nov 2006) Vol. 15, No. 11, pp. 1411-1425.
Refs: 125
ISSN: 1354-3784 CODEN: EOIDER
DIGITAL OBJECT ID: 10.1517/13543784.15.11.1411
COUNTRY: United Kingdom
DOCUMENT TYPE: Journal; General Review; (Review)
FILE SEGMENT: 016 Cancer
030 Clinical and Experimental Pharmacology
037 Drug Literature Index
038 Adverse Reactions Titles
039 Pharmacy
052 Toxicology
LANGUAGE: English
SUMMARY LANGUAGE: English
ENTRY DATE: Entered Embase: 16 Nov 2006
Last Updated on Embase: 16 Nov 2006

AB Targeting cellular proliferation persists as a mainstay of cancer therapeutic strategy. Although microtubule-targeting drugs (such as taxanes and vinca alkaloids) have been used successfully in the clinic to treat a variety of cancers, they carry substantial liabilities that have spurred drug companies to aggressively pursue new tubulin-targeting drug candidates with improved efficacy and toxicity profiles. The recent discoveries of new mitotic targets for cancer therapy (such as kinesin spindle protein, Aurora kinases and Polo-like kinase-1) have also stimulated intense work focused on identifying novel antimitotic drugs directed at these new targets. A number of novel antimitotic drugs have demonstrated encouraging activity in preclinical models and have progressed into clinical development. This review focuses on selected new antimitotic drugs under evaluation in clinical trials. © 2006 Informa UK Ltd.

L13 ANSWER 16 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN

ACCESSION NUMBER: 2005:1290072 HCAPLUS
DOCUMENT NUMBER: 144:46998
TITLE: The x-ray crystal structure of BRCA1 tandem BRCT repeat and BACH1 phosphopeptide complex and methods and compositions for antitumor drug design
INVENTOR(S): Yaffe, Michael B.; Clapperton, Julie A.; Manke, Isaac A.; Lowery, Drew M.; Ho, Timmy; Haire, Lesley F.; Smerdon, Stephen J.
PATENT ASSIGNEE(S): Massachusetts Institute of Technology, USA

SOURCE: PCT Int. Appl., 360 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2005115454	A2	20051208	WO 2005-US15981	20050509 <--
WO 2005115454	A3	20071115		
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW				
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, AP, EA, EP, OA				
AU 2005247346	A1	20051208	AU 2005-247346	20050509 <--
CA 2569003	A1	20051208	CA 2005-2569003	20050509 <--
EP 1773389	A2	20070418	EP 2005-780060	20050509 <--
R: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LI, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, AL, BA, HR, LV, MK, YU				
JP 2007537164	T	20071220	JP 2007-511664	20050509 <--
US 20090143997	A1	20090604	US 2008-229740	20080826 <--
US 20120295802	A1	20121122	US 2012-13451209	20120419 <--

PRIORITY APPLN. INFO.:
US 2004-60569131 P 20040507 <--
US 2005-126022 A3 20050509 <--
WO 2005-US15981 W 20050509 <--
US 2008-229740 A1 20080826 <--

ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT

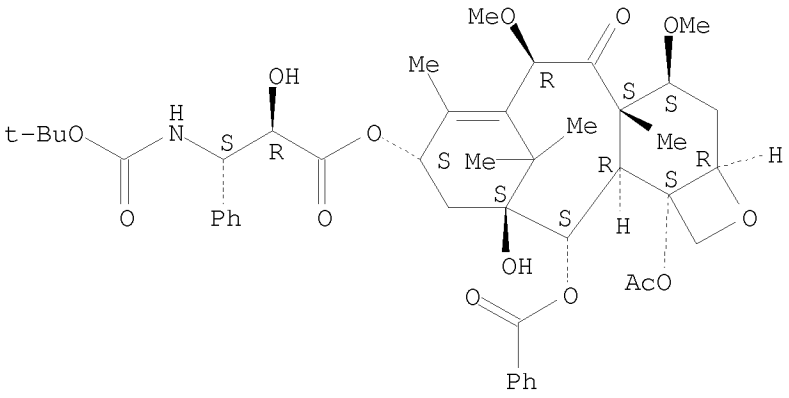
AB The present invention relates to compds. (e.g., peptidomimetics and non-peptides) that treat, prevent or stabilize cellular proliferative disorders and methods of treating, preventing, or stabilizing such disorders. The invention also provides three-dimensional structures of a BRCT domain-BACH1 phosphopeptide complex.

IT **183133-96-2, TXD 258**
RL: BSU (Biological study, unclassified); **THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(x-ray crystal structure of BRCA1 tandem BRCT repeat and BACH1 phosphopeptide complex and methods and compns. for antitumor **drug** design)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



L13 ANSWER 17 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2005:409543 HCAPLUS
DOCUMENT NUMBER: 142:457053
TITLE: Human protein IAP (inhibitor of apoptosis protein) nucleobase oligomers, including dsRNA, shRNA, and siRNA, and their use for enhancing apoptosis in cancer therapy
INVENTOR(S): Lacasse, Eric; McManus, Daniel
PATENT ASSIGNEE(S): Aegera Therapeutics, Inc., Can.
SOURCE: PCT Int. Appl., 112 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.		DATE
WO 2005042558	A1	20050512	WO 2004-CA1902		20041029 <--
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW					
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG					
US 20050148535	A1	20050707	US 2004-975974		20041028 <--
CA 2542904	A1	20050512	CA 2004-2542904		20041029 <--
EP 1682565	A1	20060726	EP 2004-789809		20041029 <--
R: DE, FR, GB					
JP 2007510408	T	20070426	JP 2006-537024		20041029 <--
PRIORITY APPLN. INFO.:			US 2003-60516192	P	20031030 <--
			WO 2004-CA1902	W	20041029 <--

AB The invention provides nucleobase oligomers and oligonucleotide duplexes that inhibit expression of an IAP (inhibitor of apoptosis protein), and methods for using them to induce apoptosis in a cell. Specifically, the invention provides nucleic acid sequences for siRNAs and shRNAs that target human XIAP, HIAP-1 or HIAP-2 genes. The nucleobase oligomers and oligomer complexes of the present invention may also be used to form pharmaceutical compns. The invention also features methods for enhancing

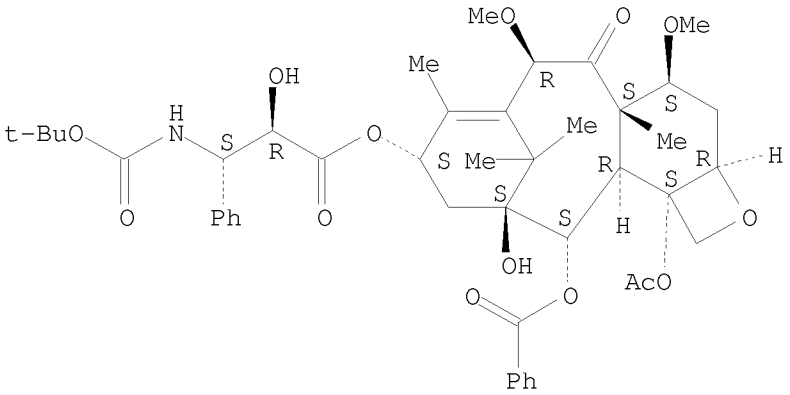
apoptosis in a cell by administering a nucleobase oligomer or oligomer complex of the invention in combination with a chemotherapeutic or chemosensitizing agent. RNAi sequences and vectors producing shRNA (short hairpin RNA) were transfected into HeLa cells and evaluated for their effect on XIAP, cIAP-1, or cIAP-2 protein levels. XIAP protein could also be reduced by RNAi clones in transfected breast cancer cell line MDA-MB-231. In addition, cell survival was reduced in XIAP RNAi transfected breast cancer cell line after the transfected cells were treated with TRAIL (tumor necrosis factor-related apoptosis inducing ligand).

IT **183133-96-2, TXD 258**
RL: **THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(human protein IAP (inhibitor of apoptosis protein) nucleobase oligomers, including dsRNA, shRNA, and siRNA, and their use for enhancing apoptosis in cancer **therapy**)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 1 THERE ARE 1 CAPLUS RECORDS THAT CITE THIS RECORD (1 CITINGS)
REFERENCE COUNT: 5 THERE ARE 5 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L13 ANSWER 18 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2005:409357 HCAPLUS
DOCUMENT NUMBER: 142:457052
TITLE: Sequences of antisense IAP (inhibitor of apoptosis protein) oligomers and their use for treatment of proliferative diseases with a chemotherapeutic agent
INVENTOR(S): Lacasse, Eric; McManus, Daniel; Durkin, Jon P.
PATENT ASSIGNEE(S): Aegera Therapeutics, Inc., Can.
SOURCE: PCT Int. Appl., 285 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE

WO 2005042030 A1 20050512 WO 2004-CA1900 20041029 <--
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG
US 20050119217 A1 20050602 US 2004-975790 20041028 <--
US 8012944 B2 20110906
AU 2004284855 A1 20050512 AU 2004-284855 20041029 <--
CA 2542884 A1 20050512 CA 2004-2542884 20041029 <--
EP 1691842 A1 20060823 EP 2004-789807 20041029 <--
R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, RO, MK, CY, AL, TR, BG, CZ, EE, HU, PL, SK, HR
BR 2004015779 A 20061226 BR 2004-15779 20041029 <--
CN 1901939 A 20070124 CN 2004-80039601 20041029 <--
JP 2007509861 T 20070419 JP 2006-537023 20041029 <--
ZA 2006003399 A 20070926 ZA 2006-3399 20041029 <--
NZ 547191 A 20090828 NZ 2004-547191 20041029 <--
RU 2376018 C2 20091220 RU 2006-117024 20041029 <--
SG 157422 A1 20091229 SG 2009-7918 20041029 <--
CN 101862459 A 20101020 CN 2010-10218334 20041029 <--
TW I332841 B 20101111 TW 2004-132984 20041029 <--
IL 175242 A 20130530 IL 2004-175242 20041029 <--
MX 2006004920 A 20070216 MX 2006-4920 20060502 <--
IN 2006MN00614 A 20070420 IN 2006-MN614 20060526 <--
NO 2006002420 A 20060731 NO 2006-2420 20060529 <--
KR 2006127393 A 20061212 KR 2006-7010619 20060530 <--
PRIORITY APPLN. INFO.: US 2003-60516263 P 20031030 <--
CN 2004-80039601 A3 20041029 <--
WO 2004-CA1900 W 20041029 <--
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT

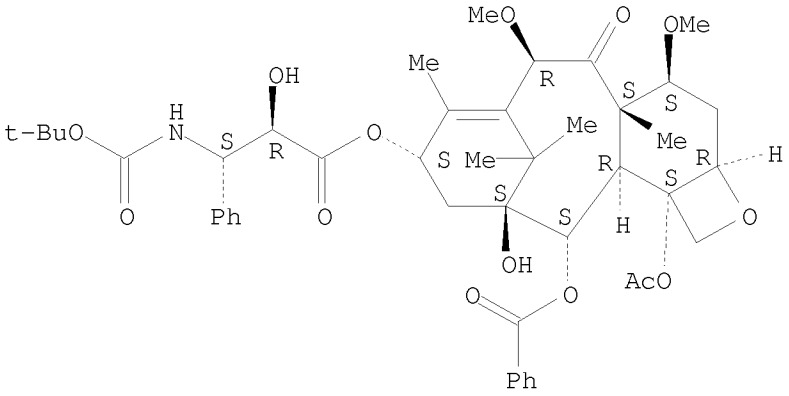
AB The invention claims the use of an antisense oligomer to human XIAP, IAP-1 or IAP-2 genes and a chemotherapeutic agent, and compns. and kits thereof, for the treatment of proliferative diseases. The invention further claims sequences for nucleobase oligomers that are antisense IAP (inhibitor of apoptosis protein) oligomers. The antisense IAP nucleobase oligomers specifically hybridize with polynucleotides encoding an IAP and reduce the amount of an IAP protein produced in a cell. Thus by reducing the IAP protein, the invention provides methods for inducing cancer cells to undergo apoptosis and for overriding anti-apoptotic signals in cancer cells. As an example of the invention, mice with s.c. H460 human lung carcinoma xenografts were injected intratumorally with XIAP antisense mixed-base 2'-O-Me RNA oligonucleotides (C5 and/or G4) and the drug vinorelbine. At the end of the 24 d treatment period, the mean relative tumor growth was reduced .apprx.70% in treated mice. The inhibition of tumor growth was correlated with down-regulation of human XIAP protein expression and an increased number of dead cells. The mice did not show any signs of cytotoxicity such as body weight loss.

IT **183133-96-2, TXD 258**
RL: **THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(sequences of antisense IAP (inhibitor of apoptosis protein) oligomers and their use for **treatment** of proliferative diseases with **chemotherapeutic** agent)

RN 183133-96-2 HCAPLUS
CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-

(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 4 THERE ARE 4 CAPLUS RECORDS THAT CITE THIS RECORD (7 CITINGS)
REFERENCE COUNT: 6 THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L13 ANSWER 19 OF 19 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2005:283298 HCAPLUS
DOCUMENT NUMBER: 142:349042
TITLE: Combinations of chlorpromazine compounds and antiproliferative drugs for the treatment of neoplasms
INVENTOR(S): Lee, Margaret S.; Nichols, James M.; Zhang, Yanzhen; Keith, Curtis
PATENT ASSIGNEE(S): Combinatorx, Incorporated, USA
SOURCE: PCT Int. Appl., 65 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 7
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2005027842	A2	20050331	WO 2004-US30368	20040916 <--
WO 2005027842	A3	20051222		
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW				
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG				
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CA 2538570	A1	20050331	CA 2004-2538570	20040916 <--
EP 1670477	A2	20060621	EP 2004-788798	20040916 <--
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IE, SI, LT, LV, FI, RO, MK, CY, AL, TR, BG, CZ, EE, HU, PL, SK, HR

BR 2004014568	A	20061107	BR 2004-14568		20040916	<--
CN 1878556	A	20061213	CN 2004-80033294		20040916	<--
JP 2007505914	T	20070315	JP 2006-527024		20040916	<--
MX 2006003066	A	20060620	MX 2006-3066		20060317	<--
NO 2006001325	A	20060606	NO 2006-1325		20060323	<--
KR 2007012618	A	20070126	KR 2006-7007244		20060414	<--
PRIORITY APPLN. INFO.:			US 2003-60504310	P	20030918	<--
			WO 2004-US30368	W	20040916	<--

OTHER SOURCE(S): MARPAT 142:349042

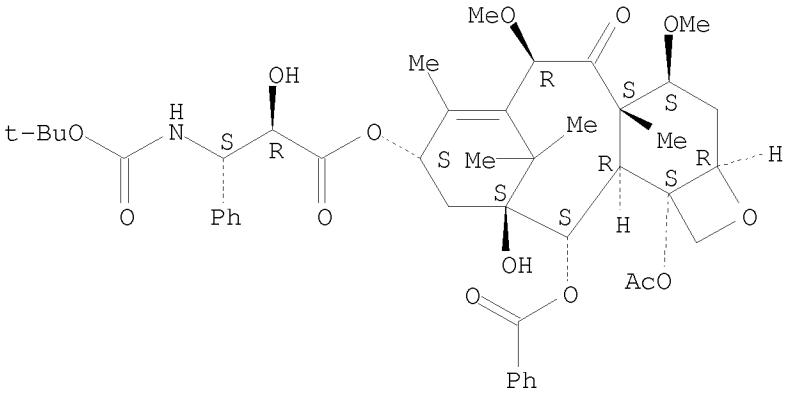
AB The invention discloses a method for treating a patient having a cancer or other neoplasm by administering chlorpromazine or a chlorpromazine analog and an antiproliferative agent simultaneously or within 14 days of each other in amts. sufficient to treat the patient.

IT **183133-96-2, TXD 258**
RL: **PAC (Pharmacological activity); THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(chlorpromazine compound-antiproliferative **drug** antitumor combination)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 5 THERE ARE 5 CAPLUS RECORDS THAT CITE THIS RECORD (7 CITINGS)

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FILE 'REGISTRY' ENTERED AT 13:50:04 ON 06 NOV 2014

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L2	31	S 183133-96-2/CRN
L3	32	S L1 OR L2
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L4		QUE E1-E41

FILE 'HCAPLUS' ENTERED AT 13:50:48 ON 06 NOV 2014
DEL SEL Y

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L7            9 S L6 AND PROSTATE

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L13          19 DUP REM L7 L9 L10 L12 (2 DUPLICATES REMOVED)

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---Logging off of STN---



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Executing the logoff script...


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FULL ESTIMATED COST                               122.39     160.61

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	**Art Unit**
	JAMES D ANDERSON	1629

CPC								
Symbol							**Type**	**Version**
A61K		31	/	337			F	2013-01-01
A61K		31	/	164			I	2013-01-01
A61K		31	/	56			I	2013-01-01
A61K		31	/	573			I	2013-01-01
A61K		45	/	06			I	2013-01-01
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CPC Combination Sets									
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K		31	/	164	I	1	1	2013-01-01
A61K		2300	/	00	A	1	2	2013-01-01
A61K		31	/	337	I	2	1	2013-01-01
A61K		2300	/	00	A	2	2	2013-01-01
A61K		31	/	56	I	3	1	2013-01-01
A61K		2300	/	00	A	3	2	2013-01-01
A61K		31	/	573	I	4	1	2013-01-01
A61K		2300	/	00	A	4	2	2013-01-01

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 30	
/JAMES D ANDERSON/ Primary Examiner.Art Unit 1629 (Primary Examiner)	11/06/2014 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	**Art Unit**
	JAMES D ANDERSON	1629

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION												
CLASS	SUBCLASS	CLAIMED						NON-CLAIMED						
514	449	A	6	1	K	31 / 337 (2006.01.01)								
CROSS REFERENCE(S)		A	6	1	K	31 / 573 (2006.01.01)								
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)													

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/JAMES D ANDERSON/ Primary Examiner.Art Unit 1629	11/06/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	**Art Unit**
	JAMES D ANDERSON	1629

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

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NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/JAMES D ANDERSON/ Primary Examiner.Art Unit 1629	11/06/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	Art Unit
	JAMES D ANDERSON	1629

CPC- SEARCHED		
Symbol	Date	Examiner
A61K31/337; A61K31/573	7/28/2014	JDA

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search	1/11/2013	JDA
EAST Search (see attached)	1/11/2013	JDA
STN Structure Search (see attached)	1/11/2013	JDA
Inventor Name Search	9/10/2013	JDA
EAST Search (see attached)	9/10/2013	JDA
STN Structure Search (see attached)	9/10/2013	JDA
Inventor Name Search	4/10/2014	JDA
EAST Search (see attached)	4/10/2014	JDA
Medline NPL Search	4/10/2014	JDA
Inventor Name Search	7/28/2014	JDA
EAST Search (see attached)	7/28/2014	JDA
STN NPL Search	7/28/2014	JDA
Inventor Name Search	11/6/2014	JDA
EAST Search (see attached)	11/6/2014	JDA
STN NPL Search	11/6/2014	JDA

INTERFERENCE SEARCH	

US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61K	31/337; 31/573	7/28/2014	JDA
514	449	7/28/2014	JDA
A61K	31/337; 31/573	11/6/2014	JDA
514	449	11/6/2014	JDA

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PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2011/0177970		CHAUCHEREAU, et al.	07-21-2011	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JDA/

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PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		BERTOLD, et al., Docetaxel Plus Prednisone or Mitoxantrone Plus Prednisone for Advanced Prostate Cancer: Updated Survival in the TAX 327 Study, Journal of Clinical Oncology, Vol. 26, No. 2, (2008), pp. 242-245.	
		Merck Index 14th 2006, No. 190, p.35, Agomelatine.	
		TAN, Novel Agents in the Treatment of Hormone-Independent Metastatic Prostate Cancer, Actas Urol Esp., (2007), Vol. 31, No. 6, pp. 680-685 (followed by non-verified English translation).	
		El Docetaxel Asociado a la Prednisona Mejora el Cancer de Prostata, [Retrieved from the internet on October 26, 2012]. Retrieved from http://www.medicinageriatrica.com.ar/viewnews.php?id=EEpVVFZVppsBCjOavj.	
		DRES, et al., Treatment alternatives for advanced prostate cancer, [Retrieved from the internet on July 29, 2014]. Retrieved from http://www.intramed.net/contenidover.asp?contenidoID=37957 (followed by non-verified English translation).	
		Taxotere (Docetaxel) Mejora Significativamente la Supervivencia de los Pacientes con Cancer de Prostata Avanzado, PMFARMA Espana, (2007)	
		Docetaxel Reduce el Riesgo de Muerte en Pacientes con Cancer de Prostata Metastatico Androgeno Independiente, [Retrieved from the internet on July 29, 2014]. Retrieved from http://www.intramed.net/contenidover.asp?contenidoID=31823 (followed by non-verified English translation).	
		Cancer de Prostata Diseminado, Quimioterapia, [Retrieved from the internet on July 29, 2014]. Retrieved from http://www.guiasalud.es/egpc/cancer_prostata/resumida/apartado06/otros02.html, pp.1-9.	
		Revision Sistematica y Modelo Economico de Efectividad Clinica y Coste-Efectividad de Docetaxel en Combinacion con Prednisona/Prednisolona para el Tratamiento de Cancer de Prostata Metastasico Refractario a Hormonas, [Retrieved from the internet on July 29,2014]. Retrieved from http://www.sefh.es/sefhboletin/vernoticiaboletin.php?id=2663.	
		FIGG, et al., Cabazitaxel Filling One of the Gaps in the Treatment of Prostate Cancer, Cancer Biology & Therapy, Vol. 10, No. 12, pp. 1233-1234, (2010)	

Examiner Signature		Date Considered	

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

[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		MIRTSCHING, Prostate Cancer Clinical Trials in Dallas, Texas Area, [Retrieved from the internet on August 19, 2014], Retrieved from http://www.healthcentral.com/prostate/c/5618/14589/dallas-texas-area, pp.3-4	

Examiner Signature	/James Anderson/	Date Considered	11/06/2014

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

[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JDA/

EAST Search History

EAST Search History (Prior Art)

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L5	1	L4	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/11/06 12:48
L6	5661	Sanofi-aventis.as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/11/06 12:49
L7	4081	"Aventis Pharma".as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/11/06 12:49
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L10	14	L9	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/11/06 12:49
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			EPO; JPO; DERWENT			
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L16	147	L15 and A61K31/573.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/11/06 12:50
L17	31	L16 and prostate.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/11/06 12:50
L18	13	L17 and (@ad<"20091029" or @pd<"20091029")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/11/06 12:50
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S1	14	"5847170"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 12:37
S2	102	cabazitaxel	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 12:40
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S4	12	XRP6258	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 12:42
S5	38	((SUNIL) near2 (GUPTA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/11 12:43
S6	4725	Sanofi-aventis.as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:15
S7	38	S6 and taxane	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:15
S8	9	("5229526" | "5319112" | "5486601" | "5739362").PN. OR ("5847170").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/11 14:18
S9	4016	"Aventis Pharma".as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:21
S10	67	S9 and taxane	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	2013/01/11 14:21

			DERWENT			
S11	6	"2005065138"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:31
S12	3	"20050065138"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:31
S13	11	("20020038038" | "6372780" | "6331635" | "6387946" | "20050065138" | "5438072" | "7241907" | "5847170").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 09:58
S14	39	((SUNIL) near2 (GUPTA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/10 09:59
S15	39	S14	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 09:59
S16	1	S15 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S17	5090	Sanofi-aventis.as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S18	4061	"Aventis Pharma".as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S19	8681	S17 or S18	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S20	11	S19 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S21	197	(cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:01
S22	29	S21 and (@ad<"20101027" or @pd<"20101027")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:01
S23	42	((SUNIL) near2 (GUPTA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/10 10:50
S24	42	S23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S25	1	S24 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S26	5421	Sanofi-aventis.as.	US-PGPUB;	OR	ON	2014/04/10

			USPAT; USOCR; EPO; JPO; DERWENT			10:50
S27	4073	"Aventis Pharma".as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S28	9021	S26 or S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S29	13	S28 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S30	13	S25 or S29	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S31	311	(cabazitaxel or XRP6258 or (XRP adj2 "6258"))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:51
S32	33	S31 and (@ad<"20101027" or @pd<"20101027")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:51
S33	7	S32 and (cabazitaxel or XRP6258 or (XRP adj2 "6258")).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:51
S34	367	cabazitaxel or XRP6258 or (XRP adj2 "6258")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:33
S35	13	S34 and (@ad<"20091029" or @pd<"20091029")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:34
S36	68	S34 and (cabazitaxel or XRP6258 or (XRP adj2 "6258")).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:34
S37	21	S36 and prostate.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:34
S38	3183	A61K31/337.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35
S39	121	S38 and A61K31/573.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35
S40	30	S39 and prostate.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35

S41	13	S40 and (@ad<"20091029" or @pd<"20091029")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	71097	"S25"	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:48
L20	1114	A61K31/337.cpcc.	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:51
L21	41	L20 and A61K31/573.cpcc.	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:51
L22	21	L21 and prostate.clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:51
L23	21	L22	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:51
L24	2563	514/449.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:51
L25	36	L24 and (cabazitaxel or XRP6258 or (XRP adj2 "6258"))	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:51
L26	36	L25	US-PGPUB; USPAT; UPAD	OR	ON	2014/11/06 12:51
S42	1028	A61K31/337.cpcc.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:37
S43	37	S42 and A61K31/573.cpcc.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:37
S44	20	S43 and prostate.clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:37
S45	2492	514/449.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:38
S46	30	S45 and (cabazitaxel or XRP6258 or (XRP adj2 "6258"))	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:38

11/6/2014 12:51:57 PM
C:\Users\janderson\Documents\EAST\Workspaces\13456720.wsp

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Alexandria, Virginia 22313-1450
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BIB DATA SHEET

CONFIRMATION NO. 1083

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/456,720	04/26/2012 RULE	514	1629	FR2009/121 US CNT

APPLICANTS

INVENTORS

Sunil GUPTA, Chester Springs, PA;

**** CONTINUING DATA ***************************

This application is a CON of PCT/IB2010/054866 10/27/2010
which claims benefit of 61/389,969 10/05/2010
and claims benefit of 61/383,933 09/17/2010
and claims benefit of 61/369,929 08/02/2010
and claims benefit of 61/355,888 06/17/2010
and claims benefit of 61/355,834 06/17/2010
and claims benefit of 61/293,903 01/11/2010
and claims benefit of 61/256,160 10/29/2009

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

05/07/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /JAMES D ANDERSON/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		PA	7	33	10

ADDRESS

ANDREA Q. RYAN
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55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807
UNITED STATES

TITLE

NOVEL ANTITUMORAL USE OF CABAZITAXEL

FILING FEE RECEIVED	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit
3910		

PTO/SB/30 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 US CNT

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. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. 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).

   a. ☐ 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.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☐ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ 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)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 18-1982.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 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.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	/Kelly L. Bender/	Date	November 4, 2014
Name (Print/Type)	Kelly L. Bender	Registration No.	52,610

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature			
Name (Print/Type)		Date	

PTO/SB/30 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Instruction Sheet for RCEs

(not to be submitted to the USPTO)

NOTES:

An RCE is not a new application, and filing an RCE will not result in an application being accorded a new filing date.

Filing Qualifications:

The application must be a utility or plant application filed on or after June 8, 1995. The application cannot be a provisional application, a utility or plant application filed before June 8, 1995, a design application, or a patent under reexamination. See 37 CFR 1.114(e).

Filing Requirements:

Prosecution in the application must be closed. Prosecution is closed if the application is under appeal, or the last Office action is a final action, a notice of allowance, or an action that otherwise closes prosecution in the application (e.g., an Office action under *Ex parte Quayle*). See 37 CFR 1.114(b).

A submission and a fee are required at the time the RCE is filed. If reply to an Office action under 35 U.S.C. 132 is outstanding (e.g., the application is under final rejection), the submission must meet the reply requirements of 37 CFR 1.111. If there is no outstanding Office action, the submission can be an information disclosure statement, an amendment, new arguments, or new evidence. See 37 CFR 1.114(c). The submission may be a previously filed amendment (e.g., an amendment after final rejection).

WARNINGS:

Request for Suspension of Action:

All RCE filing requirements must be met before suspension of action is granted. A request for a suspension of action under 37 CFR 1.103(c) does not satisfy the submission requirement and does not permit the filing of the required submission to be suspended.

Improper RCE will NOT toll Any Time Period:

Before Appeal - If the RCE is improper (e.g., prosecution in the application is not closed or the submission or fee has not been filed) and the application is not under appeal, the time period set forth in the last Office action will continue to run and the application will be abandoned after the statutory time period has expired if a reply to the Office action is not timely filed. No additional time will be given to correct the improper RCE.

Under Appeal - If the RCE is improper (e.g., the submission or the fee has not been filed) and the application is under appeal, the improper RCE is effective to withdraw the appeal. Withdrawal of the appeal results in the allowance or abandonment of the application depending on the status of the claims. If there are no allowed claims, the application is abandoned. If there is at least one allowed claim, the application will be passed to issue on the allowed claim(s). See MPEP 1215.01.

See MPEP 706.07(h) for further information on the RCE practice.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
GUPTA, et al.

Examiner:
James D. Anderson

Application No.:
13/456,720

Art Unit:
1629

Filed:
April 26, 2012

Title: **NOVEL ANTITUMORAL USE OF CABAZITAXEL**

CERTIFICATE OF EFS-WEB TRANSMISSION
I hereby certify that the correspondence below is being transmitted via the USPTO's electronic filing system in accordance with 1.6(a)(4), on

November 4, 2014
Date of Deposit

/Brian Pritchett/
Signature

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

Attached are the following documents:

			Number of Pages
☐	Application Data Sheet		
☐	Declaration		
☐	Drawings		
☐	Extension of Time		
☒	Supplemental Information Disclosure Statement and Form 1449		5
☐	Response to		
☐	Specification, Claims and Abstract	Specification	
		Claims	
		Abstract	
☐	Transmittal Letter:		
☒	Other *(specify):* REFERENCES		11
☒	Other *(specify):* REQUEST FOR CONTINUED EXAMINATION (RCE)		3
☐	Other *(specify):*		

Electronic Patent Application Fee Transmittal

Application Number:	13456720
Filing Date:	26-Apr-2012
Title of Invention:	NOVEL ANTITUMORAL USE OF CABAZITAXEL
First Named Inventor/Applicant Name:	Sunil GUPTA
Filer:	Kelly L. Bender/Brian Pritchett
Attorney Docket Number:	FR2009/121 US CNT

Filed as Large Entity

Utility under 35 USC 111(a) 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($)
Miscellaneous:				
RCE - 2nd and Subsequent Request	1820	1	1700	1700
		Total in USD ($)		**1700**

Electronic Acknowledgement Receipt

EFS ID:	20589652
Application Number:	13456720
International Application Number:	
Confirmation Number:	1083
Title of Invention:	NOVEL ANTITUMORAL USE OF CABAZITAXEL
First Named Inventor/Applicant Name:	Sunil GUPTA
Customer Number:	5487
Filer:	Kelly L. Bender/Brian Pritchett
Filer Authorized By:	Kelly L. Bender
Attorney Docket Number:	FR2009/121 US CNT
Receipt Date:	04-NOV-2014
Filing Date:	26-APR-2012
Time Stamp:	14:52:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1700
RAM confirmation Number	1103
Deposit Account	181982
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Non Patent Literature	FR2009121USCNTSUPPIDSREF1_BERTOLD_J_Clin_Oncology_2008_26_2__242_245_cited_in_EA_Dec_2013.pdf	133255 47adea504e3a7d408d7be70c3c1b9122768c5263	no	4
Warnings:					
Information:					
2	Non Patent Literature	FR2009121USCNTSUPPIDSREF2_Merck_Index_14th_2006_No_0000190.pdf	123961 e1acd4d73689e9572d497d5594efaf1290acb62c	no	1
Warnings:					
Information:					
3	Non Patent Literature	FR2009121USCNTSUPPIDSREF4_El_Docetaxel_Asociado_a_la_Prednisona_Mejorada_el_cancer_de_prostata.pdf	104628 9919ec7a935dfaba413df61818379b07cc9ee364	no	1
Warnings:					
Information:					
4	Non Patent Literature	FR2009121USCNTSUPPIDSREF6_Taxotere_Docetaxel_mejora_significativamente_la_supervivencia_.pdf	15009 2fd33f4974accbc314667a2aaff9c9b8bbad7b0b	no	1
Warnings:					
Information:					
5	Non Patent Literature	FR2009121USCNTSUPPIDSREF10_Mirtsching_Prostate_Cancer_Clinical_Trials_in_Dallas.pdf	378744 c881fb30f6a3de3b601d661582fdffd7201b3f3c	no	4
Warnings:					
Information:					
6	Non Patent Literature	FR2009121USCNTSUPPIDSREF11_FIGG_2010.pdf	235031 acbc7dc35fce5bd924d0f17a22a80d6ff21fef11	no	2
Warnings:					
Information:					
7	Non Patent Literature	ref3.pdf	5124684 c19034ea1aa91e3d3b21f2b6476f2295170c37f3	no	12
Warnings:					
Information:					
8	Non Patent Literature	ref5.pdf	864927 6b230581b4816c9d60884293291c9226ab859ca2	no	3
Warnings:					
Information:					
9	Non Patent Literature	ref7.pdf	771961 5f227eb7f4409fdfcbb85934e36ba2ff84ed3df3	no	3
Warnings:					
Information:					

10	Non Patent Literature	ref8.pdf	2362600 aabc1840c929a7fda20f92db9ec1076915776387	no	9
Warnings:					
Information:					
11	Non Patent Literature	ref9.pdf	225585 710608302be98c6572bc4fb8a3dacc11221239d2	no	1
Warnings:					
Information:					
12	Information Disclosure Statement (IDS) Form (SB08)	FR2009-121USCNT_20141103_SUPP_IDS_SB08.pdf	915263 280311c1de8d39028cefc08f8d64266560a0d7a1	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
13	Transmittal Letter	FR2009-121USCNT_20141104_SUPP_IDSL.pdf	114093 7afe0d710ef97ba966f27d94364c48b0d6bba0c9	no	2
Warnings:					
Information:					
14	Request for Continued Examination (RCE)	FR2009-121USCNT_20141104_RCE_USE_THIS_ONE.pdf	1208762 ecf761568c1702a19a7102d1a9e522aeb8634d0d	no	3
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
15	Miscellaneous Incoming Letter	FR2009-121USCNT_20141104_COT.pdf	112774 4ad1100b772b2953f14266fa67814a7561747573	no	1
Warnings:					
Information:					
16	Fee Worksheet (SB06)	fee-info.pdf	30345 678b64a46fbb67a5a49b628fcaf8d3a2bfbcad80	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	12721622	

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.

Please type a plus sign (+) inside this box → ☑

PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
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.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2011/0177970		CHAUCHEREAU, et al.	07-21-2011	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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

[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box → ☑

PTO/SB/08B (10-96)
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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		BERTOLD, et al., Docetaxel Plus Prednisone or Mitoxantrone Plus Prednisone for Advanced Prostate Cancer: Updated Survival in the TAX 327 Study, Journal of Clinical Oncology, Vol. 26, No. 2, (2008), pp. 242-245.	
		Merck Index 14th 2006, No. 190, p.35, Agomelatine.	
		TAN, Novel Agents in the Treatment of Hormone-Independent Metastatic Prostate Cancer, Actas Urol Esp., (2007), Vol. 31, No. 6, pp. 680-685 (followed by non-verified English translation).	
		El Docetaxel Asociado a la Prednisona Mejora el Cancer de Prostata, [Retrieved from the internet on October 26, 2012]. Retrieved from http://www.medicinageriatrica.com.ar/viewnews.php?id=EEpVVFZVppsBCjOavj.	
		DRES, et al., Treatment alternatives for advanced prostate cancer, [Retrieved from the internet on July 29, 2014]. Retrieved from http://www.intramed.net/contenidover.asp?contenidoID=37957 (followed by non-verified English translation).	
		Taxotere (Docetaxel) Mejora Significativamente la Supervivencia de los Pacientes con Cancer de Prostata Avanzado, PMFARMA Espana, (2007)	
		Docetaxel Reduce el Riesgo de Muerte en Pacientes con Cancer de Prostata Metastatico Androgeno Independiente, [Retrieved from the internet on July 29, 2014]. Retrieved from http://www.intramed.net/contenidover.asp?contenidoID=31823 (followed by non-verified English translation).	
		Cancer de Prostata Diseminado, Quimioterapia, [Retrieved from the internet on July 29, 2014]. Retrieved from http://www.guiasalud.es/egpc/cancer_prostata/resumida/apartado06/otros02.html, pp.1-9.	
		Revision Sistematica y Modelo Economico de Efectividad Clinica y Coste-Efectividad de Docetaxel en Combinacion con Prednisona/Prednisolona para el Tratamiento de Cancer de Prostata Metastasico Refractario a Hormonas, [Retrieved from the internet on July 29,2014]. Retrieved from http://www.sefh.es/sefhboletin/vernoticiaboletin.php?id=2663.	
		FIGG, et al., Cabazitaxel Filling One of the Gaps in the Treatment of Prostate Cancer, Cancer Biology & Therapy, Vol. 10, No. 12, pp. 1233-1234, (2010)	

Examiner Signature		Date Considered	

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

[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☑

PTO/SB/08B (10-96)
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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.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 3

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		MIRTSCHING, Prostate Cancer Clinical Trials in Dallas, Texas Area, [Retrieved from the internet on August 19, 2014], Retrieved from http://www.healthcentral.com/prostate/c/5618/14589/dallas-texas-area, pp.3-4	

Examiner Signature		Date Considered	

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

[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of **GUPTA, et al.**		Examiner:	**James D. Anderson**
		Art Unit:	**1629**
Application No.:	**13/456,720**		
Filed:	**April 26, 2012**	Conf. No.	**1083**
Title:	**NOVEL ANTITUMORAL USE OF CABAZITAXEL**		

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

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.56

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicant's duty of disclosure pursuant to 37 C.F.R. §1.56.

The submission of the document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any right to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 C.F.R. §1.97(b), as the submission is before the mailing of a first Office Action after the filing of request for continued examination under §1.114.

A concise explanation of the relevance of some or all of the items listed on the attached Form PTO/SB/08 is as follows:

Listed reference Tan is in a non-English language. A non-verified English translation is attached thereto.

Listed reference "El Docetaxel Asociado a la Prednisona Mejora el Cancer deProstata" is in a non-English language. This document relates to the treatment of prostate cancer with docetaxel in combination with prednisone.

Listed reference Dres, et al. is in a non-English language. A non-verified English translation is attached thereto.

Listed reference "Taxotere (Docetaxel) Mejora Significativamente la Supervivencia de los Pacientes con Cancer de Prostata Avanzado" is in a non-English language. This document relates to the treatment of prostate cancer with docetaxel in combination with prednisone.

Listed reference "Docetaxel Reduce el Riesgo de Muerte en Pacientes con Cancer de Prostata Metastatico Androgeno Independiente" is in a non-English language. A non-verified English translation is attached thereto.

Listed reference "Cancer de Prostata Diseminado" is in a non-English language. This document relates to the treatment of prostate cancer with, for example, docetaxel.

Listed reference "Revision Sistematica y Modelo Economico de Efectividad Clinica y Coste-Efectividad de Docetaxel en Combinacion con Prednisona/Prednisolona para el Tratamiento de Cancer de Prostata Metastasico Refractario a Hormonas" is in a non-English language. This document relates to the treatment of prostate cancer with docetaxel in combination with prednisone.

Listed reference Figg et al. is being resubmitted in order to correct an error in the Information Disclosure Statement filed April 24, 2014, wherein the year of said reference was inadvertently omitted.

The Director is authorized to charge any fees required by this paper or credit any overpayment to Account No. **18-1982**.

Respectfully submitted,

/Kelly L. Bender/
Kelly Bender, Reg. No. 52,610
Attorney/Agent for Applicant

Sanofi US
U.S. Patent Operations
55 Corporate Drive
Mail Code: 55A-505A
Bridgewater, New Jersey 08807
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Telephone: (908) 981-**6782**
Telefax: (908) 981-7830
Sanofi US Ref. FR2009/121 US CNT

Date: November 4, 2014

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

5487 7590 08/04/2014

ANDREA Q. RYAN
SANOFI
55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

EXAMINER
ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 08/04/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/456,720	04/26/2012	Sunil GUPTA	FR2009/121 US CNT	1083

TITLE OF INVENTION: NOVEL ANTITUMORAL USE OF CABAZITAXEL

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	11/04/2014

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)

5487 7590 08/04/2014
ANDREA Q. RYAN
SANOFI
55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

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.
13/456,720	04/26/2012	Sunil GUPTA	FR2009/121 US CNT	1083

TITLE OF INVENTION: NOVEL ANTITUMORAL USE OF CABAZITAXEL

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	11/04/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
ANDERSON, JAMES D	1629	514-449000

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.
13/456,720	04/26/2012	Sunil GUPTA	FR2009/121 US CNT	1083

5487 7590 08/04/2014

ANDREA Q. RYAN
SANOFI
55 Corporate Drive
MAIL CODE: 55A-505A
BRIDGEWATER, NJ 08807

EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1629	

DATE MAILED: 08/04/2014

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. 13/456,720	Applicant(s) GUPTA, SUNIL	
	Examiner JAMES D. ANDERSON	Art Unit 1629	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 *Amendments filed 7/16/2014*.
   ☐ 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 *1,4,6-10,13-17,19,24,34,35 and 37-50*. 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 See Continuation Sheet
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 _____.

/JAMES D ANDERSON/
Primary Examiner, Art Unit 1629

Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 4/28/2014 and 7/16/2014.

Information Disclosure Statement

The information disclosure statements (IDSs) submitted on 4/28/2014 and 7/16/2014 were filed after the mailing date of the Non-Final Office Action on 4/16/2014. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. Please refer to the attached annotated and signed USPTO Form 1449s.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The examiner is persuaded by Applicants' arguments and factual evidence that it is surprising and unexpected that the claimed combination of cabazitaxel and a corticoid are clinically effective in the treatment of prostate cancer that has progressed during or after treatment with docetaxel. Specifically, the 37 CFR 1.132 Declaration of Dr. Sartor filed 7/16/2014 provides convincing evidence that while the art was full of promising early clinical results, these failed to predict whether therapies would ultimately provide a clinically meaningful benefit to the desired patient populations and that mCRPC was known to be a particularly challenging and unpredictable indication.

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."

Conclusion

Claims 1, 4, 6-10, 13-17, 19, 24, 34, 35, and 37-50 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST (Telework Mondays and Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached on 571-272-5541. 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.

/JAMES D ANDERSON/
Primary Examiner, Art Unit 1629

July 28, 2014

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L1 1 CABAZITAXEL/CN

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L1 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2014 ACS on STN
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ED Entered STN: 14 Nov 1996
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OTHER CA INDEX NAMES:
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2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-
4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-
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CN **Cabazitaxel**
CN Jevtana
CN TXD 258
CN XRP 6258
FS STEREOSEARCH
DR 890654-44-1
MF C45 H57 N O14
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SR CA
LC STN Files: ADISINSIGHT, BIOSIS, CA, CAPLUS, CASREACT, CBNB, CHEMCATS, CHEMLIST, EMBASE, IMSPATENTS, IMSRESEARCH, IPA, TOXCENTER, USAN, USPAT2, USPATFULL

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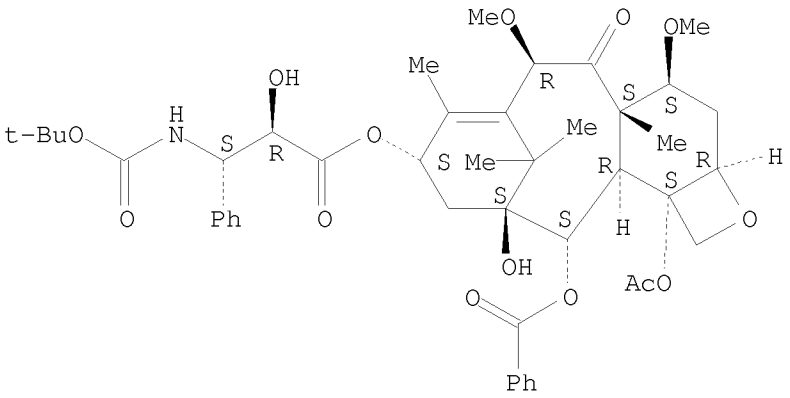

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HCAplus includes complete International Patent Classification (IPC)
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 FILE LAST UPDATED: 27 Jul 2014 (20140727/UP).  FILE COVERS 1946 TO DATE.

 MEDLINE(R) is a registered trademark of the U.S. National Library of
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 Effective June 2014, MEDLINE is now updated daily - seven days
 per week.  Alerts running on a frequency of Every Update will now
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 The 2014 MEDLINE reload was completed on January 26, 2014.
 See HELP RLOAD for details on new search capabilities introduced
 with the reload.

 This file contains CAS Registry Numbers for easy and accurate
 substance identification.

 See HELP RANGE before carrying out any RANGE search.



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COST IN U.S. DOLLARS                            SINCE FILE      TOTAL
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USE IS SUBJECT TO THE TERMS OF YOUR STN CUSTOMER AGREEMENT.
PLEASE SEE "HELP USAGETERMS" FOR DETAILS.
COPYRIGHT (C) 2014 AMERICAN CHEMICAL SOCIETY (ACS)

FILE 'MEDLINE' ENTERED AT 13:46:20 ON 28 JUL 2014
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L11            6 DUP REM L8 L10 (0 DUPLICATES REMOVED)

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L11  ANSWER 1 OF 6     MEDLINE ®  on STN
ACCESSION NUMBER:   2008503223     MEDLINE
DOCUMENT NUMBER:    PubMed ID: 18685415
TITLE:              Systemic therapy after first-line docetaxel in metastatic
                    castration-resistant prostate cancer.
```

AUTHOR: Beardsley Emma K
CORPORATE SOURCE: BC Cancer Agency, Vancouver, Canada.
AUTHOR: Chi Kim N
SOURCE: Current opinion in supportive and palliative care, **(2008 Sep)** Vol. 2, No. 3, pp. 161-6. Ref: 31
Journal code: 101297402. E-ISSN: 1751-4266. L-ISSN: 1751-4258.
DIGITAL OBJECT ID: 10.1097/SPC.0b013e32830c48a3
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
General Review; (REVIEW)
LANGUAGE: English
FILE SEGMENT: MEDLINE; Priority Journals
FILE SEGMENT: Print
ENTRY MONTH: 200810
ENTRY DATE: Entered STN: 8 Aug 2008
Last Updated on STN: 21 Oct 2008
Entered Medline: 20 Oct 2008
OS.CITING REF COUNT: 4 There are 4 MEDLINE records that cite this record
REFERENCE COUNT: 31 There are 31 cited references for this document.
AB PURPOSE OF REVIEW: There is an urgent need for systemic treatment options for patients with castration-resistant **prostate** cancer who have progressed after receiving first-line docetaxel chemotherapy. The purpose of this article is to review recent developments in this area.

RECENT FINDINGS: Retreatment with docetaxel has been employed with evidence of activity in selected populations. Mitoxantrone, the previous first-line standard based on its palliative effect, has also been used with clinical responses observed; however, the symptom benefit in this setting has not been established. Several classes of cytotoxic agents have been tested including platinum agents (satraplatin), epothilones (ixabepilone and patupilone) and taxanes (**XRP-6258**). A number of targeted therapies have also been clinically evaluated including inhibitors of cytoprotective chaperones (OGX-011) and the vascular endothelial growth factor receptor (sorafenib, sunitinib, and cediranib). An area generating great interest has been the development of agents that target the androgen receptor axis more effectively (MDV3100 and abiraterone) with encouraging early phase trial results.

SUMMARY: There is no accepted standard systemic treatment for patients with castration resistant **prostate** cancer and progressive disease after docetaxel. Novel agents are in phase II and III clinical testing in this setting.

L11 ANSWER 2 OF 6 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2007:619578 HCAPLUS
DOCUMENT NUMBER: 147:46112
TITLE: Treatment of cancer and other diseases
INVENTOR(S): Habib, Nabil
PATENT ASSIGNEE(S): Nabil Habib Lab, Lebanon; Vianova Labs, Inc.
SOURCE: PCT Int. Appl., 86pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2007064691	A1	20070607	WO 2006-US45665	20061130 <--

W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, 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, LV, LY, MA, MD, MG, MK,
MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO,
RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT,
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RW: AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE,
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CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, BW, GH,
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CA 2632903	A1	20070607	CA 2006-2632903		20061130 <--
EP 1968607	A1	20080917	EP 2006-844623		20061130 <--
EP 1968607	B1	20140115			
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US 20090226431	A1	20090910	US 2009-85892		20090306 <--
US 8293726	B2	20121023			
PRIORITY APPLN. INFO.:			US 2005-60741725	P	20051202 <--
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ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
OTHER SOURCE(S): MARPAT 147:46112
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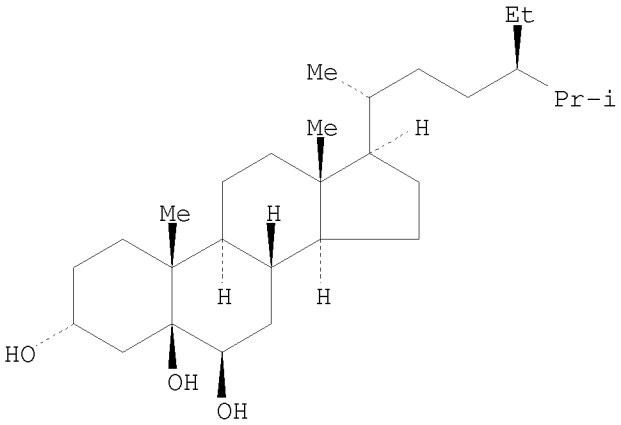


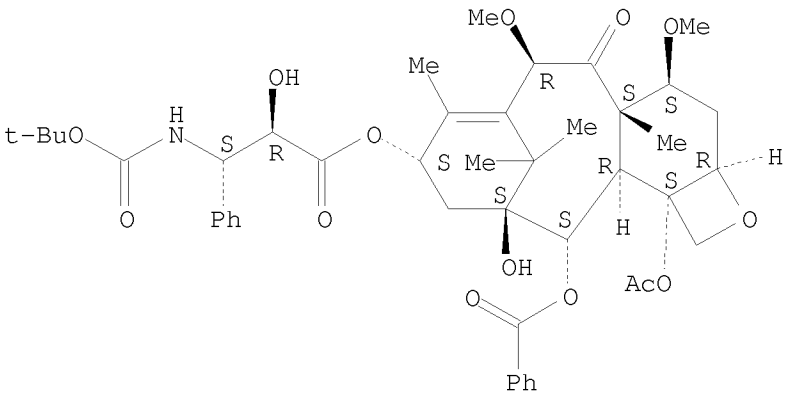
AB The present invention relates to a novel compound (e.g., 24-ethyl-cholestane-3β,5α,6α-triol), its production, its use, and to methods of treating neoplasms and other tumors as well as other diseases including hypercholesterolemia, autoimmune diseases, viral diseases (e.g., hepatitis B, hepatitis C, or HIV), and diabetes.

IT **183133-96-2, TXD 258**
RL: **PAC (Pharmacological activity); THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(**treatment** of cancer and other diseases using ethylcholestane triol and combination with other agents)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 1 THERE ARE 1 CAPLUS RECORDS THAT CITE THIS RECORD (1 CITINGS)
REFERENCE COUNT: 2 THERE ARE 2 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L11 ANSWER 3 OF 6 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2005:1290072 HCAPLUS
DOCUMENT NUMBER: 144:46998
TITLE: The x-ray crystal structure of BRCA1 tandem BRCT repeat and BACH1 phosphopeptide complex and methods and compositions for antitumor drug design
INVENTOR(S): Yaffe, Michael B.; Clapperton, Julie A.; Manke, Isaac A.; Lowery, Drew M.; Ho, Timmy; Haire, Lesley F.; Smerdon, Stephen J.
PATENT ASSIGNEE(S): Massachusetts Institute of Technology, USA
SOURCE: PCT Int. Appl., 360 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2005115454	A2	20051208	WO 2005-US15981	20050509 <--
WO 2005115454	A3	20071115		
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RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG, AP, EA, EP, OA				
AU 2005247346	A1	20051208	AU 2005-247346	20050509 <--
CA 2569003	A1	20051208	CA 2005-2569003	20050509 <--
EP 1773389	A2	20070418	EP 2005-780060	20050509 <--
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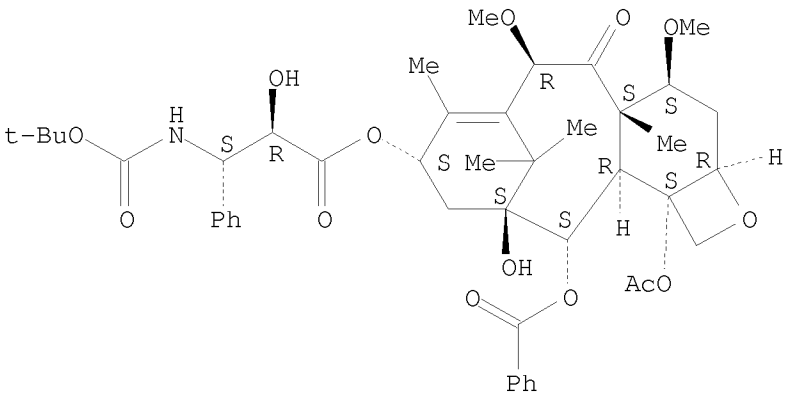
JP 2007537164	T	20071220	JP 2007-511664	20050509 <--
US 20090143997	A1	20090604	US 2008-229740	20080826 <--

US 20120295802 A1 20121122 US 2012-13451209 20120419 <--
PRIORITY APPLN. INFO.: US 2004-60569131 P 20040507 <--
US 2005-126022 A3 20050509 <--
WO 2005-US15981 W 20050509 <--
US 2008-229740 A1 20080826 <--
ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT
AB The present invention relates to compds. (e.g., peptidomimetics and non-peptides) that treat, prevent or stabilize cellular proliferative disorders and methods of treating, preventing, or stabilizing such disorders. The invention also provides three-dimensional structures of a BRCT domain-BACH1 phosphopeptide complex.
IT **183133-96-2, TXD 258**
RL: BSU (Biological study, unclassified); **THU (Therapeutic use);** BIOL (Biological study); USES (Uses)
(x-ray crystal structure of BRCA1 tandem BRCT repeat and BACH1 phosphopeptide complex and methods and compns. for antitumor **drug** design)
RN 183133-96-2 HCAPLUS
CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



L11 ANSWER 4 OF 6 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2005:409543 HCAPLUS
DOCUMENT NUMBER: 142:457053
TITLE: Human protein IAP (inhibitor of apoptosis protein) nucleobase oligomers, including dsRNA, shRNA, and siRNA, and their use for enhancing apoptosis in cancer therapy
INVENTOR(S): Lacasse, Eric; McManus, Daniel
PATENT ASSIGNEE(S): Aegera Therapeutics, Inc., Can.
SOURCE: PCT Int. Appl., 112 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE

WO 2005042558 A1 20050512 WO 2004-CA1902 20041029 <--
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RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG
US 20050148535 A1 20050707 US 2004-975974 20041028 <--
CA 2542904 A1 20050512 CA 2004-2542904 20041029 <--
EP 1682565 A1 20060726 EP 2004-789809 20041029 <--
R: DE, FR, GB
JP 2007510408 T 20070426 JP 2006-537024 20041029 <--
PRIORITY APPLN. INFO.: US 2003-60516192 P 20031030 <--
WO 2004-CA1902 W 20041029 <--

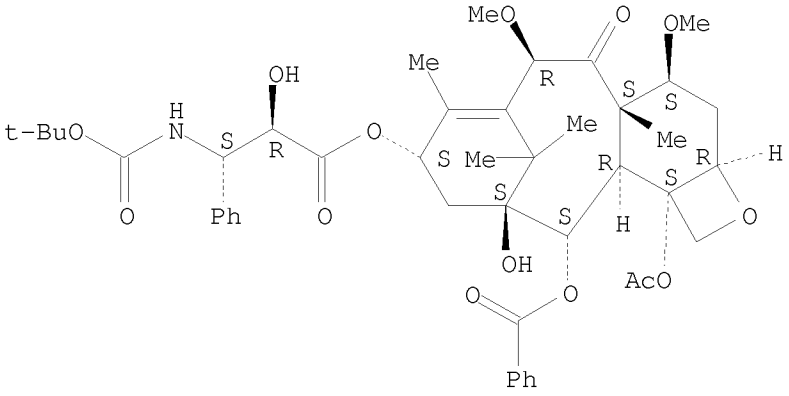
AB The invention provides nucleobase oligomers and oligonucleotide duplexes that inhibit expression of an IAP (inhibitor of apoptosis protein), and methods for using them to induce apoptosis in a cell. Specifically, the invention provides nucleic acid sequences for siRNAs and shRNAs that target human XIAP, HIAP-1 or HIAP-2 genes. The nucleobase oligomers and oligomer complexes of the present invention may also be used to form pharmaceutical compns. The invention also features methods for enhancing apoptosis in a cell by administering a nucleobase oligomer or oligomer complex of the invention in combination with a chemotherapeutic or chemosensitizing agent. RNAi sequences and vectors producing shRNA (short hairpin RNA) were transfected into HeLa cells and evaluated for their effect on XIAP, cIAP-1, or cIAP-2 protein levels. XIAP protein could also be reduced by RNAi clones in transfected breast cancer cell line MDA-MB-231. In addition, cell survival was reduced in XIAP RNAi transfected breast cancer cell line after the transfected cells were treated with TRAIL (tumor necrosis factor-related apoptosis inducing ligand).

IT **183133-96-2, TXD 258**
RL: **THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(human protein IAP (inhibitor of apoptosis protein) nucleobase oligomers, including dsRNA, shRNA, and siRNA, and their use for enhancing apoptosis in cancer **therapy**)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 1 THERE ARE 1 CAPLUS RECORDS THAT CITE THIS RECORD (1 CITINGS)
REFERENCE COUNT: 5 THERE ARE 5 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L11 ANSWER 5 OF 6 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2005:409357 HCAPLUS
DOCUMENT NUMBER: 142:457052
TITLE: Sequences of antisense IAP (inhibitor of apoptosis protein) oligomers and their use for treatment of proliferative diseases with a chemotherapeutic agent
INVENTOR(S): Lacasse, Eric; McManus, Daniel; Durkin, Jon P.
PATENT ASSIGNEE(S): Aegera Therapeutics, Inc., Can.
SOURCE: PCT Int. Appl., 285 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 1
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2005042030	A1	20050512	WO 2004-CA1900	20041029 <--
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US 8012944	B2	20110906		
AU 2004284855	A1	20050512	AU 2004-284855	20041029 <--
CA 2542884	A1	20050512	CA 2004-2542884	20041029 <--
EP 1691842	A1	20060823	EP 2004-789807	20041029 <--
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CN 1901939	A	20070124	CN 2004-80039601	20041029 <--
JP 2007509861	T	20070419	JP 2006-537023	20041029 <--
ZA 2006003399	A	20070926	ZA 2006-3399	20041029 <--

NZ 547191	A	20090828	NZ 2004-547191		20041029 <--
RU 2376018	C2	20091220	RU 2006-117024		20041029 <--
SG 157422	A1	20091229	SG 2009-7918		20041029 <--
CN 101862459	A	20101020	CN 2010-10218334		20041029 <--
TW I332841	B	20101111	TW 2004-132984		20041029 <--
IL 175242	A	20130530	IL 2004-175242		20041029 <--
MX 2006004920	A	20070216	MX 2006-4920		20060502 <--
IN 2006MN00614	A	20070420	IN 2006-MN614		20060526 <--
NO 2006002420	A	20060731	NO 2006-2420		20060529 <--
KR 2006127393	A	20061212	KR 2006-7010619		20060530 <--
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			CN 2004-80039601	A3	20041029 <--
			WO 2004-CA1900	W	20041029 <--

ASSIGNMENT HISTORY FOR US PATENT AVAILABLE IN LSUS DISPLAY FORMAT

AB The invention claims the use of an antisense oligomer to human XIAP, IAP-1 or IAP-2 genes and a chemotherapeutic agent, and compns. and kits thereof, for the treatment of proliferative diseases. The invention further claims sequences for nucleobase oligomers that are antisense IAP (inhibitor of apoptosis protein) oligomers. The antisense IAP nucleobase oligomers specifically hybridize with polynucleotides encoding an IAP and reduce the amount of an IAP protein produced in a cell. Thus by reducing the IAP protein, the invention provides methods for inducing cancer cells to undergo apoptosis and for overriding anti-apoptotic signals in cancer cells. As an example of the invention, mice with s.c. H460 human lung carcinoma xenografts were injected intratumorally with XIAP antisense mixed-base 2'-O-Me RNA oligonucleotides (C5 and/or G4) and the drug vinorelbine. At the end of the 24 d treatment period, the mean relative tumor growth was reduced .apprx.70% in treated mice. The inhibition of tumor growth was correlated with down-regulation of human XIAP protein expression and an increased number of dead cells. The mice did not show any signs of cytotoxicity such as body weight loss.

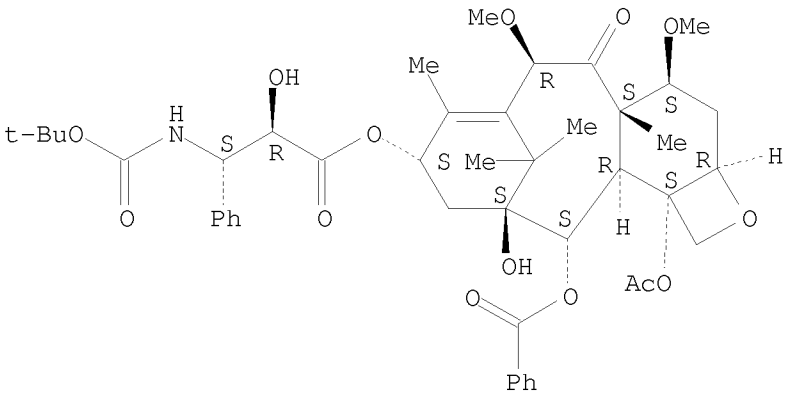
IT **183133-96-2, TXD 258**

RL: **THU (Therapeutic use)**; BIOL (Biological study); USES (Uses) (sequences of antisense IAP (inhibitor of apoptosis protein) oligomers and their use for **treatment** of proliferative diseases with **chemotherapeutic** agent)

RN 183133-96-2 HCAPLUS

CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 4 THERE ARE 4 CAPLUS RECORDS THAT CITE THIS RECORD (7 CITINGS)
REFERENCE COUNT: 6 THERE ARE 6 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

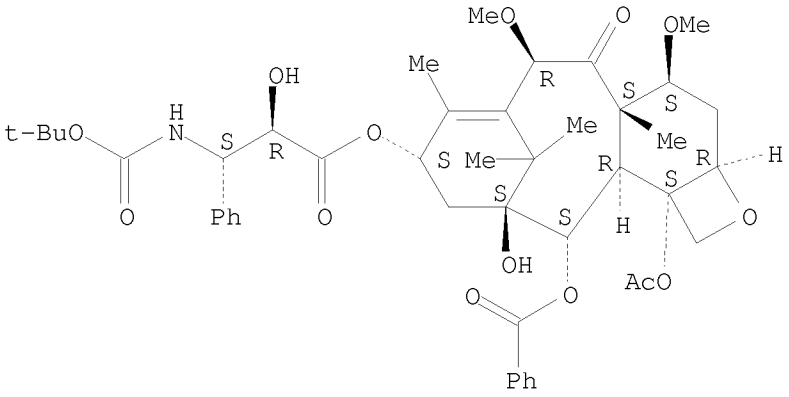
L11 ANSWER 6 OF 6 HCAPLUS COPYRIGHT 2014 ACS on STN
ACCESSION NUMBER: 2005:283298 HCAPLUS
DOCUMENT NUMBER: 142:349042
TITLE: Combinations of chlorpromazine compounds and antiproliferative drugs for the treatment of neoplasms
INVENTOR(S): Lee, Margaret S.; Nichols, James M.; Zhang, Yanzhen; Keith, Curtis
PATENT ASSIGNEE(S): Combinatorx, Incorporated, USA
SOURCE: PCT Int. Appl., 65 pp.
CODEN: PIXXD2
DOCUMENT TYPE: Patent
LANGUAGE: English
FAMILY ACC. NUM. COUNT: 7
PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.		DATE
WO 2005027842	A2	20050331	WO 2004-US30368		20040916 <--
WO 2005027842	A3	20051222			
W: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW					
RW: BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR, BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG					
AU 2004273910	A1	20050331	AU 2004-273910		20040916 <--
CA 2538570	A1	20050331	CA 2004-2538570		20040916 <--
EP 1670477	A2	20060621	EP 2004-788798		20040916 <--
R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, RO, MK, CY, AL, TR, BG, CZ, EE, HU, PL, SK, HR					
BR 2004014568	A	20061107	BR 2004-14568		20040916 <--
CN 1878556	A	20061213	CN 2004-80033294		20040916 <--
JP 2007505914	T	20070315	JP 2006-527024		20040916 <--
MX 2006003066	A	20060620	MX 2006-3066		20060317 <--
NO 2006001325	A	20060606	NO 2006-1325		20060323 <--
KR 2007012618	A	20070126	KR 2006-7007244		20060414 <--
PRIORITY APPLN. INFO.:			US 2003-60504310	P	20030918 <--
			WO 2004-US30368	W	20040916 <--

OTHER SOURCE(S): MARPAT 142:349042
AB The invention discloses a method for treating a patient having a cancer or other neoplasm by administering chlorpromazine or a chlorpromazine analog and an antiproliferative agent simultaneously or within 14 days of each other in amts. sufficient to treat the patient.
IT **183133-96-2, TXD 258**
RL: **PAC (Pharmacological activity); THU (Therapeutic use)**; BIOL (Biological study); USES (Uses)
(chlorpromazine compound-antiproliferative **drug** antitumor combination)
RN 183133-96-2 HCAPLUS
CN Benzenepropanoic acid, β-[[(1,1-dimethylethoxy)carbonyl]amino]-α-hydroxy-, (2aR,4S,4aS,6R,9S,11S,12S,12aR,12bS)-12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-11-hydroxy-4,6-

dimethoxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester, (αR,βS)- (CA INDEX NAME)

Absolute stereochemistry. Rotation (-).



OS.CITING REF COUNT: 5 THERE ARE 5 CAPLUS RECORDS THAT CITE THIS RECORD (7 CITINGS)

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(FILE 'HOME' ENTERED AT 13:41:22 ON 28 JUL 2014)

FILE 'REGISTRY' ENTERED AT 13:41:31 ON 28 JUL 2014
L1 1 S CABAZITAXEL/CN
L2 29 S 183133-96-2/CRN
L3 30 S L1 OR L2
SELECT CHEM L3 1-
L4 QUE E1-E40

FILE 'HCAPLUS' ENTERED AT 13:43:17 ON 28 JUL 2014
DEL SEL Y
L5 354 S L4(L)((PAC OR PKT OR DMA OR BAC OR THU)/RL OR (TREAT? OR CURE
L6 27 S L5 AND (AD<20091029 OR PD<20091029 OR PRD<20091029)
L7 9 S L6 AND PROSTATE
L8 5 S L7 AND (CORTICOID OR PREDNISONE OR PREDNISOLONE)

FILE 'MEDLINE' ENTERED AT 13:45:47 ON 28 JUL 2014
DEL SEL Y
L9 296 S L4 AND PROSTATE/TI,AB
L10 1 S L9 AND PY<2010

FILE 'HCAPLUS, MEDLINE' ENTERED AT 13:46:20 ON 28 JUL 2014
L11 6 DUP REM L8 L10 (0 DUPLICATES REMOVED)

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=>
Executing the logoff script...

=> LOG Y

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FULL ESTIMATED COST	36.75	75.05

STN INTERNATIONAL LOGOFF AT 13:47:18 ON 28 JUL 2014

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Antonarakis & Eisenberger, Phase III Trials with Docetaxel-Based Combinations for Metastatic Castration-Resistant Prostate Cancer: Time to Learn From Past Experiences, 31(14) J. Clin. Oncol., 1709-12 (2013)	
		Armstrong & George, New Drug Development in Metastatic Prostate Cancer, Urologic Oncol. Seminars & Orig. Invest., 430-437 (2008)	
		~~Beardsley et al., Systemic Therapy After First Line Docetaxel in Metastatic Castration Resistant Prostate Cancer, 2 Current Opinion in Supportive & Palliative Care, 161-166 (2008) (previously cited)~~ ALREADY OF RECORD (Cited by the Examiner)	
		Beer et al., Double-Blinded Randomized Study of High-Dose Calcitriol Plus Docetaxel compared with Placebo Plus Docetaxel in Androgen-Independent Prostate Cancer: A Report from the ASCENT Investigators, 25(6) J. Clin. Oncol., 669-674 (2007)	
		Berry et al., Phase III Study of Mitoxantrone Plus Low Dose Prednisone Versus Low Dose Prednisone Alone in Patients with Asymptomatic Hormone Refractory Prostate Cancer, 168(6) J. Urol., 2439-43 (2002)	
		Booth et al., From the Analyst's Couch: Oncology Trials, 2 Nature Reviews Drug Discovery, 609-610 (August 2003)	
		Cabral, Factors Determining Cellular Mechanisms of Resistance to Antimitotic Drugs, 4 Drug Resistance Updates, 3-8 (2001)	
		Carducci et al., A Phase 3 Randomized Controlled Trial of the Efficacy and Safety of Atrasentan in Men with Metastatic Hormone-Refractory Prostate Cancer, 110(9) Cancer, 1959-66 (2007)	
		D'Amico, US Food and Drug Administration Approval of Drugs for the Treatment of Prostate Cancer: A New Era Has Begun, J. Clin. Oncol., 32(4) 362-364 (2014)	
		Di Lorenzo et al., Combination of Bevacizumab and Docetaxel in Docetaxel-Pretreated Hormone-Refractory Prostate Cancer: A Phase 2 Study, 54(5) Europ. Urol., 1089-1096 (2008)	

Examiner Signature		Date Considered	

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

[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 5

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Diéras et al., Larotaxel in Combination with Trastuzumab in Patients with HER2+ Metastatic Breast Cancer: Interim Analysis of an Open Phase II Label Study, 26 (15S) J. Clin. Oncol. (Meeting Abstracts) Suppl. 1070 (May 2008)	
		Diéras et al., Phase II Multicenter Study of Larotaxel (XRP9881), a Novel Taxoid, in Patients with Metastatic Breast Cancer Who Previously Received Taxane-Based Therapy, 19 Annals of Oncol., 1255-1260 (2008)	
		Dumontet & Sikic, Mechanisms of Action of and Resistance to Antitubulin Agents: Microtubule Dynamics, Drug Transport, and Cell Death, 17(3) J. Clin. Oncol., 1061-1070 (1999)	
		Halabi et al., Prostate-Specific Antigen Changes as Surrogate for Overall Survival in Men with Metastatic Castration-Resistant Prostate Cancer Treated with Second Line Therapy, 31(31) J. Clin. Oncol., 3944-50 (2013)	
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		Kaur et al., Suramin's Development: What Did We Learn, 20 Investigational New Drugs, 209-219 (2002)	
		Kola & Landis, Can the Pharmaceutical Industry Reduce Attrition Rate?, 3 Nature Reviews Drug Discovery, 711-15 (2004) (previously cited)	
		Mackinnon et al., Molecular Biology Underlying the Clinical Heterogeneity of Prostate Cancer: An Update, 133 (7) Arch. Pathol. Lab. Med., 1033-40 (July 2009)	
		Michaelson et al., Randomized, Placebo-Controlled, Phase III Trial of Sunitinib Plus Prednisone Versus Prednisone Alone in Progressive, Metastatic, Castration-Resistant Prostate Cancer, 32(2) J. Clin. Oncol., 76-82 (2014)	
		~~Mita et al., Phase I and Pharmacokinetic Study of XRP9881 (RPR 116258A), a Novel Taxane, Administered as a 1-Hour Infusion Every 3 Weeks in Patients with Advanced Solid Tumors, 15(2) Clinical Cancer Research, 723-30 (2009) (previously cited)~~ ALREADY OF RECORD (Cited by the Examiner)	

Examiner Signature		Date Considered	

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Sheet 3 of 5

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Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Mulcahy, Phase 3 Trial of Immunotherapy for Metastatic Prostate Cancer Terminated, Medscape Medical News (October 17, 2009), [retrieved on June 26, 2014] from: http://www.medscape.com/viewarticle/582220	
		Ramiah et al., Clinical Endpoints for Drug Development in Prostate Cancer, 18 Curr. Opin. Urol., 303-308 (2008)	
		Slovin et al., Ipilimumab Alone or in Combination with Radiotherapy in Metastatic Castration-Resistant Prostate Cancer: Results from an Open-Label, Multicenter Phase I/II Study, 24 Annals of Oncol., 1813-1828 (2013)	
		Small et al., Randomized Phase II Study Comparing 4 Monthly Doses of Ipilimumab (MDX-010) as a Single Agent or in Combination with a Single Dose of Docetaxel in Patients with Hormone-Refractory Prostate Cancer, 24(18S) J. Clin. Oncol. (Meeting Abstracts) S4609 (June 2006)	
		Small et al., Granulocyte Macrophage Colony Stimulating Factor-Secreting Allogeneic Cellular Immunotherapy for Hormone-Refractory Prostate Cancer, 13 Clin. Cancer Res., 3883-3891 (2007)	
		Sternberg et al., Larotaxel with Cisplatin in the First-Line Treatment of Locally Advanced/Metastatic Urothelial Tract or Bladder Cancer: A Randomized, Active-Controlled, Phase III Trial, 85 Oncol., 208-215 (2013)	
		Susman, ASCO: Calcitriol Fails in ASCENT-2 Prostate CA Trial, MedPage Today (June 9, 2010), [retrieved on June 27, 2014] from: http://www.medpagetoday.com/MeetingCoverage/ASCO/20575	
		~~Tannock et al., Docetaxel Plus Prednisone or Mitoxantrone Plus Prednisone for Advanced Prostate Cancer, 351 NEJM, 1502-512 (2004) (previously cited)~~ ALREADY OF RECORD (Cited by the Examiner)	
		Van Cutsem et al., A Phase III Study Comparing Larotaxel to 5-FU (Continuous Intravenous 5-FU or Capecitabine) in Patients with Advanced Pancreatic Cancer (APC) Previously Treated with a Gemcitabine Containing Regimen, 21(6S) Annals of Oncol. Oral Presentations, O-0007 (July 2010)	
		Van Hook et al., Orteronel for the Treatment of Prostate Cancer, 10(5) Future Oncol., 803-811 (2014)	

Examiner Signature		Date Considered	

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Sheet 4 of 5

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Wiechec & Hanson, The Effect of Genetic Variability on Drug response in Convention Breast Cancer Treatment, 625 Eur. J. Pharmacol., 122-130 (2009)	
		Williams, Discontinued Drugs in 2008: Oncology Drugs, 18(11) Expert. Opin. Investig. Drugs 1581-1594 (2009)	
		Wirth & Froschermaier, The Antiandrogen Withdrawal Syndrome, 25 (Suppl. 2) Urol. Res., S67-71 (1997)	
		Zatloukal et al., Randomized Multicenter Phase II Study of Larotaxel (XRP9881) in Combination with Cisplatin or Gemcitabine as First-Line Chemotherapy in Nonirradiable Stage IIIB or Stage IV Non-Small Cell Lung Cancer, 3 J. Thorac. Oncol. 894-901 (2008)	
		Zielinski & Chi, Custirsen (OGX-011): A Second-Generation Antisense Inhibitor of Clusterin in Development for the Treatment of Prostate Cancer, 8(1) Future Oncol., 1239-1251 (2012)	
		Novacea, Inc. SEC Form 8-K at 1.02, (2008) [retrieved on June 27, 2014] from: http://www.sec.gov/Archives/edgar/data/1178711/000119312508077953/d8k.htm	
		Sanofi-Aventis SEC Form 20-F (Dec. 31, 2006) at 39, [retrieved on June 27, 2014] from: http://www.sec.gov/Archives/edgar/data/1121404/000119312507072848/d20f.htm	
		Avastin (bevacizumab), Prescribing Information (Label) July 2009	
		Yervoy (ipilimumab), Prescribing Information (Label), December 2013	
		A Randomized, Open-Label, Phase 3 Study of Larotaxel IV Every 3 Weeks Versus Capecitabine (Xeloda®) Tablets Twice Daily for 2 Weeks in 3-Week Cycles in Patients with Metastatic Breast Cancer (MBC) Progressing After Taxanes and Anthracycline Therapy (EFC6089) (2012), [retrieved on June 27, 2014] from: http://en.sanofi.com/img/content/study/EFC6089_summary.pdf	

Examiner Signature		Date Considered	

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[1] Unique citation designation number. [2] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 5

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		Bristol-Myers Squibb Reports Results for Phase 3 Trial of Yervoy® (Ipilimumab) in Previously-Treated Castration Resistant Prostate Cancer, Press Release September 12, 2013 [retrieved on June 27, 2014] from: http://news.bms.com/press-release/rd-news/bristol-myers-squibb-reports-results-phase-3-trial-yervoy-ipilimumab-previousl	
		Clinical Trials.gov, Satraplatin in Hormone Refractory Prostate Cancer Patients Previously Treated with one Cytotoxic Chemotherapy Regimen [retrieved on June 27, 2014] from: https://clinicaltrials.gov/ct2/show/NCT00069745?term=SPARC&cond=prostate&rank=3	
		Clinical Trials.gov, Larotaxel every 3 weeks vs. capecitabine in patients with metastatic breast cancer progressing after taxanes and anthracycline therapy [retrieved on June 24, 2014] from: https://clinicaltrials.gov/ct2/show/NCT00081796?term=larotaxel&rank=7	
		Clinical Trials.gov, Larotaxel plus cisplatin vs. gemcitabine plus cisplatin in first line treatment of patients with locally advanced/metastatic bladder cancer [retrieved on June 24, 2014] from: https://clinicaltrials.gov/ct2/show/NCT00625664?term=larotaxel&rank=4	
		Clinical Trials.gov, Larotaxel vs. 5-FU or capecitabine in patients with pancreatic cancer previously treated with gemcitabine [retrieved on June 24, 2014] from: https://clinicaltrials.gov/ct2/show/NCT00417209?term=larotaxel&rank=2	
		Press Release: OncoGenex Announces Top-Line Survival results of Phase 3 SYNERGY Trial Evaluating Custirsen for Metastatic Castration-Resistant Prostate Cancer, PRNewswire April 28, 2014	
		Press Release: Roche Provides Update on Phase III study of Avastin in Men with Late Stage Prostate Cancer, Media Release March 12, 2010 [retrieved on June 27, 2014] from: http://www.roche.com/media/media_releases/med-cor-2010-03-12.htm	
		Press Release: Takeda Announces Termination of Orteronel (TAK-700) Development for Prostate Cancer in Japan, U.S.A. and Europe, June 19, 2014 [retrieved on June 27, 2014] from: http://www.takeda.com/news/2014/20140619_6615.html	
		Jevtana NDA Clinical Overview, excerpt, (2014), pp.12-13	

Examiner Signature	/James Anderson/	Date Considered	07/28/2014

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 6

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		7,772,274		PALEPU	08-10-2010	
		2012/0077845		DALTON, et al.	03-29-2012	
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		2011/0144362		BILLOT, et al.	06-16-2011	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO	2011/063421		WOLFGANG, et al.	05-26-2011		
		WO	94/18164		OJIMA	08-18-1994		
		FR	2732340		BOUCHARD, et al.	10-04-1996		
		WO	96/30356		BOUCHARD, et al.	10-03-1996		
		WO	00/10547		BISSERY, et al.	03-02-2000		
		WO	2006/062811		GRUENEBERG, et al.	06-15-2006		
		WO	2010/117668		ELIASOF, et al.	10-14-2010		
		WO	2010/128258		MAGHERINI	11-11-2010		
		WO	2011/051894		GUPTA	05-05-2011		
		WO	2011/124689		CHAUCHEREAU, et al.	10-13-2011		

Examiner Signature		Date Considered	

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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 6

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		WO	2011/130317		MUTZ, et al.	10-20-2011		
		WO	2011/130566		SLAWIN, et al.	10-20-2011		

Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 6

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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Examiner Signature		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 4 of 6

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		SHABAFROUZ, et al., New Drugs at the Horizon for Men With Prostate Cancer, Revue Medicale Suisse, (2010), Vol. 6, No. 250, pp. 1057-1058 & 1060-1061	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 6

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

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		LORTHOLARY, et al., Phase I and Pharmacokinetics (PK) Study of RPR 116258A Given as 1-hour Infusion in Patients (pts) With Advanced Solid Tumors, Clinical Cancer Research, Vol. 6, (2000), (Supplement), Abstract 569, pp.4579s-4580s	
		OUDARD, et al., Cabazitaxel Plus Prednisone/Prednisolone Significantly Increases Overall Survival Compared to Mitoxantrone Plus Prednisone/Prednisolone in Patients With Metastatic Castration-Resistant Prostate Cancer (MCRPC) Previously Treated With Docetaxel: Final Results With Updated Overall Survival of a Multinational Phase III Trial (TROPIC), Ann. of Oncology, Vol. 21, (Suppl. 8), p. viii272, (2010), Abstract 871PD	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 6

Complete if Known	
Application Number	13/456,720
Filing Date	April 26, 2012
First Named Inventor	GUPTA, et al.
Group Art Unit	1629
Examiner Name	James D. Anderson
Attorney Docket Number	FR2009/121 - US - CNT

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		Sanofi-Aventis Press Release: Sanofi-Aventis Delivers Double-Digit EPS Growth in 2009 as the Transformation Program Progresses, (February 10, 2010), pp. 1-26	
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		Sanofi-Aventis Press Release: Sanofi-Aventis Delivers 2008 Results Above Guidance, (2009), February 11, pp. 1-27	
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		DIMASI, et al., Trends in Risks Associated With New Drug Development: Success Rates for Investigational Drugs, Nature, Vol. 87, No. 3, pp. 272-277, (2010)	

Examiner Signature	/James Anderson/	Date Considered	07/28/2014

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	**Art Unit**
	JAMES D ANDERSON	1629

CPC							
Symbol						**Type**	**Version**
A61K		31	/	337		F	2013-01-01
A61K		31	/	164		I	2013-01-01
A61K		31	/	56		I	2013-01-01
A61K		31	/	573		I	2013-01-01
A61K		45	/	06		I	2013-01-01
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CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
A61K		2300	/	00	A	1	2	2013-01-01
A61K		2300	/	00	A	4	2	2013-01-01
A61K		31	/	573	I	4	1	2013-01-01
A61K		31	/	164	I	1	1	2013-01-01
A61K		2300	/	00	A	2	2	2013-01-01
A61K		31	/	56	I	3	1	2013-01-01
A61K		31	/	337	I	2	1	2013-01-01
A61K		2300	/	00	A	3	2	2013-01-01

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/JAMES D ANDERSON/ Primary Examiner.Art Unit 1629	07/28/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	**Art Unit**
	JAMES D ANDERSON	1629

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION												
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED							
514	449	A	6	1	K	31 / 337 (2006.01.01)								
CROSS REFERENCE(S)		A	6	1	K	31 / 573 (2006.01.01)								
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)													

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/JAMES D ANDERSON/ Primary Examiner.Art Unit 1629	07/28/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	**Art Unit**
	JAMES D ANDERSON	1629

☐ 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	10	17		33	30	49								
	2		18	12	34	21	50								
	3	11	19	13	35										
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6	13		29	24	45										
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8	15		31	26	47										
9	16		32	15	48										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/JAMES D ANDERSON/ Primary Examiner.Art Unit 1629	07/28/2014	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	367	cabazitaxel or XRP6258 or (XRP adj2 "6258")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:33
L2	13	l1 and (@ad<"20091029" or @pd<"20091029")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:34
L3	68	l1 and (cabazitaxel or XRP6258 or (XRP adj2 "6258")).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:34
L4	21	l3 and prostate.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:34
L5	3183	A61K31/337.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35
L6	121	l5 and A61K31/573.cpc.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35
L7	30	l6 and prostate.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35
L8	13	l7 and (@ad<"20091029" or @pd<"20091029")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/07/28 13:35
S1	14	"5847170"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 12:37
S2	102	cabazitaxel	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 12:40
S3	21	cabazitaxel.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 12:40
S4	12	XRP6258	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 12:42

S5	38	((SUNIL) near2 (GUPTA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/11 12:43
S6	4725	Sanofi-aventis.as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:15
S7	38	S6 and taxane	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:15
S8	9	("5229526" | "5319112" | "5486601" | "5739362").PN. OR ("5847170").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/01/11 14:18
S9	4016	"Aventis Pharma".as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:21
S10	67	S9 and taxane	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:21
S11	6	"2005065138"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:31
S12	3	"20050065138"	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/01/11 14:31
S13	11	("20020038038" | "6372780" | "6331635" | "6387946" | "20050065138" | "5438072" | "7241907" | "5847170").PN.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 09:58
S14	39	((SUNIL) near2 (GUPTA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2013/09/10 09:59
S15	39	S14	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 09:59
S16	1	S15 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S17	5090	Sanofi-aventis.as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S18	4061	"Aventis Pharma".as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S19	8681	S17 or S18	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:00
S20	11	S19 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	2013/09/10 10:00

			DERWENT			
S21	197	(cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:01
S22	29	S21 and (@ad<"20101027" or @pd<"20101027")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2013/09/10 10:01
S23	42	((SUNIL) near2 (GUPTA)).INV.	US-PGPUB; USPAT; USOCR	OR	ON	2014/04/10 10:50
S24	42	S23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S25	1	S24 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S26	5421	Sanofi-aventis.as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S27	4073	"Aventis Pharma".as.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S28	9021	S26 or S27	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S29	13	S28 and (cabazitaxel or XRP6258)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S30	13	S25 or S29	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:50
S31	311	(cabazitaxel or XRP6258 or (XRP adj2 "6258"))	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:51
S32	33	S31 and (@ad<"20101027" or @pd<"20101027")	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:51
S33	7	S32 and (cabazitaxel or XRP6258 or (XRP adj2 "6258")).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2014/04/10 10:51

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L9	1028	A61K31/337.cpcc.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:37

L10	37	l9 and A61K31/573.cpcc.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:37
L11	20	l10 and prostate.clm.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:37
L12	2492	514/449.ccls.	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:38
L13	30	l12 and (cabazitaxel or XRP6258 or (XRP adj2 "6258"))	US-PGPUB; USPAT; UPAD	OR	ON	2014/07/28 13:38

7/ 28/ 2014 1:39:39 PM
C:\ Users\ janderson\ Documents\ EAST\ Workspaces\ 13456720.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13456720	GUPTA, SUNIL
	Examiner	Art Unit
	JAMES D ANDERSON	1629

CPC- SEARCHED		
Symbol	Date	Examiner
A61K31/337; A61K31/573	7/28/2014	JDA

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Name Search	1/11/2013	JDA
EAST Search (see attached)	1/11/2013	JDA
STN Structure Search (see attached)	1/11/2013	JDA
Inventor Name Search	9/10/2013	JDA
EAST Search (see attached)	9/10/2013	JDA
STN Structure Search (see attached)	9/10/2013	JDA
Inventor Name Search	4/10/2014	JDA
EAST Search (see attached)	4/10/2014	JDA
Medline NPL Search	4/10/2014	JDA
Inventor Name Search	7/28/2014	JDA
EAST Search (see attached)	7/28/2014	JDA
STN NPL Search	7/28/2014	JDA

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
A61K	31/337; 31/573	7/28/2014	JDA

INTERFERENCE SEARCH			
US Class/ CPC Symbol	**US Subclass / CPC Group**	**Date**	**Examiner**
514	449	7/28/2014	JDA

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BIB DATA SHEET

CONFIRMATION NO. 1083

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/456,720	04/26/2012 RULE	514	1629	FR2009/121 US CNT

APPLICANTS

INVENTORS

Sunil GUPTA, Chester Springs, PA;

**** CONTINUING DATA ***************************

This application is a CON of PCT/IB2010/054866 10/27/2010
which claims benefit of 61/389,969 10/05/2010
and claims benefit of 61/383,933 09/17/2010
and claims benefit of 61/369,929 08/02/2010
and claims benefit of 61/355,888 06/17/2010
and claims benefit of 61/355,834 06/17/2010
and claims benefit of 61/293,903 01/11/2010
and claims benefit of 61/256,160 10/29/2009

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

05/07/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /JAMES D ANDERSON/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		PA	7	33	10

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TITLE

NOVEL ANTITUMORAL USE OF CABAZITAXEL

FILING FEE RECEIVED	FEES: Authority has been given in Paper	☐ All Fees
3910	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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Gupta et al.**	Examiner:	**James ANDERSON**
		Art Unit:	**1629**
Application No.:	**13/456,720**	Conf No.	**1083**
Filed:	**April 26, 2012**		
Title:	**NOVEL ANTITUMORAL USE OF CABAZITAXEL**		

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

REPLY TO OFFICE ACTION PURSUANT TO 37 C.F.R. § 1.111

This paper is in response to the Office Action dated April 16, 2014 (the "Office Action"), having a response due by July 16, 2014. This response is timely filed.

Entry of the following amendments and consideration of the following remarks are respectfully requested.

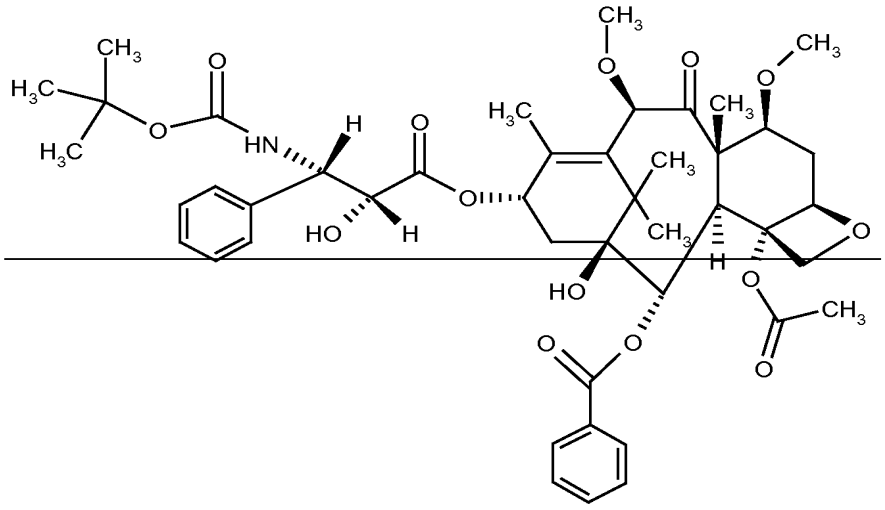
Amendments to the claims start on page 2.

Remarks to amendments and the outstanding office action begin on page 7.

Amendment Pursuant to 37 C.F.R. § 1.121

In the Claims:

1. (Currently amended) A method for treating ~~prostate cancer in~~ a patient with prostate cancer that has progressed during or after treatment with docetaxel, ~~in need thereof~~ comprising administering to said patient a dose of 20 to 25 mg/m^2 of cabazitaxel, or a hydrate or solvate thereof, ~~an effective amount of a compound of formula~~



~~which may be in base form or in the form of a hydrate or a solvate,~~

in combination with a corticoid.

2. – 3. (Cancelled)

4. (Original) The method according to claim 1, where the prostate cancer is an advanced metastatic disease.

5. (Cancelled)

6. (Currently amended) The method according to claim 1, where the cabazitaxel ~~compound~~ is in the form of an acetone solvate.

7. (Original) The method according to claim 6, in which the acetone solvate contains between 5% and 8% by weight of acetone.

8. (Currently amended) The method according to claim 35, where ~~the compound is administered at a dose of between 15 and 25 mg/m^2, and~~ the prednisone or prednisolone is administered at a dose of 10 mg/day.

9. (Currently amended) The method according to claim 8, where the cabazitaxel, or hydrate or solvate thereof, ~~compound~~ is administered at a dose of 25 mg/m^2.

10. (Currently amended) The method according to claim 1, comprising repeating the administration of cabazitaxel, or hydrate or solvate thereof, ~~such compound~~ as a new cycle every 3 weeks.

11. -12. (Cancelled)

13. (Currently amended) The method according to claim 1, wherein the ~~compound is~~ cabazitaxel is in base form.

14. (Currently amended) The method according to claim 1, wherein said ~~compound~~ cabazitaxel, or hydrate or solvate thereof, is administered in an amount to provide an AUC of about 991 ng•h/mL (CV 34%).

15. (Currently amended) The method according to claim 1, wherein said ~~compound~~ cabazitaxel, or hydrate or solvate thereof, is administered in an amount to provide an C_{max} of about 226 ng•h/mL (CV 107%).

16. (Currently amended) The method according to claim 1 wherein said ~~compound~~ cabazitaxel, or hydrate or solvate thereof, is administered in an amount to provide a plasma clearance of 48.5 L/h (CV 39%).

17. (Original) The method according to claim 1, further comprising monitoring blood counts and measuring neutrophil levels in the patient.

18. (Cancelled)

19. (Currently amended) The method according to Claim 17~~Claim 18~~, further comprising discontinuing cabazitaxel treatment in a patient with a neutrophil count of ≤1,500 cells/mm^3.

20. - 23. (Cancelled)

24. (Currently amended) A method of increasing the survival of a patient with a castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel, comprising administering a ~~clinically proven effective amount~~ dose of 20 to 25 mg/m^2 of cabazitaxel, or hydrate or solvate thereof, ~~a compound as defined in claim 1~~ to the patient in combination with prednisone or prednisolone.

25. – 33. (Cancelled)

34. (Currently amended) The method according to claim 1, where the ~~compound~~ cabazitaxel, or hydrate or solvate thereof, is administered at a dose of 25 mg/m^2.

35. (Previously presented) The method according to claim 1, wherein the corticoid is selected from the group consisting of prednisone and prednisolone.

36. (Cancelled)

37. (Currently amended) The method according to claim 24~~claim 36~~, where the ~~compound~~ cabazitaxel, or hydrate or solvate thereof, is administered at a dose of 25 mg/m^2.

38. (Currently amended) The method according to claim 24~~claim 36~~, comprising repeating the administration of said cabazitaxel, or hydrate or solvate thereof, ~~compound~~ as a new cycle every 3 weeks.

39. (Currently amended) The method according to claim 1, where the prostate cancer is a castration resistant ~~prostate cancer~~ or hormone-refractory prostate cancer.

40. (Currently amended) The method according to claim 39, where the cabazitaxel, or hydrate or solvate thereof, ~~compound~~ is administered at a dose of 25 mg/m^2.

41. (Currently amended) The method according to claim 39, comprising repeating the administration of said cabazitaxel, or hydrate or solvate thereof, ~~compound~~ as a new cycle every 3 weeks.

42. (Currently amended) The method according to claim 1, wherein ~~said patient has been previously treated with a docetaxel-based regimen and where~~ the prostate cancer is a castration resistant ~~prostate cancer~~ or hormone-refractory, metastatic prostate cancer.

43. (Currently amended) The method according to claim 42, where cabazitaxel, or hydrate or solvate thereof, ~~the compound~~ is administered at a dose of 25 mg/m^2.

44. (Currently amended) The method according to claim 42, comprising repeating the administration of said cabazitaxel, or hydrate or solvate thereof, ~~compound~~ as a new cycle every 3 weeks.

45. (New) The method according to claim 1, wherein the prostate cancer is a castration resistant or hormone-refractory, metastatic prostate cancer, and wherein the corticoid is selected from the group consisting of prednisone and prednisolone, and wherein the cabazitaxel, or hydrate or solvate thereof, is administered at a dose of 25 mg/m^2.

46. (New) The method according to claim 45, comprising repeating the administration of said cabazitaxel, or hydrate or solvate thereof, as a new cycle every 3 weeks.

47. (New) The method according to claim 1, where the cabazitaxel, or hydrate or solvate thereof, is administered at a dose of 20 mg/m^2.

48. (New) The method according to claim 8, where the cabazitaxel, or hydrate or solvate thereof, is administered at a dose of 20 mg/m^2.

49. (New) The method according to claim 24, where the cabazitaxel, or hydrate or solvate thereof, is administered at a dose of 20 mg/m^2.

50. (New) The method according to claim 42, where the cabazitaxel, or hydrate or solvate thereof, is administered at a dose of 20 mg/m^2.

Remarks

In the Office Action, the Examiner noted that claims 1, 2, 4, 6 to 11, 13 to 19, 24 and 34 to 44 are pending in the application, and that claims 1, 2, 4, 6 to 11, 13 to 19, 24, and 34 to 44 are rejected.

Support for the amendments to the claims can be found throughout the specification, for example on page 4, lines 19 to 25; page 6, lines 8 to 9 and line 13 to page 7 line 4; page 8, line 33 to page 9, line 1; in Examples 1 and 2, and in the claims as originally filed.

Support for new claims 45 to 50 can be found throughout the specification, for example on page 4, lines 19 to 28, Examples 1 and 2, and in the original claims.

Claims 2, 11, 18 and 36 are cancelled without prejudice.

Claim 19 is amended to change its dependency from herein cancelled claim 18 to claim 17.

No new matter is added by these amendments.

Applicant reserves the right to file one or more continuation, continuation-in-part, or divisional applications on the deleted subject matter.

As presently amended, claims 1, 4, 6 to 10, 13 to 17, 19, 24, 34 to 35, 37 to 50 are pending in this application.

Interview Summary

Applicant would like to thank Examiner James Anderson for his time on July 10, 2014 during the interview between the Examiner, Dr. Oliver Sartor, and Applicant's representatives Ms. Gaslonde, Mr. Mandra, and Ms. Bender. During the interview, participants discussed rejections raised in the Office Action dated April 16, 2014 and the draft 37 CFR §1.132 Declaration of Dr. Oliver Sartor. In addition, Dr. Sartor discussed the unpredictable nature of taxanes and prostate cancer treatments and the unexpected results of the invention. During the interview and in the Applicant-Initiated Interview Summary, the Examiner indicated that amending the independent claims to recite 1) treatment of prostate cancer in patients who had progressed during or after docetaxel treatment and 2) administering a dose of 20 to 25 mg/m^2 cabazitaxel or a hydrate or solvate thereof in combination with a corticoid would be allowable.

Discussion of Information Disclosure Statement

In the Office Action, it is noted that "[i]t appears that Applicants intended to file an Information Disclosure Statement with the reply filed 3/17/2014 as numerous NPL and foreign references were supplied…[h]owever the Office did not receive a PTO-SB-08 listing the supplied references." (at page 4).

Applicant confirms that an Information Disclosure Statement was intended to be submitted with the NPL and foreign references and cover letter thereto submitted on March 17, 2014 and that the corresponding FORM PTO-SB-08 has not been submitted therewith, through error. The PTO-SB-08 corresponding to the NPL and foreign documents submitted on March 17, 2014 was subsequently submitted on April 29, 2014. Applicant thanks the Examiner for identifying this mistake, and respectfully requests his consideration of this previously submitted Information Disclosure Statement.

For the sake of clarity, Applicant notes that a new Supplemental Information Disclosure Statement is being submitted concurrently herewith.

Discussion of Rejection under 35 U.S.C. § 112, second paragraph

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being, the Examiner alleges, indefinite for the stated reason that ""[c]laim 2 recites a method of claim 1, where said patient 'is not catered for by a taxane-based treatment.' However, claim 1 requires administration of cabazitaxel, which is a taxane. As such, it is unclear how the patients of claim 1 cannot be catered for by a taxane-based treatment when claim 1 requires administration of a taxane" (Office Action, page 5).

Without acquiescing to the propriety of the rejection, and solely to advance prosecution, claim 2 has been cancelled. The rejection of claim 2 under 35 U.S.C. § 112, first paragraph is therefore rendered moot.

Discussion of Rejection under 35 U.S.C. § 102(b)

Claims 1 to 2, 4, 10, 13, 24, 35 to 36, 38 to 39, 41 to 42, and 44 are rejected under 35 U.S.C. § 102(b) as being, the Examiner alleges, anticipated by Beardsley et al. (Current Opinion in Supportive and Palliative Care, 2008, vol. 2, pp. 161 to

166, hereinafter "Beardsley"). It is the Examiner's position that Beardsley "anticipate[s] administering cabazitaxel in combination with prednisone to patients with castration-resistant metastatic prostate cancer previously treated with docetaxel-containing treatment as presently claimed." (Office Action, page 6).

For an anticipation rejection, each and every element of a claim must identically appear in a single prior art reference. *See, Gechter v. Davidson*, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997).

In support of this rejection, the Office Action refers to Beardsley's statement that XRP6258 is "currently being investigated in a phase III multi-center, randomized superiority trial comparing 3-weekly XRP6258 with prednisone to mitoxantrone with prednisone in patients with castrate resistant metastatic prostate cancer previously treated with docetaxel-containing treatment." (Beardsley at 163). Importantly, the doses of cabazitaxel and prednisone are not disclosed in Beardsley.

Accordingly, it is respectfully submitted that Beardsley does not teach each and every element of the rejected claims, as previously presented, for at least the reason that Beardsley does not describe *any dose* of cabazitaxel, let alone an *effective* amount of cabazitaxel.

Nevertheless, without agreeing to the propriety of this rejection, independent claims 1 and 24 have been amended as proposed by the Examiner to include a dose amount of cabazitaxel, which element is not described in Beardsley. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) are therefore respectfully requested.

Discussion of Rejection under 35 U.S.C. § 103(a)

Claims 1, 2, 4, 8 to 11, 13 to 19, 24, and 34 to 44 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Mita et al. (Clin Cancer Res, 2009, 15(2) pp. 723-730, hereinafter "Mita") in view of Tannock et al. (N Eng J Med, 2004, 351, pp. 1502-1512, hereinafter "Tannock") and Beardsley. This rejection is respectfully traversed.

It is the Examiner's position that one would have been motivated to "combine the teachings of the references so as to administer cabazitaxel in combination with prednisone" because Mita allegedly teach that "cabazitaxel is effective in treating

prostate cancer metastatic to liver and bones whose disease has progressed through surgical castration, bicalutamide, diethetyl stilbestrol, and mitoxantrone and prednisone and hormone- and docetaxel-refractory prostate cancer metastatic to bone and iliac lymph nodes when administered as a single agent." (Office Action, page 13). Further, it is the Examiner position that the "motivation to add prednisone to such treatment is clearly seen in Tannock et al., who teach that administration of the taxane, docetaxel, in combination with prednisone is effective in treating hormone-refractory prostate cancer." (*Id.*). Beardsley is relied upon in the Office Action for the given reason that it "disclose[s] that there is an urgent need for systemic treatment options for patients with castrate-resistant prostate cancer who have progressed after receiving first-line docetaxel therapy" and that cabazitaxel is "currently being investigated in a phase III multi-center, randomized superiority trial." (Office Action, pages 11 and 14).

It has long been held that "[t]he factual determinations underpinning the legal conclusion of obviousness include 1) the scope and content of the prior art, 2) the level of ordinary skill in the art, 3) the differences between the claimed invention and the prior art, and 4) evidence of secondary factors, also known as objective indicia of non-obviousness," (*Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd., 533 F.3d 1353, 1356 (Fed. Cir. 2008)*; citing *Graham v. John Deere Co., 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed. 2d 545 (1966))*. Indeed, to render a claimed invention obvious under 35 U.S.C. § 103, the cited reference themselves, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to combine or modify them in the manner necessary to arrive at the claimed invention (*See,* MPEP § 2143.01). In addition, the proposed combination or modification must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. (*See,* MPEP § 2143.02).

The present application, which describes the results from a Phase III clinical trial, demonstrates that administration of cabazitaxel in combination with prednisone to patients with hormone-refractory metastatic prostate cancer, who were previously treated with a docetaxel-containing regimen resulted in a statistically significant longer overall survival compared to patients receiving a mitoxantrone plus prednisone. (*See*, Specification, p. 18).

The primary Mita reference describes Phase I and pharmacokinetic studies of cabazitaxel in a limited number of patients with a variety of solid tumors. The studies were designed to evaluate the safety and dosage of cabazitaxel, but "preliminary evidence of antitumor activity" was to be documented. (Mita at 724, bottom left column, top left column). While eight of the twenty-five patients had prostate tumors (*Id.* at 725, Table 1), Mita indicated that evidence of anticancer activity was noted in two patients, including one patient with "hormone- and docetaxel-refractory prostate cancer metastatic to bone and iliac lymph nodes." (*Id.* at 727).

The evidence of anticancer activity in a single patient does not provide an expectation that the claimed method would successfully treat prostate cancer. Indeed, no antitumor activity was seen in the majority of the patients treated. Moreover, it is important to note that Mita nowhere suggests that one skilled in the art should use cabazitaxel for the treatment of prostate cancer based on these results, as the efficacy data provided is only "preliminary" evidence.

Second, cancer research, and in particular clinical trials of antitumor drugs, is highly unpredictable. (*See e.g.,* Kola et al. stating "[a]pproximately 62% of all compounds that enter Phase II trials undergo attrition, and again the highest rate of attrition at this phase is in the oncology field: more than 70% of oncology compounds fail in this phase," *Nature Reviews Drug Discovery*, 2004, Vol 3., pp. 711-715 at 712, cited in attached IDS). Accordingly, given the extremely limited nature of the patients described in Mita and the unpredictability and complexity of treatment of cancer, one skilled in the art would not have the requisite reasonable expectation that patients with hormone-refractory metastatic prostate cancer, who were previously treated with a docetaxel-containing regimen, could be successfully treated by the claimed method.

As noted by the Examiner at page 17 of the Office Action, the abstract of Mita states that "the general tolerability and encouraging antitumor activity in taxane-refractory patients warrant further evaluations of XRP6258 [cabiztaxel]." Even assuming, *arguendo*, that this statement gives a general *incentive* to evaluate cabazitaxel in these taxane-refractory patients, none of the cited references provide the requisite evidence of *predictability* in the treatment of such cancer patients. Absent evidence of predictability, Mita cannot provide a reasonable expectation of success in the treatment of prostate cancer in taxane-refractory patients.

Cited reference Beardsley is a review article describing research developments on a wide variety of different approaches to treating metastatic castration-resistant prostate cancer ("mCRPC"). Beardsley notes that "given its activity in the docetaxel refractory setting" of the phase II study in breast cancer, cabazitaxel was being investigated in a phase III trial "comparing 3-weekly XRP6258 with prednisone to mitoxantrone with prednisone in patients with castrate resistant metastatic prostate cancer previously treated with docetaxel-containing treatment." (*Id.*). As previously noted, the doses of cabazitaxel and prednisone are not disclosed. Beardsley does not report any results from a phase III study on cabazitaxel or any clinical data from administration of cabazitaxel to patients with prostate cancer. Beardsley nevertheless expresses that there is an "urgent need for systemic treatment options for patients with castration-resistant prostate cancer who have progressed after receiving first-line docetaxel chemotherapy." (Abstract).

Tannock reports the results of a phase III study comparing docetaxel plus prednisone with mitoxantrone plus prednisone in metastatic hormone-refractory prostate cancer, also commonly referred to as mCRPC. Tannock does not mention cabazitaxel or the effective treatment of a patient with prostate cancer that has progressed during or after treatment with docetaxel. Accordingly, nothing in Tannock would provide one skilled in the art with the reasonable expectation that a combination of cabazitaxel with prednisone would successfully treat a patient with prostate cancer that has progressed during or after treatment with docetaxel.

Applicant therefore submits that the claimed invention as a whole was not known in the prior art, that the combination of Mita, Tannock, and Beardsley would not have provided a reasonable expectation of predictable results, and that the results of the claimed invention were unexpected and urgently needed.

In this regard, Applicant submits contemporaneously herewith a Declaration of Dr. Alton Oliver Sartor, M.D. under 37 CFR §1.132 demonstrating the unpredictable nature of taxanes and clinical treatment or prostate cancer. More specifically, Dr. Sartor explains that, in his opinion, the references cited in the Office Action, "would not give a person of ordinary skill at the relevant time a reasonable expectation that cabazitaxel could successfully treat mCRPC." (at para. 71). Dr. Sartor demonstrates that it would have been extremely difficult to predict a clinical success for the treatment of prostate cancer, even after a Phase I or Phase II study, and in particular in patients previously treated with a docetaxel-containing treatment

(see. e.g., para. 18 to 43 of the 132 Declaration). Dr. Sartor further indicates that although Beardsley describes the "urgent need for systemic treatment options for patients with castration-resistant prostate cancer who have progressed after receiving first-line docetaxel chemotherapy," none of the treatments proposed by Beardsley met this clinical need before the effective filing date of the instant application, and that this urgent need was not met until the FDA approved Jevtana (cabazitaxel) in view of the results of the instant invention (see, e.g., para. 62 to 63 of the 132 Declaration). Finally, Dr. Sartor further demonstrates that the results of the claimed invention were truly unexpected to those skilled in the art (see, e.g., para. 64 to 70).

For the foregoing reasons, claims 1, 4, 6 to 10, 13 to 17, 19, 24, 34 to 35, 37 to 45, and as presented amended, as well as new claims 46 to 50, are unobvious over the combination of Mita, Tannock, and Beardsley. Therefore, reconsideration and withdrawal of the instant rejection under 35 U.S.C. § 103(a) are respectfully requested.

Claims 6 and 7 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Mita, in view of Tannock and Beardsley as applied to claims 1 to 2, 4, 8 to 11, 13 to 19, 24, and 34 to 44, and further in view of Didier et al. (US2005/0065138).

Didier et al., which is cited for allegedly teaching "acetone solvate[] of cabazitaxel" and "acetone solvate[] containing between 5% and 8% of acetone" (Office Action, page 15), dose not remedy the deficiencies of Mita, Tannock and Beardsley, as described above and discussed in Dr. Sartor's Declaration under 37 CFR §1.132. Accordingly, Didier et al., in combination with Mita, Tannock, and Beardsley does not render claims 6 and 7 obvious. Reconsideration and withdrawal of this rejection of claims 6 and 7 are therefore respectfully requested.

Conclusion

There being no remaining issues, this application is believed in condition for favorable reconsideration and early allowance, and such actions are earnestly solicited.

In the event the Examiner wishes to contact the undersigned regarding any matter, please call (collect if necessary) the telephone number listed below.

The Director is hereby authorized to charge any additional fees which may be required by this paper, or credit any overpayment to Deposit Account No. **18-1982**.

Respectfully submitted,

/Kelly L. Bender/
Kelly Bender, Reg. No. 52,610
Attorney for Applicant

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Sanofi US Ref. FR2009/121 US CNT

Date: July 16, 2014

Electronic Patent Application Fee Transmittal

Application Number:	13456720
Filing Date:	26-Apr-2012
Title of Invention:	NOVEL ANTITUMORAL USE OF CABAZITAXEL
First Named Inventor/Applicant Name:	Sunil GUPTA
Filer:	Kelly L. Bender/Brian Pritchett
Attorney Docket Number:	FR2009/121 US CNT

Filed as Large Entity

Utility under 35 USC 111(a) 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:	19582441
Application Number:	13456720
International Application Number:	
Confirmation Number:	1083
Title of Invention:	NOVEL ANTITUMORAL USE OF CABAZITAXEL
First Named Inventor/Applicant Name:	Sunil GUPTA
Customer Number:	5487
Filer:	Kelly L. Bender/Brian Pritchett
Filer Authorized By:	Kelly L. Bender
Attorney Docket Number:	FR2009/121 US CNT
Receipt Date:	16-JUL-2014
Filing Date:	26-APR-2012
Time Stamp:	16:31:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	2879
Deposit Account	181982
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Non Patent Literature	FR2009121USCNTIDSREF1_Antonarakis_Eisenberger_2013.pdf	149229 39485f416df09059f2a3617a1daf6fd6943d6a32	no	4
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3	Non Patent Literature	FR2009121USCNTIDSREF3Beardsley_2008.pdf	79738 e79e5056bd347333c69ce2836fdb476049381282	no	6
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10	Non Patent Literature	FR2009121USCNTIDSREF10DiLorenzo2008.pdf	8658082 4bfa96102857609a352cc8c473975651ce8de139	no	8
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51	Transmittal Letter	FR2009-121USCNT_20140716_SUPP_IDSL.pdf	109781 3660d357c6f2c117904b2891e00b1e9b19c3a058	no	2
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52	Affidavit-traversing rejectns or objectns rule 132	FR2009-121USCNT_20140716_Declaration_of_Alton_Oliver_Sartor.pdf	611775 5eddf9fa5890e365860ba9aae3f310b8851c1c99	no	59
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54		FR2009-121USCNT_20140716_ROA.pdf	238165 cd5c2c200216637cb531268f77147ba58a4f7114	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	14

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Warnings:					
Information:					
		Total Files Size (in bytes):	83236319		

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
GUPTA, et al.

Examiner:
James D. Anderson

Application No.:
13/456,720

Art Unit:
1629

Filed:
April 26, 2012

Title: **NOVEL ANTITUMORAL USE OF CABAZITAXEL**

CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that the correspondence below is being transmitted via the USPTO's electronic filing system in accordance with 1.6(a)(4), on

July 16, 2014
Date of Deposit

/Brian Pritchett/
Signature

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

Attached are the following documents:

			Number of Pages
☐	Application Data Sheet		
☐	Declaration		
☐	Drawings		
☐	Extension of Time		
☒	Information Disclosure Statement and Form 1449		7
☒	Response to Non-Final Office Action		14
☐	Specification, Claims and Abstract	Specification	
		Claims	
		Abstract	
☐	Transmittal Letter:		
☒	Other *(specify):* REFERENCES		49
☒	Other *(specify): DECLARATION 1.132*		59
☐	Other *(specify):*		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of **GUPTA, et al.**		Examiner:	**James D. Anderson**
		Art Unit:	**1629**
Application No.:	**13/456,720**		
Filed:	**April 26, 2012**	Conf. No.	**1083**
Title:	**NOVEL ANTITUMORAL USE OF CABAZITAXEL**		

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

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.56

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicant's duty of disclosure pursuant to 37 C.F.R. §1.56.

The submission of the document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any right to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 C.F.R. §1.97(c), as the submission is filed after the period specified in §1.97(b) but before the mailing date of any of a final action under §1.113, a notice of allowance under §1.311, or an action that otherwise closes prosecution in the application. Applicants hereby authorize the Director to charge any fees under 37 C.F.R. §1.17(p) or any other fees required by this paper, or to credit any overpayment, to Deposit Account No. **18-1982**.

A concise explanation of the relevance of some or all of the items listed on the attached Form PTO/SB/08 is as follows:

The documents cited in the 37 CFR §1.132 Declaration filed concurrently herewith are listed in the attached Form PTO/SB/08 and copies of these documents are submitted herewith.

In addition, listed reference "Jevtana NDA Clinical Overview, excerpt" was not previously published, so the date provided on the Form PTO/SB/08 is the date of its submission to the USPTO.

Respectfully submitted,

/Kelly L. Bender/
Kelly Bender, Reg. No. 52,610
Attorney/Agent for Applicant

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Telefax: (908) 981-7830
Sanofi US Ref. FR2009/121 US CNT

Date: July 16, 2014

In re Application No.: 13/456,720	)	
	:	Examiner: James D. ANDERSON
First Named Inventor:	)	
	:	Group Art Unit: 1629
SUNIL GUPTA	)	
	:	Confirmation No.: 1083
Filed: April 26, 2012	)	
	:	
For: NOVEL ANTITUMORAL USE OF CABAZITAXEL	)	
	:	

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

Declaration Under 37 C.F.R. § 1.132 of Alton Oliver Sartor, M.D.

I, Alton Oliver Sartor, M.D., declare as follows:

1. I am the Laborde Professor of Cancer Research in the Medicine and Urology Departments of Tulane University School of Medicine. I am also the Medical Director and Associate Director for Clinical Programs of the Tulane Cancer Center.

2. I received my M.D. from Tulane University in 1982. I completed an internship at the University of Pennsylvania before training in internal medicine at Tulane University School of Medicine. I then completed a fellowship at the National Cancer Institute ("NCI") in Bethesda, Maryland in 1989. From 1989-1990 I was a Senior Staff Fellow at the Laboratory of Cellular Development and Oncology, National Institutes of Dental Research before serving as a Senior Investigator at the NCI until 1993.

3. In 1993 I returned to Louisiana to serve as Associate Professor of Medicine at the Louisiana State University ("LSU") Medical School in Shreveport, L.A. and then moved to the LSU Health Sciences Center in New Orleans, L.A. in 1998 as the Patricia

Powers Strong Professor of Oncology, Stanley S. Scott Cancer Center Director, and Hematology/Oncology Section Chief. I became the Co-Director of the Louisiana Cancer Research Consortium at its origin in 2002.

4. In 2006 I left LSU and joined the Lank Center for Genitourinary Oncology at the Dana Farber Cancer Research Institute and Harvard Medical School. In 2008 I joined Tulane University. Further information regarding my academic background and work experience can be found in my curriculum vitae, a copy of which is attached as Exhibit 1.

5. During the course of my career, my interests have focused on treating prostate cancer, particularly in patients who have failed initial therapy. I have published more than 250 scholarly articles, including many on clinical trials of novel agents to treat prostate cancer. These publications have been cited more than 10,000 times.

6. I have been appointed to numerous scientific committees. I am currently serving as Chairman of the Tulane Cancer Center Strategic Planning Committee; Medical Chair of the Genitourinary Committee of NRG Oncology (the world's largest radiation oncology research group); and served as an FDA Public Workshop Panelist in 2013 on Clinical Trial Design Issues - Drug & Device Development for Localized Prostate Cancer.

7. I have served on the editorial boards of scientific journals such as The Prostate, Urology, and Personalized Medicine in Oncology. I am currently Editor-in-Chief of the Clinical Genitourinary Cancer journal.

8. I continue to treat patients at the Tulane Cancer Center and Urology Multi-Disciplinary Clinic. I see approximately 25-50 patients per week with urologic malignancies. Currently about 1000 patients are under my care, mostly with prostate cancer. From 2005-2014, I have been named one of the "Best Doctors in America" by Best Doctors, Inc.

9. I was a principal investigator ("PI") or co-PI on numerous prospective international clinical trials evaluating new therapies for patients with advanced prostate cancer, including five pivotal trials that have led to FDA approvals. I was a co-PI on the TROPIC phase III study comparing cabazitaxel plus prednisone to mitoxantrone plus prednisone in patients with metastatic castration-resistant prostate cancer ("mCRPC") previously treated with a docetaxel-containing treatment, a study sponsored by Sanofi. I am currently a co-PI on another phase III clinical trial of cabazitaxel, also sponsored by Sanofi.

10. I have significant experience in the clinical evaluation of cancer treatments, evaluation of novel treatments for patients with prostate cancer that have failed initial therapies, and treatment of patients with advanced prostate cancer. Therefore, I believe that I am qualified to render the opinions set forth in this declaration.

11. I have read the Office Action dated April 16, 2014 ("Office Action") and the cited references. Among other rejections, I understand that the Office Action rejects the claims pending in the captioned application as unpatentable over the following references:

a. Beardsley *et al.*, *Systemic Therapy After First-Line Docetaxel in Metastatic Castration-Resistant Prostate Cancer*, 2 Current Opinion in Supportive & Palliative Care 161-66 (2008) ("Beardsley");

b. Mita *et al.*, *Phase I and Pharmacokinetic Study of XRP6258 (RPR 116258A), a Novel Taxane, Administered as a 1-Hour Infusion Every 3 Weeks in Patients with Advanced Solid Tumors*, 15(2) Clinical Cancer Res. 723-30 (2009) ("Mita");

c. Tannock *et al.*, *Docetaxel Plus Prednisone or Mitoxantrone Plus Prednisone for Advanced Prostate Cancer,* 351 New Eng. J. Med. 1502-12 (2004) ("Tannock"); and

d. US Patent Application Publication No. 2005/0065138, which names Eric Didier as an inventor ("Didier").

12. I have read US Patent Application No. 13/456,720 ("the '720 application"), which I believe corresponds to US Patent Application Publication No. 2012/0301425 ("the '425 publication").

13. I have reviewed a copy of the pending claims in the '720 application with proposed amendments. I understand that the claims will be filed in the Patent and Trademark Office as part of the response to the Office Action.

14. I understand that the earliest priority date for the '720 application is October 29, 2009 ("the relevant time"). In the paragraphs below, I will refer to the state of the art in the areas of cancer research, clinical evaluation of anti-tumor drugs, and treatment of prostate cancer at that time. I will explain how a person of ordinary skill in the art at that time would have understood the references cited in the Office Action and how such a person would have interpreted certain clinical results. My opinions would not change if the priority date were October 27, 2010.

15. In my opinion, a person of ordinary skill in the art would be an oncologist. As noted above, I have practiced oncology for nearly 30 years and have taught clinical oncology for over 20 years. As such, I am intimately familiar with how a practicing oncologist would evaluate clinical evidence.

16. The claims are directed toward the use of cabazitaxel to treat mCRPC. In my opinion, the success of such a treatment would not have been predictable to a skilled worker during the relevant time.

17. As described below, the art was full of promising early clinical results that failed to predict whether therapies would ultimately provide a clinically meaningful benefit to the desired patient populations. mCRPC was known to be a particularly challenging and unpredictable indication. The disclosure of the references cited in the Office Action did not provide sufficient guidance to overcome that unpredictability.

I. Unpredictability of Clinical Success in Developing Chemotherapeutic Treatments of Prostate Cancer

18. In 2004 Kola & Landis reported that the failure rate in phase II trials of oncology drugs was more than 70%. Kola & Landis, *Can the Pharmaceutical Industry Reduce Attrition Rates?*, 3 Nature Reviews Drug Discovery 711-15, 712 (Aug. 2004).

19. Booth *et al.* report that cancer drugs have a lower than average success rate than other therapeutic areas at phase III. Booth *et al.*, *From the Analyst's Couch: Oncology's Trials*, 2 Nature Reviews Drug Discovery 609-10, 609 (Aug. 2003). "[E]arly development trials do not seem to be very predictive of success rates for later development . . . ." *Id.* "Phase II trials in oncology do not show significant predictability for Phase III outcomes." *Id.* at 610. When studies more often fail than succeed, calling positive results reasonably expected is simply scientifically wrong, and persons of ordinary skill familiar with this evidence would not disagree.

20. A person of ordinary skill would have understood that the attrition rate in phase III trials of mCRPC therapies was particularly high. The cancer treatments described

below are real-life examples of how difficult it would have been to predict clinical success for a novel therapy.

A. **Larotaxel**

21. Larotaxel is another taxane developed by Sanofi. It showed promise in phase I studies with objective responses in several tumor types. Zatloukal *et al., Randomized Multicenter Phase II Study of Larotaxel (XRP9881) in Combination with Cisplatin or Gemcitabine as First-Line Chemotherapy in Nonirradiable Stage IIIB or Stage IV Non-Small Cell Lung Cancer*, 3 J. Thorac. Oncol. 894-901, 895 (2008) ("Zatloukal").

22. Larotaxel had also shown activity in taxoid-resistant tumors in preclinical studies. Diéras *et al., Phase II Multicenter Study of Larotaxel (XRP9881), a Novel Taxoid, in Patients with Metastatic Breast Cancer Who Previously Received Taxane-Based Therapy*, 19 Annals of Oncol. 1255-60, 1255 (2008). Activity was "demonstrated in cell lines expressing the multidrug-resistant phenotype and in *mdr*-expressing murine tumor models." *Id.*

23. Larotaxel was evaluated in a phase II trial in metastatic breast cancer patients previously treated with a taxane. *Id.* The patients were stratified by resistance to taxane therapy. *Id.* at 1256. The primary endpoint was overall response rate ("ORR"). *Id.* In the non-resistant group, the ORR was 42%, and in the resistant group the ORR was 19%. *Id.* at 1257. One taxane-resistant patient (of 67 treated, 43 per protocol) exhibited a complete response, and 12 resistant patients exhibited a partial response. *Id.* The safety profile was reported as "similar to that of the taxanes." *Id.* at 1259. Neutropenia and diarrhea were some of the most significant toxicities. *Id.* at 1258-59.

24. At the 2008 American Society of Clinical Oncology ("ASCO") annual meeting, an interim analysis was presented of a phase II trial evaluating larotaxel in combination

with trastuzumab in patients with metastatic breast cancer. Diéras *et al., Larotaxel (L) in Combination with Trastuzumab in Patients with HER2+ Metastatic Breast Cancer (MBC): Interim Analysis of an Open Phase II Label Study*, 26 (15S) J. Clin. Oncol. (Meeting Abstracts) Suppl. 1070 (May 2008). The authors reported "good activity in pretreated [patients] with high tumor burden" and "manageable toxicity." *Id.*

25. Larotaxel was also evaluated in a phase II trial in combination with cisplatin or gemcitabine as a first line therapy in non-small cell lung cancer. Zatloukal at 894-95. The response rates were 26.7% and 18.2% respectively. *Id.* at 894, 897. The authors concluded that both "combinations were effective and manageable, however all measured efficacy parameters (response rate, progression free survival, and survival) seemed to favor the combination with cisplatin." *Id.* at 894.

26. Based on these phase II results, three phase III studies were initiated:

- Larotaxel every 3 weeks vs. capecitabine in patients with metastatic breast cancer progressing after taxanes and anthracycline therapy. (https://clinicaltrials.gov/ct2/show/NCT00081796?term=larotaxel&rank=7).
- Larotaxel vs. 5-FU in patients with pancreatic cancer previously treated with gemcitabine. (https://clinicaltrials.gov/ct2/show/NCT00417209?term=larotaxel&rank=2).
- Larotaxel plus cisplatin vs. gemcitabine plus cisplatin in first line treatment of patients with locally advanced/metastatic bladder cancer. (https://clinicaltrials.gov/ct2/show/NCT00625664?term=larotaxel&rank=4)

27. Larotaxel did not meet the primary endpoint, overall survival, in the phase III study in pancreatic cancer. Van Cutsem *et al., A Phase III Study Comparing Larotaxel to 5-FU (Continuous Intravenous 5-FU or Capecitabine) in Patients with Advanced Pancreatic Cancer (APC) Previously Treated with a Gemcitabine Containing Regimen*, 21(6S) Annals of Oncol. Oral Presentations O-007 (July 2010). Patients treated with larotaxel had a higher incidence of toxicities, including diarrhea, alopecia, sensory neuropathy, myalgia, and

neutropenia than patients treated with 5-FU. *Id.* The main hematological toxicities in patients treated with larotaxel were neutropenia and complicated neutropenia. *Id.*

28. Larotaxel was not shown to be superior to the comparator capecitabine in the phase III breast cancer study. Sanofi-Aventis SEC Form 20-F (Dec. 31, 2006) at 39, *available at* http://www.sec.gov/Archives/edgar/data/1121404/000119312507072848/d20f.htm. The progression free survival was longer in the capecitabine group, and overall survival was not statistically different between the study arms. *A Randomized, Open-Label, Phase 3 Study of Larotaxel IV Every 3 Weeks Versus Capecitabine (Xeloda®) Tablets Twice Daily for 2 Weeks in 3-Week Cycles in Patients with Metastatic Breast Cancer (MBC) Progressing After Taxanes and Anthracycline Therapy (EFC6089), available at* http://en.sanofi.com/img/content/study/EFC6089_summary.pdf (last visited June 24, 2014). Larotaxel had higher incidence of neutropenia and more permanent withdrawals from treatment due to an adverse event. *Id.*

29. During the phase III study in bladder cancer, the data monitoring committee recommended reducing the dose of larotaxel and cisplatin in part due to the incidence of toxicity, mainly infections. Sternberg *et al., Larotaxel with Cisplatin in the First-Line Treatment of Locally Advanced/Metastatic Urothelial Tract or Bladder Cancer: A Randomized, Active-Controlled, Phase III Trial (CILAB),* 85 Oncology 208-15, 210-11 (2013). In light of the necessary dose adjustment and the lack of larotaxel efficacy versus comparators in the phase III trials in pancreatic cancer and breast cancer, "it was deemed unlikely that the [bladder cancer] trial would meet its primary efficacy endpoint." *Id.* The study was prematurely discontinued. Preliminary data indicated that treatment with larotaxel/cisplatin was associated with worse

progression free survival than the comparator; there was no difference in overall survival. *Id.* at 213.

30. After three phase III failures, Sanofi decided to stop clinical development of larotaxel even though the company regarded the initial clinical data as promising. The preclinical and phase I-II data failed to predict efficacy and a manageable side-effect profile in larger treatment populations. Although not in prostate cancer, it is of particular interest that a phase II study in breast cancer patients previously treated with taxanes failed to predict clinical efficacy and safety in a phase III breast cancer trial, or any other phase III trial.

B. Failures in CRPC

31. In addition to the unpredictability and failures discussed above, there were a number of drugs that failed in phase III studies in CRPC despite promising phase II results in the same indication.

32. Kaur *et al.* report on the disappointing clinical results of suramin, a polysulphonated naphthylurea, in androgen independent (i.e., castration-resistant) prostate cancer. Kaur *et al., Suramin's Development: What Did We Learn?*, 20 Investigational New Drugs 209-19, 209 (2002). An early phase II trial showed promising results; of 38 patients enrolled, three exhibited complete responses, three exhibited partial responses, and five patients had PSA[1] declines of 75% or more. *Id.* at 210. A phase III trial comparing suramin plus hydrocortisone to placebo plus hydrocortisone showed statistically significant PSA and pain relief advantages, but no survival advantages and some toxicity, leading the FDA to decline

[1] PSA, or prostate specific antigen, is a protein produced by cells of the prostate gland that is often elevated in men with prostate cancer. However, a number of benign conditions can also cause a man's PSA levels to rise, such as benign prostatic hyperplasia (enlargement of the prostate).

approval. *Id.* The authors note that the early results might have been misleading because of the failure to fully consider the effect of anti-androgen withdrawal, the fluctuation of PSA by factors independent of antitumor effect, and the palliative and anti-tumor activity of hydrocortisone itself. *Id.* at 217.

33. Beardsley reports that the SPARC trial, evaluating satraplatin plus prednisone against placebo plus prednisone in men with CRPC progressing after prior chemotherapy, showed an increase in progression free survival ("PFS") with satraplatin, but not overall survival. Beardsley at 162-63; *Satraplatin in Hormone Refractory Prostate Cancer Patients Previously Treated with One Cytotoxic Chemotherapy Regimen*, https://clinicaltrials.gov/ct2/show/NCT00069745?term=SPARC&cond=prostate&rank=3 (first received Sept. 30, 2003, last updated Aug. 1 2012). Beardsley states that "the clinical significance of this difference in PFS is open to interpretation." Beardsley at 162. Phase II studies in patients with CRPC had demonstrated considerable activity and acceptable toxicity. *Id.*

34. Carducci *et al.* report that atrasentan, a selective endothelial-A receptor antagonist, failed to delay disease progression in patients with mCRPC in a phase III trial. Carducci *et al., A Phase 3 Randomized Controlled Trial of the Efficacy and Safety of Atrasentan in Men with Metastatic Hormone-Refractory Prostate Cancer*, 110(9) Cancer 1959-66, 1959, 1962 (2007). A phase II trial demonstrated a significant effect on PSA, bone alkaline phosphatase, and other markers of bone remodeling in men with mCRPC. *Id.* at 1960. The phase II study showed a nonsignificant trend in delaying disease progression. *Id.* That trend did not translate into positive phase III results; the primary endpoint was not met, and there was no difference in survival. *Id.* at 1962-63. Atrasentan in combination with docetaxel was later

evaluated in a phase III clinical trial in mCRPC patients, which did not show an increase in overall survival. Antonarakis & Eisenberger, *Phase III Trials with Docetaxel-Based Combinations for Metastatic Castration-Resistant Prostate Cancer: Time to Learn From Past Experiences*, 31(14) J. Clin. Oncol. 1709-12, 1710 (2013) ("Antonarakis & Eisenberger").

35. A randomized phase II study of DN-101, a high dose oral formulation of calcitriol, in combination therapy with docetaxel compared to placebo plus docetaxel reported an association of DN-101 with improved survival and no increase in the toxicity of docetaxel. Beer *et al., Double-Blinded Randomized Study of High-Dose Calcitriol Plus Docetaxel Compared with Placebo Plus Docetaxel in Androgen-Independent Prostate Cancer: A Report from the ASCENT Investigators*, 25(6) J. Clin. Oncol. 669-74, 669-70, 673 (2007). Although the addition of calcitriol did not produce a statistically significant improvement in PSA response, the authors cautioned that "it is worthwhile to consider the limitations of the PSA response as a predictor of survival benefit that have come to light since ASCENT was designed." *Id.* at 673. These results led to the initiation of a phase III trial (ASCENT-2) comparing DN-101 plus weekly docetaxel to the standard 3-weekly regimen of docetaxel. *Id.* However, in the phase III trial DN-101 failed to meet the primary endpoint of prolonging overall survival. Williams, *Discontinued Drugs in 2008: Oncology Drugs*, 18(11) Expert Opin. Investig. Drugs 1581-94, 1593 (2009); *see also* Novacea, Inc. SEC Form 8-K at 1.02 (April 4, 2008), *available at* http://www.sec.gov/Archives/edgar/data/1178711/000119312508077953/d8k.htm ("In November 2007, Novacea and Schering terminated the ASCENT-2 of Asentar™ due to an unexplained balance of deaths between the treatment and control arms of the trial"). At the 2010 annual meeting of ASCO, Ian Tannock, M.D., Ph.D. was quoted as saying, "[w]hat we can learn from ASCENT-2 is that even large randomized phase II trials may be poor predictors of results

in phase III." Susman, *ASCO: Calcitriol Fails in ASCENT-2 Prostate CA Trial*, MedPage Today (June 9, 2010), http://www.medpagetoday.com/MeetingCoverage/ASCO/20575.

36. In October 2008 Cell Genesys, Inc. announced the termination of a phase III clinical trial comparing its immunotherapy GVAX to docetaxel plus prednisone in asymptomatic, mCRPC patients because of a lack of effect on survival. Mulcahy, *Phase 3 Trial of Immunotherapy for Metastatic Prostate Cancer Terminated*, Medscape (October 17, 2008), http://www.medscape.com/viewarticle/582220. The study was terminated after an unplanned futility analysis by the data monitoring committee indicated that the trial had less than a 30% chance of meeting its primary endpoint. *Id.* In August 2008 Cell Genesys had terminated another phase III trial of GVAX (VITAL-2). *Id.* VITAL-2 compared the combination of GVAX plus docetaxel to docetaxel plus prednisone in symptomatic mCRPC patients. *Id.* The study was terminated due to an imbalance of deaths, with more deaths in the GVAX arm. *Id.* Two phase I/II studies in patients with mCRPC had indicated that GVAX provided a survival benefit over predicted survival. Higano *et al., Phase 1/2 Dose-Escalation Study of a GM-CSF-Secreting, Allogeneic, Cellular Immunotherapy for Metastatic Hormone-Refractory Prostate Cancer*, 113(5) Cancer 975-84, 983 (2008) (Survival "exceeded the expected survival times by 5 and 13 months in 2 of the 3 dose groups and matched predicted survival in the third."); Small *et al., Granulocyte Macrophage Colony-Stimulating Factor Secreting Allogeneic Cellular Immunotherapy for Hormone-Refractory Prostate Cancer*, 13 Clin. Cancer Res. 3883-91, 3888 (2007) (one patient with a complete response and survival time exceeded the predicted survival).

37. In March 2010 Roche reported that a phase III trial of its endothelial growth factor-specific angiogenesis inhibitor Avastin® (bevacizumab) in combination with docetaxel and prednisone did not increase overall survival compared to docetaxel plus

prednisone in men with CRPC. *Roche Provides Update on Phase III study of Avastin in Men with Late Stage Prostate Cancer*, Media Release (March 12, 2010), http://www.roche.com/media/media_releases/med-cor-2010-03-12.htm. At the time, Avastin® was approved for metastatic colorectal cancer, non-squamous non-small cell lung cancer, and metastatic breast cancer as a combination therapy and for glioblastoma as a single agent. July 2009 Avastin® Labeling. A phase II study of bevacizumab and docetaxel in mCRPC patients previously treated with docetaxel had reported 55% of patients with a "major" PSA response and 37.5% with objective responses. Di Lorenzo *et al., Combination of Bevacizumab and Docetaxel in Docetaxel-Pretreated Hormone-Refractory Prostate Cancer: A Phase 2 Study*, 54 Europ. Urol. 1089-96, 1089, 1092 (2008).

38. Sunitinib, an inhibitor of vascular endothelial growth factor receptors, platelet-derived growth factor receptors, and other receptor tyrosine kinases, is approved for treatment of advanced renal cell carcinoma, gastrointestinal stromal tumors, and pancreatic neuroendocrine tumors. Michaelson *et al., Randomized, Placebo-Controlled, Phase III Trial of Sunitinib Plus Prednisone Versus Prednisone Alone in Progressive, Metastatic, Castration-Resistant Prostate Cancer*, 32(2) J. Clin. Oncol. 76-83, 76-77 (2014). Three phase II trials of sunitinib in progressive mCRPC "suggested antitumor activity" and an acceptable safety profile. *Id.* at 77. A phase III study was performed comparing sunitinib plus prednisone to prednisone alone in men with progressive mCRPC after docetaxel-based chemotherapy. *Id.* The study was terminated early based on the recommendation of the data monitoring committee after a second interim analysis determined that a difference in overall survival, the primary endpoint, was statistically improbable. *Id.* at 77. Patient tolerability was described as "poor" with 27% of patients halting sunitinib treatment before disease progression because of toxicity. *Id.* at 80.