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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 10/29/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER
SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
10/29/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

apeters@honigman.com
hberven@honigman.com
patent@honigman.com

EXELIXIS 2013
Azurity v. Exelixis
IPR2025-00210

APPLICATION NO.	ISSUE DATE	PATENT NO.
18/436,836	29-Oct-2024	12128039

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Kalamazoo, MI 49002-0402

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	10/29/2024	12128039	224990/10-039C11US/543389	5374

91684 7590 10/09/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

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 Center (https://patentcenter.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 Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Jo Ann Wilson, San Francisco, CA;
Khalid Shah, Half Moon Bay, CA;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Exelixis, Inc., Alameda, CA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18436836
Filing Date	2024-02-08
First Named Inventor	Jo Ann Wilson
Art Unit	1625
Examiner Name	Seaman, D Margaret M.
Attorney Docket Number	224990/10-039C11US/543389

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	11091439		2021-08-17	Exelixis, Inc.	
Change(s) applied to document, /J.H./ 10/2/2024	2	11098015		2021-08-24	Brown et al. ~~Exelixis, Inc~~.	
	3	11091440		2021-08-17	Exelixis, Inc.	
	4	11298349		2021-06-03	Exelixis, Inc.	
	5	6030643		2000-02-29	Adams et al. ~~G.D. Searle & Co~~.	

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

U.S.PATENT APPLICATION PUBLICATIONS

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

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

FOREIGN PATENT DOCUMENTS

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

Change(s) applied to document, /K.P./ 5/6/2024	39	20140323522		10 2014-~~08~~-14	~~EXELIXIS, INC.~~ Aftab et al.	
	40	20150057310		02/2015 ~~2014-10-09~~	~~EXELIXIS, INC.~~ Brown et al.	
	41	20150196545		07/2015 ~~2014-10-30~~	~~EXELIXIS, INC.~~ Aftab et al.	
	42	20150202196		7 2015-0~~7~~-26	~~EXELIXIS, INC.~~ Bannen et al.	
	43	20150376133		12 2015-~~07~~-16	~~EXELIXIS, INC.~~ Bannen et al.	
	44	20160000772		01/2016 ~~2015-07-23~~	~~EXELIXIS, INC.~~ Aftab et al.	
	45	20160051532		02/2016 ~~2015-12-31~~	~~EXELIXIS, INC.~~ Aftab et al.	
	46	20160185725		6 2016-0~~7~~-07	~~EXELIXIS, INC.~~ Bannen et al.	
	47	20050209247		2005-09-22	~~CHIRON CORPORATION~~ Cai et al.	
	48	20070078159		2007-04-05	MATSUSHIMA, et al.	
	49	20110059081		2011-03-10	~~QUINTILES TRANSNATIONAL CORP.~~ Bacus	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

Change(s) applied to document, /K.P./ 5/6/2024	28	20130330377		12 2013-~~09~~-26	~~EXELIXIS, INC.~~ Wilson	
	29	20130337015		12 2013-~~09~~-26	~~EXELIXIS, INC.~~ Wilson	
	30	20140057943		02/2014 ~~2013-12-12~~	~~EXELIXIS, INC.~~ Smith et al.	
	31	20140057908		02/2014 ~~2013-12-19~~	~~EXELIXIS, INC.~~ Smith et al.	
	32	20140066444		3 2014-~~02~~-27	~~EXELIXIS, INC.~~ Smith et al.	
	33	20140155396		6 2014-~~02~~-27	~~EXELIXIS, INC.~~ Bannen et al.	
	34	20140179736		6 2014-~~03~~-06	~~EXELIXIS, INC.~~ Schwab et al.	
	35	20070054928		2007-03-08	BANNEN, et al.	
	36	20140200242		7 2014-~~06~~-05	~~EXELIXIS, INC.~~ Wilson	
	37	20140228401		8 2014-~~06~~-26	~~EXELIXIS, INC.~~ Aftab et al.	
	38	20140302012		10 2014-~~07~~-17	~~EXELIXIS, INC.~~ DeCillis et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

Change(s) applied to document. /K.P./ 5/6/2024	17	20120070368		2012-03-22	~~EXELIXIS, INC.~~ Bannen et al.	
	18	20120184523		2012-07-19	~~EXELIXIS, INC.~~ Bannen et al.	
	19	20120252840		2012-10-04	~~EXELIXIS, INC.~~ Aftab et al.	
	20	20120282179		2012-11-08	~~EXELIXIS, INC.~~ Aftab et al.	
	21	20130030172		2013-01-31	~~EXELIXIS, INC.~~ Wilson et al.	
	22	20130142790		2013-06-31	~~EXELIXIS, INC.~~ Gilmer et al.	
	23	20130143881		2013-06-31	~~EXELIXIS, INC.~~ Cannon et al.	
	24	20130150363		2013-06-06	~~EXELIXIS, INC.~~ Gilmer et al.	
	25	20130197230		2013-08-06	~~EXELIXIS, INC.~~ Wilson et al.	
	26	20130252940		2013-09-13	~~EXELIXIS, INC.~~ Bannen et al.	
	27	20130252956		2013-09-01	~~EXELIXIS, INC.~~ Kallender et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	6	20150202196		2015-07-23	BANNEN, et al.	
	7	20160000772		2016-01-07	AFTAB, et al.	
	8	20160051532		2016-02-25	AFTAB, et al.	
	9	20160229805		2016-08-11	WILSON, et al.	
	10	20170143689		2017-05-25	WILSON, et al.	
	11	20170266178		2017-09-21	WILSON, et al.	
	12	20170275251		2017-09-28	BROWN, et al.	
	13	20180002289		2018-01-04	BROWN, et al.	
	14	20180037552		2018-02-08	BROWN, et al.	
Change(s) applied to document, /K.P./ 5/6/2024	15	20090274693		2009-11-05	~~EXELIXIS, INC.~~ Gilmer et al.	
	16	20110077233		2011-03-31	~~EXELIXIS, INC.~~ Bannen et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

Change(s) applied to document, /K.P./ 5/6/2024	9	8476298		2013-07-02	~~EXELIXIS, INC.~~ Bannen et al.	
	10	8497284		2013-07-30	~~EXELIXIS, INC.~~ Bannen et al.	
	11	8673912		2014-03-18	~~EXELIXIS, INC.~~ Cannon et al.	
	12	8877776		2014-11-04	~~EXELIXIS, INC.~~ Brown et al.	
	13	9174947		2015-11-03	~~EXELIXIS, INC.~~ Bannen et al.	
	14	9365516		2016-06-14	~~EXELIXIS, INC.~~ Wilson et al.	
	15	7166722		2007-01-23	MATSUNAGA, et al.	
	16	7169789		2007-01-30	KUBO, et al.	
	17	5358941		1994-10-25	BECHARD, et al.	
	18	9717720		2017-08-01	WILSON, et al.	
	19	9969692		2018-05-15	WILSON, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2024-02-08
First Named Inventor	Jo Ann Wilson
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	224990/10-039C11US/543389

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	9724342		2017-08-08	WILSON, et al.	
	2	9809549		2017-11-07	BROWN, et al.	
Change(s) applied to document, /K.P./ 5/6/2024	3	7579473		2009-08-25	~~EXELIXIS, INC.~~ Bannen et al.	
	4	7977345		2011-07-12	~~EXELIXIS, INC.~~ Bannen et al.	
	5	7999006		2011-08-16	~~EXELIXIS, INC.~~ Lamb	
	6	8067436		2011-11-29	~~EXELIXIS, INC.~~ Bannen et al.	
	7	8178532		2012-05-15	~~EXELIXIS, INC.~~ Bannen et al.	
	8	8314232		2012-11-20	~~EXELIXIS, INC.~~ Deschamps et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

HONIGMAN

Li Gao, Ph.D.
Office: 517.377.0708
Mobile: 517.256.2694
lgao@honigman.com

Via Patent Center

September 27, 2024

Mail Stop ISSUE FEE
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313

Re: US Patent Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024
Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds
Attorney Docket No.: 224990/10-039C11-US/543389

Dear Sir or Madam:

Enclosed for filing please find the following documents:

1. This Cover Letter to the Commissioner for Patents;
2. Fee Transmittal (PTOL-85 Part B); and
3. Certificate of Transmission under 37 C.F.R. § 1.8(a).

The Applicant believes that due with this submission is the $1,200.00 Issue Fee set forth in 37 C.F.R. § 1.18(a)(1). The Applicant hereby authorizes the Patent Office to charge this total of $1,200.00 to Deposit Account Number 503145 with reference to attorney docket number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Very truly yours,

HONIGMAN LLP

/Li Gao, Ph.D./

Li Gao, Ph.D.
Reg. No. 71,343

LXG/ayp
Enclosures

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

91684 7590 08/22/2024
JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

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 transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

TITLE OF INVENTION: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	11/22/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
SEAMAN, D MARGARET M	1625	514-312000

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/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or 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 Honigman LLP
2 Heidi M. Berven, Ph.D.
3 Li Gao, Ph.D.

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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Exelixis, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Alameda, CA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☑ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☑ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☑ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 503145

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 /Li Gao, Ph.D./ Date September 27, 2024

Typed or printed name Li Gao, Ph.D. Registration No. 71,343

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: 1625
Examiner: Seaman, D. Margaret M.
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8(a)

The undersigned hereby certifies that the following documents are being submitted in accordance with 37 C.F.R. § 1.6(a)(4) on the 27th day of September 2024.

1. Cover Letter to the Commissioner for Patents;
2. Fee Transmittal (PTOL-85 Part B); and
3. This Certificate of Transmission under 37 C.F.R. § 1.8(a).

/Amy L. Peters/

Amy L. Peters (for Li Gao, Ph.D., Reg. No. 71,343)

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**09/27/2024 02:22:46 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	67355036	AUTHORIZED BY	Li Gao
CUSTOMER #	91684	FILING DATE	02/08/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jo Ann Wilson

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 503145	**E20249QE23089405**	**Amy Peters**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1501	UTILITY ISSUE FEE	1200.00	1	1200.00
			TOTAL AMOUNT:	**$1,200.00**

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage

submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**09/27/2024 02:22:46 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

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CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	67355036	FILING DATE	02/08/2024
CUSTOMER #	91684	FIRST NAMED INVENTOR	Jo Ann Wilson
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Li Gao

Documents

TOTAL DOCUMENTS: 3

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs.pdf		3	-	407 KB
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs-LET..pdf	(1-1)	1	Miscellaneous Incoming Letter	190 KB
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs-IFEE.pdf	(2-2)	1	Issue Fee Payment (PTO-85B)	128 KB
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs-LET..pdf	(3-3)	1	Miscellaneous Incoming Letter	95 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs.pdf	55A7868CF3980597B1CCD1FE8AFADB5FD3B58B25F41EE25B0DD6722DD8613D964C4127F2FF9CA6C751604975021FC88583B14BF022394CBC59C0D34E50E3867C
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs-LET..pdf	DC9358253A5BCA728059C1CE4A38A909109E8271FD8F986559D2410EFBC9BE1B0B7B2F91C092FFF796DAA1C9D79073C25F27A7508D79754FE23A3435E99C4456
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs-IFEE.pdf	E6BD8370680B528C1AC67F683D735A72E42A0E4FA8F4746C72B3CF8A77B99CC8879DBB4F37CDD9EF139507BE878EDC43FFA0DD5874EFE337D4AD4C61408F4426
2024-09-27_EX10-039C11-US_Issue_Fee_Payment_Docs-LET..pdf	409D63D0476EB42E1EABE9CFE6FBF855E8B877B9A4204120326F2F08F5AEE4263FD8A64CE7AA15E1702BC4E2E7829E4906BD706A0264F07C0790A21D8ACC7A0E

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

91684 7590 08/22/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/22/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

TITLE OF INVENTION: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	11/22/2024

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

91684 7590 08/22/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

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 transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

TITLE OF INVENTION: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	11/22/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
SEAMAN, D MARGARET M	1625	514-312000

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

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. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 08/22/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/22/2024

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 30 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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) 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));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/436,836	Applicant(s) Wilson et al.	
	Examiner D MARGARET M SEAMAN	Art Unit 1625	AIA (FITF) 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 paper dated 08/06/2024.
   ☐ 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 35-56 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ 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 _____.

/D MARGARET M SEAMAN/
Primary Examiner, Art Unit 1625

Notice of Pre-AIA or AIA Status

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

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: The rejections of record in paper dated 07/31/2024 have been overcome by applicant's arguments in paper dated 08/06/2024. Claims 35-56 are in condition for allowance.

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D MARGARET M SEAMAN whose telephone number is (571)272-0694. The examiner can normally be reached M-F 8am-4pm Eastern.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Kosar can be reached on 571-272-0913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D MARGARET M SEAMAN/
Primary Examiner, Art Unit 1625

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

CPC						
Symbol					**Type**	**Version**
A61K	/	31	/	47	F	2013-01-01
C07D	/	215	/	233	I	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	22	
/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625	19 August 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61K	/	31	/	47	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 22	
/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625 (Primary Examiner) 19 August 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure none

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 22	
/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625 (Primary Examiner) (Date) 19 August 2024	O.G. Print Claim(s) 1	O.G. Print Figure none

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

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

CLAIM		DATE								
Final	Original	04/01/2024	04/22/2024	07/26/2024	08/19/2024					
	1	-								
	2	-								
	3	-								
	4	-								
	5	-								
	6	-								
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	37	✓	=	✓	=					
	38	✓	=	✓	=					
	39	✓	=	✓	=					
	40	✓	=	✓	=					
	41	✓	=	✓	=					
	42	✓	=	✓	=					

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

CLAIM		DATE								
Final	Original	04/01/2024	04/22/2024	07/26/2024	08/19/2024					
	43	✓	=	✓	=					
	44	✓	=	✓	=					
	45	✓	=	✓	=					
	46	✓	=	✓	=					
	47	✓	=	✓	=					
	48	✓	=	✓	=					
	49	✓	=	✓	=					
	50	✓	=	✓	=					
	51	✓	=	✓	=					
	52	✓	=	✓	=					
	53	✓	=	✓	=					
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	56	✓	=	✓	=					

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

CPC - Searched*		
Symbol	**Date**	**Examiner**
C07D2158/233	04/01/2024	dms
A61K31/47	04/01/2024	dms
above updated	04/22/2024	dms
above updated	07/26/2024	dms
above updated	08/19/2024	dms

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
InventorName Search	04/01/2024	dms
parent patent search	04/01/2024	dms
updated invenor name search	04/22/2024	dms
update inventor name search	07/26/2024	dms
updated inventor name search	08/19/2024	dms

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
C07D	215/233	08/19/2024	dms
A61K	31/47	08/19/2024	dms

Bibliographic Data

Application No: 18/436,836

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /D MARGARET M SEAMAN/ (Examiner's Signature) [ ] (Initials)

Title: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
02/08/2024 RULE	514	1625	224990/10-039C11US/543389

APPLICANTS

Exelixis, Inc., Alameda, CA, UNITED STATES

INVENTORS

Jo Ann Wilson, San Francisco, CA, UNITED STATES

Khalid Shah,

CONTINUING DATA

This application is a CON of 18462739 09/07/2023ABN

18462739 is a CON of 17679634 02/24/2022ABN

17679634 is a CON of 17170275 02/08/2021 PAT 11298349

17170275 is a CON of 17152394 01/19/2021ABN

17152394 is a CON of 16706323 12/06/2019ABN

16706323 is a DIV of 16151653 10/04/2018 PAT 10543206

16151653 is a DIV of 15348716 11/10/2016 PAT 10123999

15348716 is a DIV of 13984559 03/20/2014 PAT 9717720

13984559 is a 371 of PCT/US2012/024591 02/10/2012

PCT/US2012/024591 has PRO of 61441520 02/10/2011

PCT/US2012/024591 has PRO of 61441527 02/10/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/22/2024

STATE OR COUNTRY

UNITED STATES

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Suite 200
Kalamazoo, MI 49002-0402
UNITED STATES

FILING FEE RECEIVED

$6,560

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 08/09/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
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650 Trade Centre Way
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EXAMINER	
SEAMAN, D MARGARET M	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
08/09/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

apeters@honigman.com
hberven@honigman.com
patent@honigman.com

Applicant-Initiated Interview Summary	**Application No.** 18/436,836	**Applicant(s)** Wilson et al.		
	Examiner D MARGARET M SEAMAN	**Art Unit** 1625	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
D MARGARET M SEAMAN	Primary Examiner	Telephonic
Li Gao	Attorney	

Date of Interview: 06 August 2024

Issues Discussed:

Non-statutory Double Patenting

ODP of record in paper dated 07/31/2024 have been overcome by the arguments presented in the interview summary of 08/06/2024. These arguments will be presented in the official response to the office action dated 07/31/2024.

/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

UNITED STATES
PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**08/06/2024 03:39:16 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	66675413	FILING DATE	02/08/2024
CUSTOMER #	91684	FIRST NAMED INVENTOR	Jo Ann Wilson
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Li Gao

Documents

TOTAL DOCUMENTS: 4

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2024-08-06_EX10-039C11-US_Response_Docs.pdf		8	-	411 KB
2024-08-06_EX10-039C11-US_Response_Docs-LET..pdf	(1-1)	1	Miscellaneous Incoming Letter	119 KB
2024-08-06_EX10-039C11-US_Response_Docs-A....pdf	(2-2)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	105 KB
2024-08-06_EX10-039C11-US_Response_Docs-REM.pdf	(3-7)	5	Applicant Arguments/Remarks Made in an Amendment	193 KB
2024-08-06_EX10-039C11-US_Response_Docs-	(8-8)	1	Miscellaneous Incoming Letter	94 KB

LET..pdf

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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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 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.

HONIGMAN

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lgao@honigman.com

Via Patent Center

August 6, 2024

Commissioner for Patents
United States Patent and Trademark Office
P. O. Box 1450
Alexandria, VA 22313

Re: US Patent Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024
Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds
Attorney Docket No.: 224990/10-039C11-US/543389

Dear Sir or Madam:

Enclosed for filing please find the following documents:

1. This Cover Letter to the Commissioner for Patents;
2. Response to Non-Final Office Action dated July 31, 2024; and
3. Certificate of Transmission under 37 C.F.R. § 1.8(a).

It is believed that no fees are due for this submission. However, if there are any charges required, or any credits, directly related to this filing, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Very truly yours,

HONIGMAN LLP

/Li Gao, Ph.D./

Li Gao, Ph.D.
Reg. No. 71,343

LXG/ayp
Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: 1625
Examiner: Seaman, D. Margaret M.
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

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

RESPONSE TO NON-FINAL OFFICE ACTION DATED JULY 31, 2024

This submission is responsive to the Non-Final Office Action in this application dated July 31, 2024.

Applicant's Remarks begin on page 2.

REMARKS

Claim Status

Claims 35-56 are currently pending in this application. No amendment has been made to the claims.

Interview Summary

The Applicant's representatives Li Gao, Ph.D. (Reg. No. 71,343) and Heid M. Berven, Ph.D. (Reg. No. 48,951), thank Examiner Seaman for the telephone interview held on August 6, 2024 regarding the Office Action dated July 31, 2024. The interview focused on the Applicant's reasons for why the double patenting rejections raised by Examiner Seaman in the Office Action dated July 31, 2024 should be withdrawn. Examiner Seamen agreed with the Applicant, and indicated that the double patenting rejections would be removed and the claims would be allowed upon the filing of a response.

Double Patenting

In the Office Action dated July 31, 2024, the Examiner rejected claims 35-56 on the ground of nonstatutory double patenting as being unpatentable over claims of the following patents.

(1) U.S. Patent No. 11091439;

(2) U.S. Patent No. 12016854;

(3) U.S. Patent No. 11091440;

(4) U.S. Patent No. 11298349;

(5) U.S. Patent No 11504362; and

(6) U.S. Patent No. 11433064.

According to the Examiner, although the claims of the currently pending application are not identical, they are not patentably distinct from the claims of the reference patents, because "the claims are drawn to pharmaceutical compositions and methods of treatment. (Office Action, page 3)." "The specification teaches that the pure and crystalline compositions are substantially pure compounds/salts. (Office Action, page 4)." As a result, the Examiner alleges the currently pending claims are double patenting over the cited patents.

The Applicant respectfully disagrees. The doctrine of double patenting in general and nonstatutory double patenting in particular seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. As between the claims of a pending application and a reference patent, the Examiner must determine whether the grant of a second patent would give rise to an unjustified extension of the rights granted in the first patent. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). (Office Action, page 2, citing *In re Berg*, 140 F.3d 1428 (Fed. Cir. 1998)).

The patents asserted by Examiner do not meet these requirements. The Applicant addresses each of the patent references cited by the Examiner in order in the following paragraphs, and requests withdrawal of the rejections and allowance of the currently pending claims.

(1) U.S. Patent No. 11091439

The currently pending claims are patentably distinct over the claims of U.S. Patent No. 11091439 (the '439 Patent).

Claims 1-5 of US 11091439 (the '439 Patent) are directed to crystalline malate salts of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N′-(4-fluorophenyl) cyclopropane-1,1-dicarboxamide, which is Compound IA of the present application. Compound IA is also known as cabozantinib. In contrast, claims 35-56 of the present application are directed to a pharmaceutical composition of Compound IB (cabozantinib L-malate salt) that contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol as well as a method of treating cancer using the pharmaceutical composition. In short, claims 1-5 of the '439 Patent do not recite a pharmaceutical composition or a method of treating cancer, nor that the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

In the Office Action, the Examiner asserted that "the specification teaches that the pure and crystalline compositions are substantially pure compounds/salts" (Office Action, page 4). The Applicant respectfully disagrees.

First, the '439 Patent discloses that the crystalline form of cabozantinib malate salt is

"substantially pure N-1 form" or "substantially pure N-2 form" (Col. 9, lines 26-33). This disclosure, however, does not teach or suggest that a pharmaceutical composition of cabozantinib is substantially pure. Furthermore, "substantially pure" is defined in the '439 Patent as containing "at least about 90% wt.%" (Col. 18, lines 40-52). As stated above, the claimed composition contains 100 ppm or less 6,7-dimethoxy-quinoline-4-ol, which is equivalent to 0.01 wt.% or less. The '439 Patent does not disclose or suggest this level of purity of a pharmaceutical composition of Compound IB.

Because a person of ordinary skill in the art could not envision the pharmaceutical compositions as currently claimed by the Applicant, the claims are novel, non-obvious, and patenably distinct over claims 1-5 of the '439 Patent.

The Applicant therefore respectfully requests withdrawal of the rejection.

(2) US Patent No. 12016854

As a first matter, U.S. Patent No. 12016854 (the '854 Patent) has an expiration date of June 8, 2038, while the present application is expected to expire February 10, 2032. Thus, the term of the present patent application, once issued, would end six years earlier and would not extend beyond the expiration date of the '854 Patent. In short, there would be no unjustified extension of the rights granted in the '854 Patent if the currently pending claims are allowed and issued.

Moreover, the currently pending claims are patentably distinct over the claims of the '854 Patent. Claims 1-7 of the '854 Patent are directed to a liquid pharmaceutical composition containing cabozantinib, ethanol, d-α-tocopheryl polyethylene glycol succinate, and polyethyleneglycol. The '854 Patent does not disclose or suggest that the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. Thus, the currently pending claims are novel, nonobvious, and patentably distinct over claims 1-7 of the '854 Patent.

The Applicant therefore respectfully requests withdrawal of the rejection.

(3) US Patent No. 11091440

The currently pending claims are patentably distinct over the claims of U.S. Patent No. 11091440 (the '440 Patent). Claims 1-3 of the '440 Patent are directed to a pharmaceutical

composition comprising crystalline cabozantinib malate salts. The claims do not recite that the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol, as in the currently pending claims.

In addition, the '440 Patent shares the same specification as the '439 Patent. As stated above, the specification discloses "substantially pure N-1 form" or "substantially pure N-2 form" of cabozantinib malate salt, but not a pharmaceutical composition containing 100 ppm or less 6,7-dimethoxy-quinoline-4-ol.

Because a person of ordinary skill in the art could not envision the pharmaceutical compositions as currently claimed by the Applicant, the claims are novel, non-obvious, and patenably distinct from claims 1-3 of the '440 Patent.

The Applicant therefore respectfully requests withdrawal of the rejection.

(4) U.S. Patent No. 11298349

The Applicant respectfully submits that in the course of prosecution of the instant application, on April 19, 2024, a terminal disclaimer to U.S. Patent No. 11298349 (the '349 Patent) was filed.

The Applicant therefore respectfully requests withdrawal of the rejection.

(5) U.S. Patent No. 11504362

As a first matter, U.S. Patent No. 11504362 (the '362 Patent) has an expiration date of June 8, 2038, while the present application is expected to expire February 10, 2032. Thus, the term of the present patent application, once issued, would end six years earlier and would not extend beyond the expiration date of the '362 Patent. In short, there would be no unjustified extension of the rights granted in the '362 Patent if the currently pending claims are allowed and issued.

Moreover, the currently pending claims are patentably distinct over the claims of the '362 Patent. Claims 1-13 of the '362 Patent are directed to a liquid pharmaceutical composition comprising cabozantinib (S)-malate, from 50% to 95% polyethyleneglycols (w/w), from 1% to 30% d-α-tocopheryl polyethylene glycol succinate (w/w), and from 0.5% to 20% ethanol (w/w). The '362 Patent shares the same specification as the '854 Patent and does not disclose or suggest

that the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. Thus, claims 35-56 of the present application are novel, nonobvious, and patentably distinct over claims 1-13 of the '362 Patent.

The Applicant therefore respectfully requests withdrawal of the rejection.

(6) U.S. Patent No. 11433064

The currently pending claims are patentably distinct over the claims of U.S. Patent No. 11433064 (the '064 Patent). Claims 1-4 of the '064 Patent are directed to a method of treating glioblastoma using cabozantinib in combination with one or both of temozolomide and radiation. The claims and specification of the '064 Patent do not disclose or suggest a pharmaceutical composition containing 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. Thus, claims 35-56 of the present application are novel, nonobvious, and patentably distinct over claims 1-4 of the '064 Patent. The Applicant therefore respectfully requests withdrawal of the rejection.

CONCLUSION & FEES DUE

The Applicant believes this submission is fully responsive to the Non-Final Office Action in this application dated July 31, 2024. The Applicant reserves the right to file divisional applications or take such other appropriate action as deemed necessary to protect the subject matter restricted, cancelled, or withdrawn from this application.

It is believed that no fees are due at this time. However, if there are any charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Respectfully submitted,

HONIGMAN LLP

/Li Gao, Ph.D./

Dated: August 6, 2024

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: 1625
Examiner: Seaman, D. Margaret M.
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8(a)

The undersigned hereby certifies that the following documents are being submitted in accordance with 37 C.F.R. § 1.6(a)(4) on the 6th day of August 2024.

1. Cover Letter to the Commissioner for Patents;
2. Response to Non-Final Office Action dated July 31, 2024; and
3. This Certificate of Transmission under 37 C.F.R. § 1.8(a).

/Amy L. Peters/

Amy L. Peters (for Li Gao, Ph.D., Reg. No. 71,343)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 07/31/2024

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HONIGMAN LLP
650 Trade Centre Way
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Kalamazoo, MI 49002-0402

EXAMINER	
SEAMAN, D MARGARET M	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
07/31/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

apeters@honigman.com
hberven@honigman.com
patent@honigman.com

Office Action Summary	Application No. 18/436,836	Applicant(s) Wilson et al.	
	Examiner D MARGARET M SEAMAN	Art Unit 1625	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on RCE dated07/17/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 35-56 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 35-56 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159.

See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

3. Claims 35-56 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims of U.S. Patent No. 11091439, 12016854, 11091440, 11298349, 11504362 and 11433064. Although the claims at issue are not identical, they are not patentably distinct from each other because the claims are drawn to pharmaceutical compositions and

methods of treatment using pure compound (L) maleic salt. The specification teaches that the pure and crystalline compositions are substantially pure compounds/salts. Due to this, the instant claims are double patenting over the cited prior patents.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D MARGARET M SEAMAN whose telephone number is (571)272-0694. The examiner can normally be reached M-F 8am-4pm Eastern.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Kosar can be reached on 571-272-0913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D MARGARET M SEAMAN/
Primary Examiner, Art Unit 1625

Notice of References Cited	Application/Control No. 18/436,836	Applicant(s)/Patent Under Reexamination Wilson et al.	
	Examiner D MARGARET M SEAMAN	Art Unit 1625	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-11091439-B2	2021-08-17	Brown; Adrian St. Clair	A61P5/14	1/1
*	B	US-12016854-B2	2024-06-25	Shah; Khalid	A61K31/47	1/1
*	C	US-11091440-B2	2021-08-17	Brown; Adrian St. Clair	A61P43/00	1/1
*	D	US-11298349-B2	2022-04-12	Wilson; Jo Ann	A61P35/00	1/1
*	E	US-11504362-B2	2022-11-22	Shah; Khalid	A61K9/0095	1/1
*	F	US-11433064-B2	2022-09-06	Aftab; Dana T.	A61K45/06	1/1
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

CPC - Searched*		
Symbol	**Date**	**Examiner**
C07D2158/233	04/01/2024	dms
A61K31/47	04/01/2024	dms
above updated	04/22/2024	dms
above updated	07/26/2024	dms

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
InventorName Search	04/01/2024	dms
parent patent search	04/01/2024	dms
updated invenor name search	04/22/2024	dms
update inventor name search	07/26/2024	dms

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
C07D	215/233	04/22/2024	dms
A61K	31/47	04/22/2024	dms

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

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

CLAIM		DATE								
Final	Original	04/01/2024	04/22/2024	07/26/2024						
	1	-								
	2	-								
	3	-								
	4	-								
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	39	✓	=	✓						
	40	✓	=	✓						
	41	✓	=	✓						
	42	✓	=	✓						

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

CLAIM		DATE								
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	52	✓	=	✓						
	53	✓	=	✓						
	54	✓	=	✓						
	55	✓	=	✓						
	56	✓	=	✓						

Bibliographic Data

Application No: 18/436,836

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /D MARGARET M SEAMAN/ (Examiner's Signature) [ ] (Initials)

Title: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
02/08/2024 RULE	514	1625	224990/10-039C11US/543389

APPLICANTS

Exelixis, Inc., Alameda, CA, UNITED STATES

INVENTORS

Jo Ann Wilson, San Francisco, CA, UNITED STATES

Khalid Shah,

CONTINUING DATA

This application is a CON of 18462739 09/07/2023ABN

18462739 is a CON of 17679634 02/24/2022ABN

17679634 is a CON of 17170275 02/08/2021 PAT 11298349

17170275 is a CON of 17152394 01/19/2021ABN

17152394 is a CON of 16706323 12/06/2019ABN

16706323 is a DIV of 16151653 10/04/2018 PAT 10543206

16151653 is a DIV of 15348716 11/10/2016 PAT 10123999

15348716 is a DIV of 13984559 03/20/2014 PAT 9717720

13984559 is a 371 of PCT/US2012/024591 02/10/2012

PCT/US2012/024591 has PRO of 61441520 02/10/2011

PCT/US2012/024591 has PRO of 61441527 02/10/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/22/2024

STATE OR COUNTRY

UNITED STATES

ADDRESS

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HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402
UNITED STATES

FILING FEE RECEIVED

$6,560

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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L17	1	("12016854").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:22 AM
L18	1	("11091439").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:26 AM
L19	1	("11724986").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:34 AM
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L33	1	("11124482").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:52 AM
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L35	1	("11141413").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:54 AM
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L37	1	("10543206").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:55 AM
L38	1	("10736886").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:56 AM
L39	1	("11198731").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:57 AM
L40	1	("10851061").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:59 AM
L41	1	("11279675").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:00 AM
L42	1	("11504362").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:01 AM
L43	1	("11123338").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:04 AM
L44	1	("11504363").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:04 AM
L45	1	("11612597").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:05 AM

L46	1	("11433064").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:06 AM
L47	1	("8497284").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:07 AM
L48	1	("8673912").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:08 AM
L49	1	("9724342").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:09 AM
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L53	1	("9861624").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:16 AM
L54	1	("10273211").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:16 AM
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L56	1	("7977345").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:18 AM
L57	1	("9174947").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:18 AM
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L60	1	("7579473").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:20 AM
L61	1	("11091439").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:46 AM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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L3	2	("10543206").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:54 PM
L4	6	("10123999").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:04 PM
L5	5	("9717720").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:12 PM
L6	6	"20120035212"	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:59 PM
L7	2	("8877776").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 03:21 PM
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L31	1	("10039757").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:51 AM
L32	1	("10034873").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:52 AM
L33	1	("11124482").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:52 AM
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L35	1	("11141413").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:54 AM
L36	1	("11116759").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:55 AM
L37	1	("10543206").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 09:55 AM
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L41	1	("11279675").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:00 AM
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L43	1	("11123338").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:04 AM
L44	1	("11504363").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:04 AM
L45	1	("11612597").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:05 AM

L46	1	("11433064").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:06 AM
L47	1	("8497284").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:07 AM
L48	1	("8673912").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:08 AM
L49	1	("9724342").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:09 AM
L50	1	("9717720").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:10 AM
L51	1	("10166225").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/07/26 10:15 AM
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PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18436836
Filing Date	2024-02-08
First Named Inventor	Jo Ann Wilson
Art Unit	1625
Examiner Name	Seaman, D Margaret M.
Attorney Docket Number	224990/10-039C11US/543389

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	11091439		2021-08-17	Exelixis, Inc.	
	2	11098015		2021-08-24	Exelixis, Inc.	
	3	11091440		2021-08-17	Exelixis, Inc.	
	4	11298349		2021-06-03	Exelixis, Inc.	
	5	6030643		2000-02-29	G.D. Searle & Co.	

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

U.S.PATENT APPLICATION PUBLICATIONS

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

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FOREIGN PATENT DOCUMENTS

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18436836
	Filing Date	2024-02-08
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	Attorney Docket Number	224990/10-039C11US/543389

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

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	BERGE et al., "Pharmaceutical salts," J Pharm. Sci., 66 (1): 1-19 (January 1977)	☐
	2	VIPPAGUNTA, et al., "Crystalline solids", Advanced Drug Delivery Reviews, Vol. 48, pp. 3-26, 2001	☐
	3	BIGHLEY, Lyle D., et al., Salt Forms of Drugs and Absorption, in 13 Encyclopedia of Pharmaceutical Technology 453 (James Swarbrick & James C. Boylan eds., 1995)	☐
	4	Herbert A. Lieberman et al., Pharmaceutical Dosage Forms: Tablets, Vol. 1 (2d. Ed., 1989) (PTX-553) Chap. 2-3	☐
	5	Esa Landenpaa et al., Crushing Strength, Disintegration Time and Weight Variation of Tablets Compressed from Three Avicel® PH Grades and Their Mixtures, 43 EURO. J. PHARMACEUTICS AND BIOPHARMACEUTICS 315 (1997) (DTX-355)	☐
	6	Mira Jivraj et al., An Overview of the Different Excipients Useful for the Direct Compression of Tablets, 3 PSTT 58 (2000) (DTX-344)	☐
	7	Tong et al., In situ Salt Screening—A Useful Technique for Discovery Support and Preformulation Studies, Phann. Dev. Technol. 3 (2), 215-223 (1998) (DTX-243)	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18436836
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	1625
	Examiner Name	Seaman, D Margaret M.
	Attorney Docket Number	224990/10-039C11US/543389

	8	FDA, Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances, Center for Drug Evaluation and Research (February 1987) (DTX-170)	☐
	9	FDA Guidance for Industry, Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommend Approaches (DTX-091)	☐
	10	Complaint for patent infringement - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 1 (D.Del. Feb. 23, 2022)	☐
	11	COMPLAINT for PATENT INFRINGEMENT - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00945, No. 1 (D.Del. Jul. 18, 2022)	☐
	12	ANSWER to 1 Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 9 (D.Del. Feb. 25, 2022)	☐
	13	ANSWER to 9 Answer to Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 15 (D.Del. Mar. 18, 2022)	☐
	14	ANSWER to Counterclaims - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 41 (D.Del. Aug. 30, 2022)	☐
	15	ANSWER to 37 Amended Answer to Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 46 (D.Del. Sep. 15, 2022)	☐
	16	Opening Post-Trial Brief on Invalidity - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 169 (D.Del. Dec. 12, 2023)	☐
	17	RESPONSIVE Post-Trial Brief on Noninfringement - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 173 (D.Del. Jan. 23, 2024)	☐
	18	Answer to 1 Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00945, No. 9 (D.Del. Aug. 9, 2022)	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
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	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
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	Examiner Name	Seaman, D Margaret M.
	Attorney Docket Number	224990/10-039C11US/543389

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

EXAMINER SIGNATURE

Examiner Signature	/D MARGARET M SEAMAN/	Date Considered	07/26/2024

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(**Not for submission under 37 CFR 1.99)**

Application Number	18436836
Filing Date	2024-02-08
First Named Inventor	Jo Ann Wilson
Art Unit	1625
Examiner Name	Seaman, D Margaret M.
Attorney Docket Number	224990/10-039C11US/543389

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Li Gao, Ph.D./	Date (YYYY-MM-DD)	2024-07-24
Name/Print	Li Gao, Ph.D.	Registration Number	71343

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

HONIGMAN

Li Gao, Ph.D.
Office: 517.377.0708
Mobile: 517.256.2694
lgao@honigman.com

Via Patent Center

July 24, 2024

Commissioner for Patents
United States Patent and Trademark Office
P. O. Box 1450
Alexandria, VA 22313

Re: US Patent Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024
Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds
Attorney Docket No.: 224990/10-039C11-US/543389

Dear Sir or Madam:

Enclosed for filing please find the following documents:

1. This Cover Letter to the Commissioner for Patents;
2. Request for Continued Examination;
3. Request for Continued Examination Transmittal (PTO/SB/30);
4. Information Disclosure Statement (PTO/SB/08a);
5. Non-Patent Literature (18 documents); and
6. Certificate of Transmission under 37 C.F.R. § 1.8(a).

It is believed that the Information Disclosure Statement filed herewith satisfies the requirement under 37 C.F.R. § 1.114 for a submission accompanying a Request for Continued Examination. The fee set forth in 37 C.F.R. § 1.17(e)(1) is also submitted herewith.

The Applicant notes that the filing of the enclosed Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement qualifies as prior art under 35 U.S.C. § § 102 or 103, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). It is believed that no fee is due pursuant to 37 C.F.R. § 1.97(b)(4).

It is believed that due for this submission is the $1,360.00 fee set forth in 37 C.F.R. § 1.17(e)(1) for a first Request for Continued Examination. The Applicant hereby authorizes the Office to charge this $1,360.00 to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges required, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Very truly yours,

HONIGMAN LLP

/Li Gao, Ph.D./

Li Gao, Ph.D.
Reg. No. 71,343

LXG/ayp
Enclosures

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	18/436,836	Filing Date	2024-02-08	Docket Number (if applicable)	224990/10-039C11-US/54338	Art Unit	1625
First Named Inventor	Jo Ann Wilson et al.			Examiner Name	D MARGARET M SEAMAN		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☐ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

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

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 503145

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Li Gao, Ph.D./	Date (YYYY-MM-DD)	2024-07-24
Name	Li Gao, Ph.D.	Registration Number	71343

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18436836
Filing Date	2024-02-08
First Named Inventor	Jo Ann Wilson
Art Unit	1625
Examiner Name	Seaman, D Margaret M.
Attorney Docket Number	224990/10-039C11US/543389

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	11091439		2021-08-17	Exelixis, Inc.	
	2	11098015		2021-08-24	Exelixis, Inc.	
	3	11091440		2021-08-17	Exelixis, Inc.	
	4	11298349		2021-06-03	Exelixis, Inc.	
	5	6030643		2000-02-29	G.D. Searle & Co.	

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

U.S.PATENT APPLICATION PUBLICATIONS

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

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

FOREIGN PATENT DOCUMENTS

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18436836
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	1625
	Examiner Name	Seaman, D Margaret M.
	Attorney Docket Number	224990/10-039C11US/543389

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

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	BERGE et al., "Pharmaceutical salts," J Pharm. Sci., 66 (1): 1-19 (January 1977)	☐
	2	VIPPAGUNTA, et al., "Crystalline solids", Advanced Drug Delivery Reviews, Vol. 48, pp. 3-26, 2001	☐
	3	BIGHLEY, Lyle D., et al., Salt Forms of Drugs and Absorption, in 13 Encyclopedia of Pharmaceutical Technology 453 (James Swarbrick & James C. Boylan eds., 1995)	☐
	4	Herbert A. Lieberman et al., Pharmaceutical Dosage Forms: Tablets, Vol. 1 (2d. Ed., 1989) (PTX-553) Chap. 2-3	☐
	5	Esa Landenpaa et al., Crushing Strength, Disintegration Time and Weight Variation of Tablets Compressed from Three Avicel® PH Grades and Their Mixtures, 43 EURO. J. PHARMACEUTICS AND BIOPHARMACEUTICS 315 (1997) (DTX-355)	☐
	6	Mira Jivraj et al., An Overview of the Different Excipients Useful for the Direct Compression of Tablets, 3 PSTT 58 (2000) (DTX-344)	☐
	7	Tong et al., In situ Salt Screening—A Useful Technique for Discovery Support and Preformulation Studies, Phann. Dev. Technol. 3 (2), 215-223 (1998) (DTX-243)	☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18436836
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	1625
	Examiner Name	Seaman, D Margaret M.
	Attorney Docket Number	224990/10-039C11US/543389

	8	FDA, Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances, Center for Drug Evaluation and Research (February 1987) (DTX-170)	☐
	9	FDA Guidance for Industry, Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommend Approaches (DTX-091)	☐
	10	Complaint for patent infringement - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 1 (D.Del. Feb. 23, 2022)	☐
	11	COMPLAINT for PATENT INFRINGEMENT - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00945, No. 1 (D.Del. Jul. 18, 2022)	☐
	12	ANSWER to 1 Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 9 (D.Del. Feb. 25, 2022)	☐
	13	ANSWER to 9 Answer to Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 15 (D.Del. Mar. 18, 2022)	☐
	14	ANSWER to Counterclaims - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 41 (D.Del. Aug. 30, 2022)	☐
	15	ANSWER to 37 Amended Answer to Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 46 (D.Del. Sep. 15, 2022)	☐
	16	Opening Post-Trial Brief on Invalidity - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 169 (D.Del. Dec. 12, 2023)	☐
	17	RESPONSIVE Post-Trial Brief on Noninfringement - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00228, No. 173 (D.Del. Jan. 23, 2024)	☐
	18	Answer to 1 Complaint - Exelixis, Inc. v. MSN Laboratories Private Limited et al, 1_22-cv-00945, No. 9 (D.Del. Aug. 9, 2022)	☐

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	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	1625
	Examiner Name	Seaman, D Margaret M.
	Attorney Docket Number	224990/10-039C11US/543389

If you wish to add additional non-patent literature document citation information please click the Add button			
EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	18436836
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	1625
	Examiner Name	Seaman, D Margaret M.
	Attorney Docket Number	224990/10-039C11US/543389

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Li Gao, Ph.D./	Date (YYYY-MM-DD)	2024-07-24
Name/Print	Li Gao, Ph.D.	Registration Number	71343

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: 1625
Examiner: Seaman, D. Margaret M.
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8(a)

The undersigned hereby certifies that the following documents are being submitted in accordance with 37 C.F.R. § 1.6(a)(4) on the 24th day of July 2024.

1. Cover Letter to the Commissioner for Patents;
2. Request for Continued Examination;
3. Request for Continued Examination Transmittal (PTO/SB/30);
4. Information Disclosure Statement (PTO/SB/08a);
5. Non-Patent Literature (18 documents); and
6. This Certificate of Transmission under 37 C.F.R. § 1.8(a).

/Amy L. Peters/

Amy L. Peters (for Li Gao, Ph.D., Reg. No. 71,343)

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**07/24/2024 12:29:04 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	66498617	FILING DATE	02/08/2024
CUSTOMER #	91684	FIRST NAMED INVENTOR	Jo Ann Wilson
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Li Gao

Documents

TOTAL DOCUMENTS: 23

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2024-07-24_EX10-039C11-US_RCE-IDS_Filing_Docs.pdf		16	-	412 KB
2024-07-24_EX10-039C11-US_RCE-IDS_Filing_Docs-LET..pdf	(1-2)	2	Miscellaneous Incoming Letter	122 KB
2024-07-24_EX10-039C11-US_RCE-IDS_Filing_Docs-RCEX.pdf	(3-8)	6	Request for Continued Examination (RCE)	129 KB
2024-07-24_EX10-039C11-US_RCE-IDS_Filing_Docs-	(9-10)	2	Request for Continued Examination (RCE)	37 KB

RCEX.pdf				
2024-07-24_EX10-039C11-US_RCE-IDS_Filing_Docs-IDS.pdf	(11-15)	5	Information Disclosure Statement (IDS) Form (SB08)	42 KB
2024-07-24_EX10-039C11-US_RCE-IDS_Filing_Docs-LET..pdf	(16-16)	1	Miscellaneous Incoming Letter	95 KB
NPL1_MSN2_BERGE_1977-2.pdf		19	Non Patent Literature	1224 KB
NPL2_MSN2_Vippagunta_2001_CrystallineSolids.pdf		24	Non Patent Literature	1785 KB
NPL3_MSN2_Bighley.pdf		49	Non Patent Literature	5160 KB
NPL4_MSN2_Herbert A. Lieberman.pdf		122	Non Patent Literature	7373 KB
NPL5_MSN2_Esa Landenpaa.pdf		8	Non Patent Literature	231 KB
NPL6_MSN2_Mira Jivraj.pdf		6	Non Patent Literature	139 KB
NPL7_MSN2_Tong.pdf		10	Non Patent Literature	816 KB
NPL8_MSN2_FDA Guideline.pdf		20	Non Patent Literature	454 KB
NPL9_MSN2_FDA Guidance.pdf		2	Non Patent Literature	81 KB
NPL10_MSN2_Complaint for patent infringement.pdf		14	Non Patent Literature	110 KB
NPL11_MSN2_COMPLAINT for PATENT INFRINGEMENT.pdf		9	Non Patent Literature	75 KB

NPL12_MSN2_ANSWER to 1 Complaint.pdf	21	Non Patent Literature	97 KB
NPL13_MSN2_ANSWER to 9 Answer to Complaint.pdf	10	Non Patent Literature	94 KB
NPL14_MSN2_ANSWER to Counterclaims.pdf	8	Non Patent Literature	58 KB
NPL15_MSN2_ANSWER to 37 Amended Answer to Complaint.pdf	16	Non Patent Literature	88 KB
NPL16_MSN2_Opening Post-Trial Brief on Invalidity.pdf	44	Non Patent Literature	1733 KB
NPL17_MSN2_RESPONSIVE Post-Trial Brief on Noninfringement.pdf	28	Non Patent Literature	1371 KB
NPL18_MSN2_Answer to 1 Complaint.pdf	15	Non Patent Literature	78 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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NPL4_MSN2_Herbert A. Lieberman.pdf	5DED8755DEC4B09B0420981B73D71AD55DC374853801C827C20A2E04953459505BD76A54531FA64D85EA01525598ED9DC054F0A220016B02074BB7B290F73A8C
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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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	07/24/2024 12:29:04 PM Z ET	224990/10-039C11US/543389

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	66498617	AUTHORIZED BY	Li Gao
CUSTOMER #	91684	FILING DATE	02/08/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jo Ann Wilson

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 503145	E20247NC29385911	Amy Peters

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1801	REQUEST FOR CONTINUED EXAMINATION (RCE) - 1ST REQUEST (SEE 37 CFR 1.114)	1360.00	1	1360.00
			TOTAL AMOUNT:	$1,360.00

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If a new application is being filed and the application includes the necessary components for 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

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: 1625
Examiner: Seaman, D. Margaret M.
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

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

REQUEST FOR CONTINUED EXAMINATION UNDER 37 C.F.R. § 1.114

This submission is responsive to the Notice of Allowance in this application dated May 1, 2024.

Remarks begin on page 2.

REMARKS

REQUEST FOR CONTINUED EXAMINATION

It is believed that the Information Disclosure Statement filed herewith satisfies the requirement under 37 C.F.R. § 1.114 for a submission accompanying a Request for Continued Examination. The fee set forth in 37 C.F.R. § 1.17(e)(1) is also submitted herewith.

INFORMATION DISCLOSURE STATEMENT

The Applicant notes that the filing of the enclosed Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement qualifies as prior art under 35 U.S.C. § § 102 or 103, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). It is believed that no fee is due pursuant to 37 C.F.R. § 1.97(b)(4).

OTHER C-MET INHIBITOR CASES

The Applicant wishes to make the Examiner aware of the Applicant's other applications related to c-Met inhibitors and their use in the treatment of cancer. For the Examiner's convenience, the Applicant is providing a list of the Applicant's applications directed to the treatment of cancer using c-Met inhibitors. The Applicant understands the Examiner has electronic access to these applications and to the Office Actions that have issued in these applications, and has therefore not included copies with this Response. The Applicant will gladly provide the applications and Office Actions to the Examiner, however, upon request.

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
10/573,336	09/18/2006		Koontz, Tammy J.	Abandoned
11/571,140	12/21/2006	7977345	Moore, Susanna	Expired
11/586,751	10/26/2006	9174947	Ward, Paul V.	Issued
11/753,462	05/24/2007	8178532	Ward, Paul V.	Issued
11/753,503	05/24/2007	8476298	Ward, Paul V.	Expired
11/753,514	05/24/2007	8067436	Bernhardt, Emily A.	Issued
12/393,806	02/26/2009	7579473	Seaman, D. Margaret M.	Issued
12/911,442	10/25/2010		Ward, Paul, V.	Abandoned
13/087,094	04/14/2011		Chickos, Sarah, J.	Abandoned
13/129,183	05/13/2011		Seaman, D. Margaret M.	Abandoned

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
13/132,650	06/03/2011		Seaman, D. Margaret M.	Abandoned
13/145,054	10/20/2011	8877776	Carter, Kendra D	Issued
13/249,815	09/30/2011	8497284	Bernhardt, Emily A.	Issued
13/384,451	07/12/2012	8673912	Anderson, Rebecca L.	Issued
13/389,266	07/12/2012		Perreira, Melissa Jean	Abandoned
13/427,093	03/22/2012		Ward, Paul V.	Abandoned
13/438,964	04/04/2012		Brown-Pettigrew, Angela C.	Abandoned
13/634,275	09/12/2012		Anderson, Rebecca L.	Abandoned
13/753,031	01/29/2013		Pagonakis, Anna	Abandoned
13/753,146	01/29/2013		Pagonakis, Anna	Abandoned
13/810,537	08/26/2013	9724342	Pallay, Michael B.	Issued
13/810,546	08/27/2013		Branson, Daniel L.	Abandoned
13/876,290	11/05/2013		Stone, Christopher R.	Abandoned
13/876,306	11/08/2013		Lee, Andrew P.	Abandoned
13/876,318	10/25/2013		Karol, Jody Lynn	Abandoned
13/888,592	05/07/2013		Ward, Paul V.	Abandoned
13/928,977	06/27/2013		Bernhardt, Emily A.	Abandoned
13/984,559	03/20/2014	9717720	Rozof, Timothy R.	Issued
14/021,614	09/09/2013		Matos Negron, Taina Del Mar	Abandoned
14/115,236	02/28/2014		Anderson, James D.	Abandoned
14/166,545	01/28/2014		Not Yet Assigned	Abandoned
14/173,973	02/06/2014		Johannsen, Diana B.	Abandoned
14/340,871	07/25/2014	9809549	Carter, Kendra D.	Issued
14/346,570	03/21/2014	10166225	Wang, Shengjun	Issued
14/353,251	04/21/2014	9365516	Murray, Jeffrey H.	Issued
14/356,927	05/08/2014		Baek, Bong-Sook	Abandoned
14/356,938	05/08/2014		Cerioni, Daniel Lee	Abandoned
14/398,188	10/31/2014	9861624	Henley III, Raymond J.	Issued
14/426,580	03/06/2015		Jean-Louis, Samira J.M.	Abandoned
14/518,733	10/20/2014		Wright, Sarah C.	Abandoned
14/668,312	03/25/2015		Brown-Pettigrew, Angela C.	Abandoned
14/699,683	04/29/2015		Perreira, Melissa Jean	Abandoned
14/776,337	09/14/2015	10273211	Badio, Barbara P.	Issued
14/782,493	10/05/2015		Saeed, Kamal A.	Abandoned
14/782,537	10/05/2015	11564915	Alley, Genevieve S.	Issued
14/843,480	09/02/2015		Shen, Wu Cheng Winston	Abandoned
14/847,801	09/08/2015		Ward, Paul V.	Abandoned
14/933,801	11/05/2015		Brown-Pettigrew, Angela C.	Abandoned
15/066,872	03/10/2016		Ward, Paul V.	Abandoned

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
15/118,738	08/12/2016	10501418	Chandrakumar, Nizal S.	Issued
15/126,767	09/16/2016	10159666	Solola, Taofiq A.	Issued
15/133,708	04/20/2016	9969692	Murray, Jeffrey H.	Issued
15/305,854	10/21/2016		McMillian, Kara Renita	Abandoned
15/348,716	11/10/2016	10123999	Rozof, Timothy R.	Issued
15/500,312	01/30/2017	11124481	Seaman, D. Margaret M.	Issued
15/501,582	02/03/2017	11065240	Seaman, D. Margaret M.	Issued
15/426,804	02/07/2017	10039757	Pallay, Michael B.	Issued
15/612,703	06/02/2017	10034873	Pallay, Michael B.	Issued
15/617,725	06/08/2017		Neagu, Irina	Abandoned
15/618,593	06/09/2017		Carter, Kendra D.	Abandoned
15/621,527	06/13/2017		Carter, Kendra D.	Abandoned
15/688,310	08/28/2017	11124482	Ward, Paul V.	Issued
15/955,246	04/17/2018		Not Yet Assigned	Abandoned
16/026,708	07/03/2018	10548888	Pallay, Michael B.	Issued
16/093,426	10/12/2018	11141413	Weddington, Kevin E.	Issued
16/095,221	10/19/2018		Saeed, Ali S.	Abandoned
16/142,691	09/26/2018	11116759	Howell, Theodore R.	Issued
16/151,653	10/04/2018	10543206	Rozof, Timothy R.	Issued
16/190,869	11/14/2018		Solola, Taofiq A.	Abandoned
16/230,267	12/21/2018		Kantamneni, Shobha	Pending
16/251,617	01/18/2019	10736886	Perreira, Melissa Jean	Issued
16/336,724	03/26/2019		Sharon X. Wen	Abandoned
16/362,863	03/25/2019		Reese, Heidi L.	Abandoned
16/479,143	07/18/2019	11198731	Lu, Cheng	Issued
16/671,834	11/01/2019	10851061	Chandrakumar, Nizal S.	Issued
16/617,352	11/26/2019	11279675	Seaman, D. Margaret M.	Issued
16/620,379	12/06/2019	11504362	Oh, Taylor V.	Issued
16/706,323	12/06/2019		Rozof, Timothy R.	Abandoned
16/722,563	12/20/2019	11123338	Pallay, Michael B.	Issued
16/776,139	01/29/2020		Solola, Taofiq A.	Abandoned
16/787,212	02/11/2020	11504363	Anderson, James D.	Issued
16/796,250	02/20/2020		Neagu, Irina	Abandoned
16/905,307	06/18/2020	11612597	Timothy R. Rozof	Issued
16/919,562	07/02/2020	11433064	Perreira, Melissa Jean	Issued
16/921,542	07/06/2020		Ward, Paul V.	Abandoned
17/031,196	09/24/2020		Solola, Taofiq A.	Pending
17/070,514	10/14/2020	11091439	Rozof, Timothy R.	Issued
17/070,790	10/14/2020		Seaman, D. Margaret M.	Abandoned

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
17/084,312	10/29/2020	11724986	Chandrakumar, Nizal S.	Issued
17/149,365	01/14/2021	11091440	Rozof, Timothy R.	Issued
17/152,394	01/19/2021		Not Yet Assigned	Abandoned
17/170,275	02/08/2021	11298349	Seaman, D. Margaret M.	Issued
17/171,752	02/09/2021	11098015	Rozof, Timothy R.	Issued
17/212,851	03/25/2021	11760726	Chandrakumar, Nizal S.	Issued
17/371,372	07/09/2021		Rozof, Timothy R.	Abandoned
17/425,661	07/23/2021		Not Yet Assigned	Pending
17/409,098	08/23/2021		Not Yet Assigned	Abandoned
17/466,328	09/03/2021		Seaman, D. Margaret M.	Abandoned
17/468,103	09/07/2021		Kevin E. Weddington	Abandoned
17/497,201	10/08/2021		Seaman, D. Margaret M.	Abandoned
17/505,275	10/19/2021		Rozof, Timothy R.	Abandoned
17/505,307	10/19/2021		Pallay, Michael B.	Abandoned
17/519,327	11/04/2021		Lu, Cheng	Pending
17/538,310	11/30/2021		Not Yet Assigned	Abandoned
17/668,098	02/09/2022	11731941	Seaman, D. Margaret M.	Issued
17/679,634	02/24/2022		Seaman, D. Margaret M.	Abandoned
17/869,427	07/20/2022		Not Yet Assigned	Abandoned
17/873,918	07/26/2022		Not Yet Assigned	Pending
17/888,356	08/15/2022		Weddington, Kevin E.	Abandoned
17/957,505	09/30/2022		Not Yet Assigned	Abandoned
17/965,529	10/13/2022		James D. Anderson	Abandoned
17/975,765	10/28/2022	12,016,854	Oh, Taylor V.	Issued
18/059,840	11/29/2022		Not Yet Assigned	Abandoned
18/069,467	12/21/2022		Not Yet Assigned	Abandoned
18/112,214	02/21/2023	11,969,419	Rozof, Timothy R.	Issued
18/157,568	01/20/2023		Not Yet Assigned	Abandoned
18/176,604	03/01/2023		Not Yet Assigned	Abandoned
18/344,267	06/29/2023		Timothy R. Rozof	Pending
18/359,214	07/26/2023		Not Yet Assigned	Pending
18/363,994	08/02/2023		Not Yet Assigned	Pending
18/462,739	09/07/2023		Not Yet Assigned	Abandoned
18/463,412	09/08/2023		Not Yet Assigned	Abandoned
18/465,462	09/12/2023		Not Yet Assigned	Abandoned
18/490,248	10/19/2023		Saeed, Ali S.	Pending
18/491,407	10/20/2023		Pallay, Michael B.	Pending
18/423,824	01/26/2024		Not Yet Assigned	Pending
18/606,236	03/15/2024		Not Yet Assigned	Pending

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
18/612,538	03/21/2024		Not Yet Assigned	Pending
18/641,587	04/22/2024		Not Yet Assigned	Pending
18/661,030	05/10/2024		Not Yet Assigned	Pending
18/733,183	06/04/2024		Not Yet Assigned	Pending

Conclusion

It is believed that due for this submission is the $1,360.00 fee set forth in 37 C.F.R. § 1.17(e)(1) for a first Request for Continued Examination. The Applicant hereby authorizes the Office to charge this $1,360.00 to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges required, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Respectfully submitted,

HONIGMAN LLP

/Li Gao, Ph.D./

Dated: July 24, 2024

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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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389

CONFIRMATION NO. 5374

91684
JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

PUBLICATION NOTICE



Date Mailed: 06/13/2024

Title:PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Publication No.US-2024-0189298-A1
Publication Date:06/13/2024

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be viewed using the USPTO's publicly available Searchable Databases via the Patent Public Search tool at www.uspto.gov. The direct link to access the Patent Public Search tool is currently https://ppubs.uspto.gov/pubwebapp/static/pages/ppubsbasic.html.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through Patent Center, the USPTO's electronic patent application filing and management system. The direct link to access this status information is currently https://patentcenter.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of Patent Center.

Further assistance in electronically accessing the publication, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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

91684 7590 05/01/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 05/01/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

TITLE OF INVENTION: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	08/01/2024

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 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted 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. 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: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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 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. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

91684 7590 05/01/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

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 transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

TITLE OF INVENTION: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	08/01/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
SEAMAN, D MARGARET M	1625	514-312000

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/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or 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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

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. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 05/01/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER	
SEAMAN, D MARGARET M	
ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/01/2024

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 30 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. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) 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));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/436,836	Applicant(s) Wilson et al.	
	Examiner D MARGARET M SEAMAN	Art Unit 1625	AIA (FITF) 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 paper dated 04/19/2024.
   ☐ 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 35-56 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ 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 _____.

/D MARGARET M SEAMAN/
Primary Examiner, Art Unit 1625

Notice of Pre-AIA or AIA Status

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

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: The rejections stated in paper dated 04/05/2024 have been overcome by applicant's arguments and terminal disclaimers dated 04/19/2024. Claims 35-56 are in condition for allowance.

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."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D MARGARET M SEAMAN whose telephone number is (571)272-0694. The examiner can normally be reached M-F 8am-4pm Eastern.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Kosar can be reached on 571-272-0913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available

to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D MARGARET M SEAMAN/
Primary Examiner, Art Unit 1625

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

CPC - Searched*		
Symbol	**Date**	**Examiner**
C07D2158/233	04/01/2024	dms
A61K31/47	04/01/2024	dms
above updated	04/22/2024	dms

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
InventorName Search	04/01/2024	dms
parent patent search	04/01/2024	dms
updated invenor name search	04/22/2024	dms

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
C07D	215/233	04/22/2024	dms
A61K	31/47	04/22/2024	dms

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

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

CLAIM		DATE								
Final	Original	04/01/2024	04/22/2024							
	1	-								
	2	-								
	3	-								
	4	-								
	5	-								
	6	-								
	7	-								
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	9	-								
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	32	-								
	33	-								
	34	-								
	35	✓	=							
	36	✓	=							
	37	✓	=							
	38	✓	=							
	39	✓	=							
	40	✓	=							
	41	✓	=							
	42	✓	=							

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

CLAIM		DATE								
Final	Original	04/01/2024	04/22/2024							
	43	✓	=							
	44	✓	=							
	45	✓	=							
	46	✓	=							
	47	✓	=							
	48	✓	=							
	49	✓	=							
	50	✓	=							
	51	✓	=							
	52	✓	=							
	53	✓	=							
	54	✓	=							
	55	✓	=							
	56	✓	=							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

CPC						
Symbol					**Type**	**Version**
A61K	/	31	/	47	F	2013-01-01
C07D	/	215	/	233	I	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	22	
/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625	22 April 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61K	/	31	/	47

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625	22 April 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	none

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

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

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 22	
/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625 (Primary Examiner) (Date) 22 April 2024	O.G. Print Claim(s) 1	O.G. Print Figure none

Bibliographic Data

Application No: 18/436,836

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /D MARGARET M SEAMAN/ (Examiner's Signature) [ ] (Initials)

Title: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
02/08/2024 RULE	514	1625	224990/10-039C11US/543389

APPLICANTS

Exelixis, Inc., Alameda, CA, UNITED STATES

INVENTORS

Jo Ann Wilson, San Francisco, CA, UNITED STATES

Khalid Shah,

CONTINUING DATA

This application is a CON of 18462739 09/07/2023

18462739 is a CON of 17679634 02/24/2022ABN

17679634 is a CON of 17170275 02/08/2021 PAT 11298349

17170275 is a CON of 17152394 01/19/2021ABN

17152394 is a CON of 16706323 12/06/2019ABN

16706323 is a DIV of 16151653 10/04/2018 PAT 10543206

16151653 is a DIV of 15348716 11/10/2016 PAT 10123999

15348716 is a DIV of 13984559 03/20/2014 PAT 9717720

13984559 is a 371 of PCT/US2012/024591 02/10/2012

PCT/US2012/024591 has PRO of 61441520 02/10/2011

PCT/US2012/024591 has PRO of 61441527 02/10/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/22/2024

STATE OR COUNTRY

UNITED STATES

ADDRESS

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402
UNITED STATES

FILING FEE RECEIVED

$6,560

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L2	4	("11298349").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:52 PM
L3	2	("10543206").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:54 PM
L4	6	("10123999").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:04 PM
L5	5	("9717720").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:12 PM
L6	6	"20120035212"	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:59 PM
L7	2	("8877776").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 03:21 PM
L10	4	("11298349").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/22 09:53 AM
L11	2	("10543206").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/22 09:53 AM
L12	6	("10123999").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/22 09:53 AM
L13	5	("9717720").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/22 09:53 AM
L14	6	"20120035212"	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/22 09:53 AM
L15	2	("8877776").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/22 09:53 AM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
18/436,836	02/08/2024	Wilson et al.	224990/10-039C11US/ 543389

	EXAMINER	
JONATHAN P. O"BRIEN, PH.D./Exelixis HONIGMAN LLP 650 Trade Centre Way Suite 200 Kalamazoo, MI 49002-0402	--	
	ART UNIT	PAPER
	--	20240427-RnHxb9

DATE MAILED: 27 April 2024

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Notice of Potential Erroneous Release of Patent Application Titles

On February 5, 2024, the United States Patent and Trademark Office (USPTO), replaced the Electronic Patent Assignment System (EPAS) and Electronic Trademark Assignment System (ETAS) with Assignment Center.

Between February 5, 2024 and March 29, 2024, the USPTO, unintentionally, through a computer programming error, permitted bibliographic information to be viewed by unauthorized individuals with access to registered Assignment Center accounts. This bibliographic information was limited to the application number (the two-digit series code plus the six-digit serial number) and title of the invention.

You are receiving this notification because your application's patent title may have been viewed during that time frame by individual(s) who lacked permission to do so. The software error was first reproduced by USPTO on March 28, 2024, and was corrected on March 29, 2024. Only application numbers and titles were disclosed; it is important to note that your specification and claims were not part of the information made available and were not accessed.

Any improper access of the application information between the dates of February 5, 2024 and March 29, 2024, is not considered a publication of such applications under 35 U.S.C. 122(b). No rights in United States patents are threatened by the access to unpublished applications. It is extremely unlikely that the title could disclose the invention in a way that would constitute patent-defeating prior art in any jurisdiction. To the extent any issue is raised, the USPTO will assist applicants by confirming that the disclosure was erroneous and inadvertent.

We're committed to data security and are taking enhanced steps to prevent incidents such as this from happening in the future. The USPTO sincerely regrets this error and is instituting more testing controls, both manual and automated testing, to prevent similar processing errors in the future.

Inquiries regarding this matter may be directed to Mark Polutta, Senior Legal Advisor, at (571) 272-7709 or Andrew Stclair, Legal Advisor, at (571) 270-0238, both of the Office of Patent Legal Administration or via email addressed to Patent.Practice@uspto.gov.



Henry "Jamie" Holcombe
Chief Information Officer
US Patent and Trademark Office
Office +1 (571) 272-9400

Dated: April 27th, 2024

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.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 04/23/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER	
SEAMAN, D MARGARET M	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
04/23/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

apeters@honigman.com
hberven@honigman.com
patent@honigman.com

Applicant-Initiated Interview Summary	**Application No.** 18/436,836	**Applicant(s)** Wilson et al.		
	Examiner D MARGARET M SEAMAN	**Art Unit** 1625	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
D MARGARET M SEAMAN	Primary Examiner	Telephonic
Li Gan	Attorney of Record	
Heidi Berven	Attorney	

Date of Interview: 18 April 2024

Issues Discussed:

35 U.S.C. 102

Discussed the 102(e) rejection.The reference does not have the "less than 100ppm" in the claims or specification of the Brown reference. This rejection will be removed.

/D MARGARET M SEAMAN/ Primary Examiner, Art Unit 1625	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Application Number * 18/436,836 *	Application/Control No. 18/436,836	Applicant(s)/Patent under Reexamination Wilson et al.	
	Examiner SEAMAN, D MARGARET M	Art Unit 1625	

Document Code - DISQ	Internal Document - DO NOT MAIL

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: 19 April 2024	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

/KIMBERLY R WHITE/

Technology Center: OPLC

Telephone: (571)272-6179

2 TDs approved

HONIGMAN

Li Gao, Ph.D.
Office: 517.377.0708
Mobile: 517.256.2694
lgao@honigman.com

Via Patent Center

April 19, 2024

Commissioner for Patents
United States Patent and Trademark Office
P. O. Box 1450
Alexandria, VA 22313

Re: US Patent Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024
Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds
Attorney Docket No.: 224990/10-039C11-US/543389

Dear Sir or Madam:

Enclosed for filing please find the following documents:

1. This Cover Letter to the Commissioner;
2. Response to Non-Final Office Action dated April 5, 2024;
3. Terminal Disclaimers (2); and
4. Certificate of Transmission under 37 C.F.R. § 1.8(a).

The Applicant believes that due with this submission is the $340.00 fee for two terminal disclaimers. The Applicant hereby authorizes the Office to charge this total of $340.00 to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Very truly yours,

HONIGMAN LLP

/Li Gao, Ph.D./

Li Gao, Ph.D.
Reg. No. 71,343

LXG/ayp
Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: 1625
Examiner: Seaman, D. Margaret M.
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

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

RESPONSE TO NON-FINAL OFFICE ACTION DATED APRIL 5, 2024

This submission is responsive to the Non-Final Office Action in this application dated April 5, 2024.

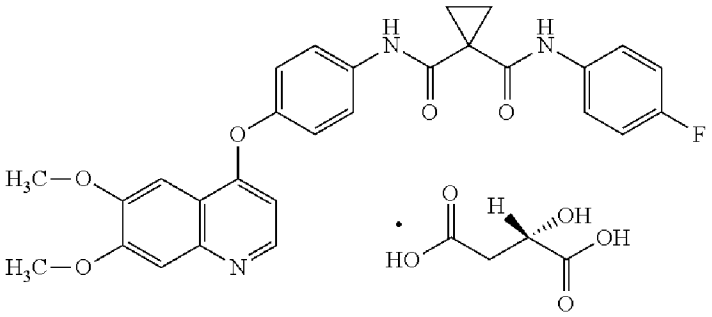
Amendments to the claims begin on page 2.

Applicant's Remarks begin on page 5.

CLAIM AMENDMENTS

1-34. Cancelled.

35. (Previously presented) A pharmaceutical composition for oral administration comprising Compound IB:



IB

and a pharmaceutically acceptable carrier, wherein the pharmaceutical composition is a tablet or a capsule, and wherein the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

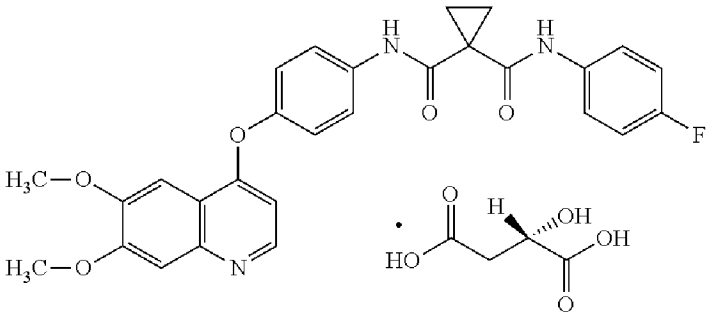
36. (Currently Amended) The pharmaceutical composition of claim [[1]]35, wherein the pharmaceutical composition contains 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

37. (Currently Amended) The pharmaceutical composition of claim [[2]]36, wherein the pharmaceutical composition contains 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

38. (Currently Amended) The pharmaceutical composition of claim [[3]]37, wherein the pharmaceutical composition contains 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

39. (Currently Amended) The pharmaceutical composition of claim [[4]]38, wherein the pharmaceutical composition contains 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

40. (Previously presented) A method of treating cancer, comprising administering to a subject in need thereof a pharmaceutical composition comprising Compound IB:



IB

and a pharmaceutically acceptable carrier, wherein the pharmaceutical composition is a tablet or a capsule, and wherein the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

41. (Currently Amended) The method of claim [[6]]40, wherein the pharmaceutical composition contains 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

42. (Currently Amended) The method of claim [[7]]41, wherein the pharmaceutical composition contains 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

43. (Currently Amended) The method of claim [[8]]42, wherein the pharmaceutical composition contains 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

44. (Currently Amended) The method of claim [[9]]43, wherein the pharmaceutical composition contains 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

45. (Currently Amended) The method of claim [[6]]40, wherein the cancer is renal cancer.

46. (Currently Amended) The method of claim [[6]]40, wherein the cancer is prostate cancer.

47. (Currently Amended) The method of claim [[6]]40, wherein the cancer is hepatocellular carcinoma.

48. (Currently Amended) The method of claim [[7]]41, wherein the cancer is renal cancer.

49. (Currently Amended) The method of claim [[7]]41, wherein the cancer is prostate cancer.

50. (Currently Amended) The method of claim [[7]]41, wherein the cancer is hepatocellular carcinoma.

51. (Currently Amended) The method of claim [[8]]42, wherein the cancer is renal cancer.

52. (Currently Amended) The method of claim [[8]]42, wherein the cancer is prostate cancer.

53. (Currently Amended) The method of claim [[8]]42, wherein the cancer is hepatocellular carcinoma.

54. (Currently Amended) The method of claim [[9]]43, wherein the cancer is renal cancer.

55. (Currently Amended) The method of claim [[9]]43, wherein the cancer is prostate cancer.

56. (Currently Amended) The method of claim [[9]]43, wherein the cancer is hepatocellular carcinoma.

REMARKS

Claim Status

Claims 1-34 are cancelled.

Claims 35 and 40 are previously presented.

Claims 36-39 and 41-56 are currently amended to update claim dependencies. The amendments are supported by the specification and claims as originally filed. No new matter has been added by introduction of the claim amendments.

Thus, claims 35-56 are currently pending.

Interview Summary

The Applicant thanks Examiner Seaman for the telephone interview with the Applicant's representatives, Heidi Berven, Ph.D., Reg. No. 48,951, and the undersigned attorney on April 18, 2024. The discussion focused on the rejection over U.S. Patent 8877776 (Brown) and by extension its corresponding PCT publication, WO201008341, as pre-AIA 35 U.S.C. 102 references, as well as the disclosure of Brown. The discussion also included the double patenting rejection raised by Examiner Seaman.

The Applicant submitted that Brown does not teach a pharmaceutical composition of Compound IB that contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. Examiner Seaman agreed, and concluded that the claims of the captioned application are novel over Brown. The Applicant also noted that terminal disclaimers would be filed to U.S. 11298349 and U.S. 9717720. Examiner Seaman indicated that she intends to allow the application after the claims are amended to correct certain claim dependencies as provided in this response and terminal disclaimers are filed.

Rejections under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 35-56 under pre-AIA 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 8877776 (Brown), asserting that Brown teaches Compound IB and treatment of cancer. The Applicant notes that Brown claims priority to provisional application 61/145,421, filed January 16, 2009, and further claims priority to

WO2010083414 (the '414 PCT Publication), which published on July 22, 2010. Thus, both Brown and the '414 PCT qualify as prior art under pre-AIA 35 U.S.C. § 102.

Nevertheless, the Applicant respectfully submits that claims 35-56 are novel over Brown and the '414 PCT. Brown discloses a generic pharmaceutical composition of Compound IB and treatment of cancer, but Brown does not teach a pharmaceutical composition of Compound IB that contains 6,7-dimethoxy-quinoline-4-ol, let alone 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol, which is equivalent to 0.01 wt.% or less. Brown does not disclose any level of purity in the pharmaceutical composition of Compound IB. A person of ordinary skill in the art reading Brown would not envision the pharmaceutical composition claimed by the Applicant.

Accordingly, claims 35-56 are novel and the rejection should be withdrawn.

Double Patenting

The Examiner rejected claims 35-56 on the ground of nonstatutory double patenting as obvious over claims 1-3 of U.S. Patent No. 11298349 and claims 1-12 of U.S. Patent No. 9717720.

Without acceding to the Examiner's grounds for rejection and to expedite prosecution, the Applicant files terminal disclaimers to U.S. 11298349 and U.S. 9717720 with this response. The Applicant therefore respectfully requests removal of the rejection.

The Examiner also provisionally rejected claims 35-56 on the ground of nonstatutory double patenting as obvious over claims of copending U.S. Application No. 18/462739 (reference application). The reference application has lapsed, rendering the rejection moot.

Accordingly, the Applicant respectfully requests removal of the rejections and allowance of claims 35-56.

CONCLUSION & FEES DUE

The Applicant believes this submission is fully responsive to the Non-Final Office Action in this application dated April 5, 2024. The Applicant reserves the right to file divisional applications or take such other appropriate action as deemed necessary to protect the subject matter restricted, cancelled, or withdrawn from this application.

The Applicant believes that due with this submission is the $340.00 fee for two terminal disclaimers. The Applicant hereby authorizes the Office to charge this total of $340.00 to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Respectfully submitted,

HONIGMAN LLP

/Li Gao, Ph.D./

Dated: April 19, 2024

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PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 224990/10-039C11-US/543389

In re Application of: Jo Ann Wilson et al.

Application No.: 18/436,836

Filed: February 8, 2024

For: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

The applicant, Exelixis, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 11,298,349 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 71343

/Li Gao, Ph.D./ — Signature
April 19, 2024 — Date

Li Gao, Ph.D. — Typed or printed name

Attorney of Record — Title
517-377-0708 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 224990/10-039C11-US/543389

In re Application of: Jo Ann Wilson et al.

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Filed: February 8, 2024

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expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

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/Li Gao, Ph.D./ — Signature
April 19, 2024 — Date

Li Gao, Ph.D. — Typed or printed name

Attorney of Record — Title
517-377-0708 — Telephone Number

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: 1625
Examiner: Seaman, D. Margaret M.
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8(a)

The undersigned hereby certifies that the following documents are being submitted in accordance with 37 C.F.R. § 1.6(a)(4) on the 19th day of April 2024.

1. Cover Letter to the Commissioner;
2. Response to Non-Final Office Action dated April 5, 2024;
3. Terminal Disclaimers (2); and
4. This Certificate of Transmission under 37 C.F.R. § 1.8(a).

/Amy L. Peters/

Amy L. Peters (for Li Gao, Ph.D., Reg. No. 71,343)

UNITED STATES
PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**04/19/2024 03:22:46 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	65169521	FILING DATE	02/08/2024
CUSTOMER #	91684	FIRST NAMED INVENTOR	Jo Ann Wilson
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Li Gao

Documents

TOTAL DOCUMENTS: 7

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action.pdf		11	-	447 KB
2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action-LET..pdf	(1-1)	1	Miscellaneous Incoming Letter	120 KB
2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action-A...pdf	(2-2)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	105 KB
2024-04-19_EX10-039C11-	(3-5)	3	Claims	112 KB

US_Response_to_Non-Final_Office_Action-CLM.pdf				
2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action-REM.pdf	(6-8)	3	Applicant Arguments/Remarks Made in an Amendment	113 KB
2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action-DIST.pdf	(9-9)	1	Terminal Disclaimer Filed	95 KB
2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action-DIST.pdf	(10-10)	1	Terminal Disclaimer Filed	95 KB
2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action-LET..pdf	(11-11)	1	Miscellaneous Incoming Letter	94 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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2024-04-19_EX10-039C11-US_Response_to_Non-Final_Office_Action-DIST.pdf	D83BC864D60FA1C57EA040C2728DD9C0BD732B8AB7B9845AF0D8FB9F73C7C1513DC6E2AE10204CFE4BACDC5202D74D708A50DDA2C7ECDAF66E033B0D9D7DB18E
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	04/19/2024 03:22:46 PM Z ET	224990/10-039C11US/543389

Title of Invention

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PATENT CENTER #	65169521	AUTHORIZED BY	Li Gao
CUSTOMER #	91684	FILING DATE	02/08/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jo Ann Wilson

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 503145	E20244IF23146904	Amy Peters

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1814	STATUTORY DISCLAIMER, INCLUDING TERMINAL DISCLAIMER	170.00	2	340.00
			TOTAL AMOUNT:	$340.00

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.

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New International Application Filed with the USPTO as a Receiving Office

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 18/436,836	Filing Date 02/08/2024	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	04/19/2024	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/KATARA D SINGLETARY/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 04/05/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER	
SEAMAN, D MARGARET M	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
04/05/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

apeters@honigman.com
hberven@honigman.com
patent@honigman.com

Office Action Summary	Application No. 18/436,836	Applicant(s) Wilson et al.	
	Examiner D MARGARET M SEAMAN	Art Unit 1625	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 35-56 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 35-56 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Priority

2. This application was filed 02/08/2024 and is a CON of 18/462739 (09/07/2023) which is a CON of 17/67634(02/24/2022, ABN) which is a CON of 17/170275 (02/08/2021, US Pat 11298349) which is a CON of 17/152394 (01/19/2021, ABN) which is a CON of 16/706323 (12/06/2019, ABN) which is a DIV of 16/151653 (10/04/2018, US Pat 10543206) which is a DIV of 15/348716 (11/10/20016, US Pat 10123999) which is a DIV of 13/984559 (03/20/2014, US Pat 9717720) which is a 371 of PCT/US2012/025491 (02/10/202) which claims priority to 61/441527 (02/10/2011) and 61/441520 (02/10/2011). Claims 1-34 have been canceled. Claims 35-56 are before the Examiner.

Claim Rejections - 35 USC § 102

3. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis (i.e., changing from AIA to pre-AIA) for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

4. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 35-56 are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by US Patent 8877776 Brown. Brown teaches the instant compound salt and treatment of cancer as is instantly claimed.

The applied reference has a common assignee with the instant application. Based upon the pre-AIA 35 U.S.C. 102(e) date of the reference, it constitutes prior art. This rejection under pre-AIA 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor or joint inventors (i.e., the inventive entity) of this application and is thus not the invention "by

another," or if the same invention is not being claimed, by an appropriate showing under 37 CFR 1.131(a).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to

file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The filing of a terminal disclaimer by itself is not a complete reply to a nonstatutory double patenting (NSDP) rejection. A complete reply requires that the terminal disclaimer be accompanied by a reply requesting reconsideration of the prior Office action. Even where the NSDP rejection is provisional the reply must be complete. See MPEP § 804, subsection I.B.1. For a reply to a non-final Office action, see 37 CFR 1.111(a). For a reply to final Office action, see 37 CFR 1.113(c). A request for reconsideration while not provided for in 37 CFR 1.113(c) may be filed after final for consideration. See MPEP §§ 706.07(e) and 714.13.

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The actual filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/apply/applying-online/eterminal-disclaimer.

7. Claims 35-56 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 11298349 and claims 1-12 of US Patent No. 9717720. Although the claims at issue are not identical, they are not patentably distinct from each other because the patents claim the same pharmaceutical composition but in different ways. The method of treating cancer could have been claimed, but was not.

8. Claims 35-56 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims of copending Application No. 18/462739 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the application claims the same compositions in different wordings. The method of treating cancer can be claimed.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D MARGARET M SEAMAN whose telephone number is (571)272-0694. The examiner can normally be reached M-F 8am-4pm Eastern.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Kosar can be reached on 571-272-0913. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D MARGARET M SEAMAN/
Primary Examiner, Art Unit 1625

Notice of References Cited	Application/Control No. 18/436,836	Applicant(s)/Patent Under Reexamination Wilson et al.	
	Examiner D MARGARET M SEAMAN	Art Unit 1625	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-8877776-B2	2014-11-04	Brown; Adrian St. Clair	A61P5/14	514/312
*	B	US-11298349-B2	2022-04-12	Wilson; Jo Ann	A61P35/00	1/1
*	C	US-9717720-B2	2017-08-01	Wilson; Jo Ann	A61K31/47	1/1
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

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

CLAIM		DATE								
Final	Original	04/01/2024								
	1	-								
	2	-								
	3	-								
	4	-								
	5	-								
	6	-								
	7	-								
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	27	-								
	28	-								
	29	-								
	30	-								
	31	-								
	32	-								
	33	-								
	34	-								
	35	✓								
	36	✓								
	37	✓								
	38	✓								
	39	✓								
	40	✓								
	41	✓								
	42	✓								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	**Art Unit**
	D MARGARET M SEAMAN	1625

CLAIM		DATE								
Final	Original	04/01/2024								
	43	✓								
	44	✓								
	45	✓								
	46	✓								
	47	✓								
	48	✓								
	49	✓								
	50	✓								
	51	✓								
	52	✓								
	53	✓								
	54	✓								
	55	✓								
	56	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/436,836	Wilson et al.
	Examiner	Art Unit
	D MARGARET M SEAMAN	1625

CPC - Searched*		
Symbol	Date	Examiner
C07D2158/233	04/01/2024	dms
A61K31/47	04/01/2024	dms

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
InventorName Search	04/01/2024	dms
parent patent search	04/01/2024	dms

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2024-02-08
First Named Inventor	Jo Ann Wilson
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	224990/10-039C11US/543389

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	9724342		2017-08-08	WILSON, et al.	
	2	9809549		2017-11-07	BROWN, et al.	
	3	7579473		2009-08-25	EXELIXIS, INC.	
	4	7977345		2011-07-12	EXELIXIS, INC.	
	5	7999006		2011-08-16	EXELIXIS, INC.	
	6	8067436		2011-11-29	EXELIXIS, INC.	
	7	8178532		2012-05-15	EXELIXIS, INC.	
	8	8314232		2012-11-20	EXELIXIS, INC.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	9	8476298		2013-07-02	EXELIXIS, INC.	
	10	8497284		2013-07-30	EXELIXIS, INC.	
	11	8673912		2014-03-18	EXELIXIS, INC.	
	12	8877776		2014-11-04	EXELIXIS, INC.	
	13	9174947		2015-11-03	EXELIXIS, INC.	
	14	9365516		2016-06-14	EXELIXIS, INC.	
	15	7166722		2007-01-23	MATSUNAGA, et al.	
	16	7169789		2007-01-30	KUBO, et al.	
	17	5358941		1994-10-25	BECHARD, et al.	
	18	9717720		2017-08-01	WILSON, et al.	
	19	9969692		2018-05-15	WILSON, et al.	

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	20	10034873		2018-07-31	WILSON, et al.	
	21	10039757		2018-09-08	WILSON, et al.	
	22	10166225		2019-01-01	AFTAB, et al.	
	23	10123999		2018-11-13	WILSON, et al.	

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

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080161305		2008-07-03	FORSYTH, et al.	
	2	20110077233		2011-03-31	BANNEN, et al.	
	3	20120252840		2012-10-04	AFTAB, et al.	
	4	20140066444		2014-03-26	SMITH, et al.	
	5	20150057310		2015-02-26	BROWN, et al.	

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	Examiner Name	TBD
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	6	20150202196		2015-07-23	BANNEN, et al.	
	7	20160000772		2016-01-07	AFTAB, et al.	
	8	20160051532		2016-02-25	AFTAB, et al.	
	9	20160229805		2016-08-11	WILSON, et al.	
	10	20170143689		2017-05-25	WILSON, et al.	
	11	20170266178		2017-09-21	WILSON, et al.	
	12	20170275251		2017-09-28	BROWN, et al.	
	13	20180002289		2018-01-04	BROWN, et al.	
	14	20180037552		2018-02-08	BROWN, et al.	
	15	20090274693		2009-11-05	EXELIXIS, INC.	
	16	20110077233		2011-03-31	EXELIXIS, INC.	

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	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	17	20120070368		2012-03-22	EXELIXIS, INC.	
	18	20120184523		2012-07-19	EXELIXIS, INC.	
	19	20120252840		2012-10-04	EXELIXIS, INC.	
	20	20120282179		2012-11-08	EXELIXIS, INC.	
	21	20130030172		2013-01-31	EXELIXIS, INC.	
	22	20130142790		2013-01-31	EXELIXIS, INC.	
	23	20130143881		2013-01-31	EXELIXIS, INC.	
	24	20130150363		2013-06-06	EXELIXIS, INC.	
	25	20130197230		2013-06-06	EXELIXIS, INC.	
	26	20130252940		2013-06-13	EXELIXIS, INC.	
	27	20130252956		2013-08-01	EXELIXIS, INC.	

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	Attorney Docket Number	224990/10-039C11US/543389

	28	20130330377		2013-09-26	EXELIXIS, INC.	
	29	20130337015		2013-09-26	EXELIXIS, INC.	
	30	20140057943		2013-12-12	EXELIXIS, INC.	
	31	20140057908		2013-12-19	EXELIXIS, INC.	
	32	20140066444		2014-02-27	EXELIXIS, INC.	
	33	20140155396		2014-02-27	EXELIXIS, INC.	
	34	20140179736		2014-03-06	EXELIXIS, INC.	
	35	20070054928		2007-03-08	BANNEN, et al.	
	36	20140200242		2014-06-05	EXELIXIS, INC.	
	37	20140228401		2014-06-26	EXELIXIS, INC.	
	38	20140302012		2014-07-17	EXELIXIS, INC.	

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	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	39	20140323522		2014-08-14	EXELIXIS, INC.	
	40	20150057310		2014-10-09	EXELIXIS, INC.	
	41	20150196545		2014-10-30	EXELIXIS, INC.	
	42	20150202196		2015-02-26	EXELIXIS, INC.	
	43	20150376133		2015-07-16	EXELIXIS, INC.	
	44	20160000772		2015-07-23	EXELIXIS, INC.	
	45	20160051532		2015-12-31	EXELIXIS, INC.	
	46	20160185725		2016-01-07	EXELIXIS, INC.	
	47	20050209247		2005-09-22	CHIRON CORPORATION	
	48	20070078159		2007-04-05	MATSUSHIMA, et al.	
	49	20110059081		2011-03-10	QUINTILES TRANSNATIONAL CORP.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	50	20140256938		2014-09-11	WISON, et al.	
	51	20160220554		2016-08-04	SMITH, et al.	
	52	20080004273		2008-01-03	RAEPPEL, et al.	
	53	20140121239		2014-05-01	AFTAB, et al.	
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	60	20090203729		2009-08-13	INOUE, et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Jo Ann Wilson
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	Attorney Docket Number	224990/10-039C11US/543389

	61	20190030021		2019-01-31	WILSON, et al.	
	62	20170057921		2017-03-02	WILSON, et al.	
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	66	20190151302		2019-05-23	AFTAB, et al.	
	67	20190091215		2019-03-28	AFTAB, et al.	
	68	20050049267		2005-03-03	SUTO, et al.	

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

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2009136663	WO		2009-11-12	TAKEDA PHARMACEUTICAL COMPANY LIMITED		☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	2	2005030140	WO		2005-04-07	EXELIXIS, INC.		☐
	3	2010083414	WO		2010-07-22	EXELIXIS, INC.		☐
	4	2011017639	WO		2011-02-10	EXELIXIS, INC.		☐
	5	2012009722	WO		2012-01-19	EXELIXIS, INC.		☐
	6	2012109510	WO		2012-06-16	WILSON, Jo Ann		☐
	7	2010113183	WO		2010-10-07	MSN LABORATORIES LIMITED		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Kurzrock R et al. "379 POSTER A phase I study of XL 184, a MET, VEGFR2, and RET kinase inhibitor, administered orally to patients (pts) with advanced malignancies, including a subgroup of pts with medullary thyroid cancer (MTC)." Eropean journal of cancer. supplement, vol 6, no 12, 2008-10-01, 119.	☐
	2	European Medicines Agency, "Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: chemical substances", May 2000.	☐
	3	Sigma-Aldrich Corporation, "Cabozantinib Material Safety Data Sheet", Version 5.0, October 20, 2014, retrieved from the internet at http://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=CDS009101&brand=ALDRICH&PageToGoToURL=http%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fproduct%2Faldrich%2Fcds009101%3Flang%3Den on October 1, 2015.	☐

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
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	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	4	United States Department of Health and Human Services, "Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products", Revision 2, November 2003, retrieved from the internet at www.fda.gov/downloads/drugs/guidancecomplianceregulatory information/guidances/ucm073369.pdf on October 1, 2015.	☐
	5	International Search Report for PCT/US2012/024591, mailed May 25, 2012.	☐
	6	KIBBE, A.H. Handbook of Pharmaceutical Excipients, 3rd edition: American Pharmactical Association and Pharmaceutical Press, ISBN 0-85369-381-1, 2000 (pages 110,244,305,143,102,501,534,386,160).	☐
	7	Li, Lubricants, 2014, Vol 2, 21-43. (Year: 2014).	☐
	8	"Overview of PHarmaceutical Excipients Used in Tablets and Capsules", 2008, Drug Topics, https://www.drugtopics.com/view/ overview-pharmaceutical-excipients-used-tablets-and-capsules. (Year: 2008).	☐
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	13	WILLHAUCK, M. J., "Neue Therapieoptionen bei fortgeschrittenen Schilddrusenkarzinomen" Deutsche Medizinische Wochenschrift 2011, 136, 1165-1168.	☐
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	First Named Inventor	Jo Ann Wilson
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	Attorney Docket Number	224990/10-039C11US/543389

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	16	MOLOGNI, L., "Development of RET Kinase Inhibitors for Targeted Cancer Therapy" Current Medicinal Chemistry 2011,18, 162-175.	☐
	17	KURZROCK, R., et al., "Activity of XL184 (Cabozantinib), an oral tyrosine kinase inhibitor, in patients with medullary thyroid cancer", Journal of Clinical Oncology, Vol. 29, No. 19, pp. 2660-2666, July 1, 2011. Retrieved from the Internet: URL:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3646303/.	☐
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	21	Michael Aulton e Kevin Taylor, Pharmaceutics: The Science of Dosage Form Design, 2nd Edition, pages 1 to 679 (Publication Year: 2001).	☐
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	23	Ravi Salgia et al., "A phase 1 dose-escalation study of the safety and pharmacokinetics (PK) of XL184, a VEGFR and MET kinase inhibitor, administered orally to patients (pts) with advanced malignancies", Mol Cancer Ther (2007) 6 (11_Supplement): A152 (Publication Date: November 1, 2007).	☐

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

EXAMINER SIGNATURE

Examiner Signature	/D MARGARET M SEAMAN/	Date Considered	04/01/2024

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
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	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Li Gao, Ph.D./	Date (YYYY-MM-DD)	2024-02-08
Name/Print	Li Gao, Ph.D.	Registration Number	71343

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.M.S/

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	103	((("WILSON") near3 ("Jo") near3 ("Ann")) OR (("SHAH") near3 ("Khalid"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:52 PM
L2	4	("11298349").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:52 PM
L3	2	("10543206").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:54 PM
L4	6	("10123999").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:04 PM
L5	5	("9717720").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:12 PM
L6	6	"20120035212"	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:59 PM
L7	2	("8877776").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 03:21 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	103	((("WILSON") near3 ("Jo") near3 ("Ann")) OR (("SHAH") near3 ("Khalid"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:52 PM
L2	4	("11298349").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:52 PM
L3	2	("10543206").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 01:54 PM
L4	6	("10123999").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:04 PM
L5	5	("9717720").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:12 PM
L6	6	"20120035212"	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 02:59 PM
L7	2	("8877776").pn.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 03:21 PM
L8	2193	c07d215/233	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 03:44 PM
L9	26038	a61k31/47	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/04/01 03:44 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

Bibliographic Data

Application No: 18/436,836

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☐ No ☐ Met After Allowance

Verified and Acknowledged: /D MARGARET M SEAMAN/ (Examiner's Signature) [ ] (Initials)

Title: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
02/08/2024 RULE	514	1625	224990/10-039C11US/543389

APPLICANTS

Exelixis, Inc., Alameda, CA, UNITED STATES

INVENTORS

Jo Ann Wilson, San Francisco, CA, UNITED STATES

Khalid Shah,

CONTINUING DATA

This application is a CON of 18462739 09/07/2023

18462739 is a CON of 17679634 02/24/2022ABN

17679634 is a CON of 17170275 02/08/2021 PAT 11298349

17170275 is a CON of 17152394 01/19/2021ABN

17152394 is a CON of 16706323 12/06/2019ABN

16706323 is a DIV of 16151653 10/04/2018 PAT 10543206

16151653 is a DIV of 15348716 11/10/2016 PAT 10123999

15348716 is a DIV of 13984559 03/20/2014 PAT 9717720

13984559 is a 371 of PCT/US2012/024591 02/10/2012

PCT/US2012/024591 has PRO of 61441520 02/10/2011

PCT/US2012/024591 has PRO of 61441527 02/10/2011

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/22/2024

STATE OR COUNTRY

UNITED STATES

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JONATHAN P. O"BRIEN, PH.D./Exelixis
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Kalamazoo, MI 49002-0402
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FILING FEE RECEIVED

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389	5374

91684 7590 03/21/2024

JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

EXAMINER
CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
OPAP	

NOTIFICATION DATE	DELIVERY MODE
03/21/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

apeters@honigman.com
hberven@honigman.com
patent@honigman.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 18/436,836	**Applicant(s)** Wilson et al.	
	Examiner FIKIRTE A GEREMEW	**Art Unit** OMBL	**AIA (FITF) Status** No

1. THE REQUEST FILED 08 February 2024 IS **GRANTED** .

   The above-identified application has met the requirements for prioritized examination
   - A. ☑ for an original nonprovisional application (Track I).
   - B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:
   - A. filing a **petition for extension of time** to extend the time period for filing a reply;
   - B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;
   - C. filing a **request for continued examination** ;
   - D. filing a notice of appeal;
   - E. filing a request for suspension of action;
   - F. mailing of a notice of allowance;
   - G. mailing of a final Office action;
   - H. completion of examination as defined in 37 CFR 41.102; or
   - I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to FIKIRTE GEREMEW at (703) 756-1930. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/FIKIRTE A GEREMEW/ PROGRAM SUPPORT SPECIALIST, OMBL	

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 18/436,836

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	* 2			OR	x 100 =	200
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x =	0
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	2020

APPLICATION AS AMENDED - PART II

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

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

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

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

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

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

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
18/436,836	02/08/2024		2420	224990/10-039C11US/543389	22	2

CONFIRMATION NO. 5374

UPDATED FILING RECEIPT

91684
JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

Date Mailed: 03/04/2024

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Jo Ann Wilson, San Francisco, CA;
Khalid Shah, Half Moon Bay, CA;

Applicant(s)

Exelixis, Inc., Alameda, CA;

Power of Attorney: The patent practitioners associated with Customer Number 91684

Domestic Priority data as claimed by applicant

This application is a CON of 18/462,739 09/07/2023
which is a CON of 17/679,634 02/24/2022 ABN
which is a CON of 17/170,275 02/08/2021 PAT 11,298,349
which is a CON of 17/152,394 01/19/2021 ABN
which is a CON of 16/706,323 12/06/2019 ABN
which is a DIV of 16/151,653 10/04/2018 PAT 10,543,206
which is a DIV of 15/348,716 11/10/2016 PAT 10,123,999
which is a DIV of 13/984,559 03/20/2014 PAT 9,717,720
which is a 371 of PCT/US2012/024591 02/10/2012
which claims benefit of 61/441,520 02/10/2011
and claims benefit of 61/441,527 02/10/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 02/22/2024
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/436,836**
Projected Publication Date: 06/13/2024
Non-Publication Request: No
Early Publication Request: No
Title

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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

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

NOT GRANTED

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

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**02/28/2024 02:13:38 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	64482715	AUTHORIZED BY	Li Gao
CUSTOMER #	91684	FILING DATE	02/08/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jo Ann Wilson

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 503145	**E20242RE14289307**	**Amy Peters**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1202	EACH CLAIM IN EXCESS OF 20	100.00	2	200.00
			TOTAL AMOUNT:	**$200.00**

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 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.

HONIGMAN

Li Gao, Ph.D.
Office: 517.377.0708
Mobile: 517.256.2694
lgao@honigman.com

Via Patent Center

February 28, 2024

Commissioner for Patents
United States Patent and Trademark Office
P. O. Box 1450
Alexandria, VA 22313

Re: US Patent Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024
Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds
Attorney Docket No.: 224990/10-039C11-US/543389

Dear Sir or Madam:

Enclosed for filing please find the following documents:

1. This Cover Letter to the Commissioner;
2. Response to Notice to File Missing Parts dated February 27, 2024;
3. Request for Corrected Filing Receipt;
4. Copy of Filing Receipt mailed February 27, 2024 (Marked-up);
5. Copy of Application Data Sheet filed February 8, 2024; and
6. Certificate of Transmission under 37 C.F.R. § 1.8(a).

The Applicant believes that due with this submission is the $200.00 fee for two claims in exceses of twenty. The Applicant hereby authorizes the Office to charge this total of $200.00 to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Very truly yours,

HONIGMAN LLP

/Li Gao, Ph.D./

Li Gao, Ph.D.
Reg. No. 71,343

LXG/ayp
Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: To be Determined
Examiner: To be Determined
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION DATED FEBRUARY 27, 2024

This submission is responsive to the Notice to File Missing Parts of Nonprovisional Application in this application dated February 27, 2024.

Applicant's Remarks begin on page 2.

REMARKS

Notice to File Missing Parts

The United States Patent and Trademark Office issued a Notice to File Missing Parts of Nonprovisional Application on February 27, 2024. The Notice requires submission of excess claims fees. In response, the Applicant submits herewith the $200.00 fee for two claims in excess of twenty.

Conclusion & Fees Due

The Applicant believes this submission is fully responsive to the Notice to File Missing Parts of Nonprovisional Application Filed Under 37 C.F.R. § 1.53(b) dated February 27, 2024. The Applicant reserves the right to file divisional applications or take such other appropriate action as deemed necessary to protect the subject matter restricted, cancelled, or withdrawn from this application.

The Applicant believes that due with this submission is the $200.00 fee for two claims in exceses of twenty. The Applicant hereby authorizes the Office to charge this total of $200.00 to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Respectfully submitted,

HONIGMAN LLP

/Li Gao, Ph.D./

Dated: February 28, 2024

Li Gao, Ph.D., Reg. No. 71,343
222 N. Washington Square, Suite 400
Lansing, MI 48933
Telephone: (517) 377-0708
Facsimile: (517) 377-0709

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: To be Determined
Examiner: To be Determined
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

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

REQUEST TO CORRECT THE FILING RECEIPT DATED FEBRUARY 27, 2024

The present communication is filed to request correction of the Filing Receipt dated February 27, 2024, for the above-captioned application. The Filing Receipt contains the following error made by the Office. The Office inadvertently added a space after "Inc" and before the "," in the Applicant name.

Marked-up:

Exelixis, ~~Inc .,~~ Inc., Alameda, CA;

Clean version:

Exelixis, Inc., Alameda, CA;

The Applicant submits herewith a copy of the Updated Filing Receipt dated February 27, 2024, with the requested correction marked thereon and a copy of the Application Data Sheet filed with this application on February 8, 2024, containing the correct depiction of the Applicant name.

It is believed that no fees are required for this request. However, if there are any charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Respectfully submitted,

HONIGMAN LLP

/Li Gao, Ph.D./

Dated: February 28, 2024

Li Gao, Ph.D., Reg. No. 71,343
222 North Washington Square, Suite 400
Lansing, Michigan 48933-1800
Telephone: (517) 377-0708

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
18/436,836	02/08/2024		2220	224990/10-039C11US/543389	22	2

CONFIRMATION NO. 5374

FILING RECEIPT

91684
JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

Date Mailed: 02/27/2024

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Jo Ann Wilson, San Francisco, CA;
Khalid Shah, Half Moon Bay, CA;

Applicant(s)

Exelixis, ~~Inc.,~~ Alameda, CA; Inc.,

Power of Attorney: The patent practitioners associated with Customer Number 91684

Domestic Priority data as claimed by applicant

This application is a CON of 18/462,739 09/07/2023
which is a CON of 17/679,634 02/24/2022 ABN
which is a CON of 17/170,275 02/08/2021 PAT 11,298,349
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and claims benefit of 61/441,527 02/10/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 02/22/2024

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/436,836**

Projected Publication Date: 06/06/2024

Non-Publication Request: No

Early Publication Request: No

Title

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

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SelectUSA

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PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

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

Secrecy Order 37 CFR 5.2:

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

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jo Ann		Wilson	

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

City	San Francisco	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	74 Seward Street		
Address 2			
City	San Francisco	State/Province	CA
Postal Code	94114	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Khalid		Shah	

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

City	Half Moon Bay	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	281 Eagle Trace Drive		
Address 2			
City	Half Moon Bay	State/Province	CA
Postal Code	94019	Country	US

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

Correspondence Information:

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

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

Customer Number	91684		
Email Address	patent@honigman.com	Add Email	Remove Email

Application Information:

Title of the Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds		
Attorney Docket Number	224990/10-039C11US/543389	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

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

Representative Information:

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

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	91684		

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	18462739	2023-09-07
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
18462739	Continuation of	17679634	2022-02-24
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17679634	Continuation of	17170275	2021-02-08	11298349	2022-04-12

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
17170275	Continuation of	17152394	2021-01-19
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
17152394	Continuation of	16706323	2019-12-06
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16706323	Division of	16151653	2018-10-04	10543206	2020-01-28

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16151653	Division of	15348716	2016-11-10	10123999	2018-11-13

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15348716	Division of	13984559	2014-03-20	9717720	2017-08-01

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13984559	a 371 of international	PCT/US2012/024591	2012-02-10
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2012/024591	Claims benefit of provisional	61441520	2011-02-10
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2012/024591	Claims benefit of provisional	61441527	2011-02-10

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

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Applicant Information:

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

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

◉ Assignee	○ Legal Representative under 35 U.S.C. 117	○ Joint Inventor
○ Person to whom the inventor is obligated to assign.	○ Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Exelixis, Inc.

Mailing Address Information For Applicant:

Address 1	1851 Harbor Bay Parkway		
Address 2			
City	Alameda	**State/Province**	CA
Country	US	Postal Code	94502
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Li Gao, Ph.D./			Date (YYYY-MM-DD)	2024-02-08
First Name	Li	Last Name	Gao, Ph.D.	Registration Number	71,343

Additional Signature may be generated within this form by selecting the Add button.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 18/436,836
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: To be Determined
Examiner: To be Determined
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: 5374

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8(a)

The undersigned hereby certifies that the following documents are being submitted in accordance with 37 C.F.R. § 1.6(a)(4) on the 28th day of February 2024.

1. Cover Letter to the Commissioner;
2. Response to Notice to File Missing Parts dated February 27, 2024;
3. Request for Corrected Filing Receipt;
4. Copy of Filing Receipt mailed February 27, 2024 (Marked-up);
5. Copy of Application Data Sheet filed February 8, 2024; and
6. This Certificate of Transmission under 37 C.F.R. § 1.8(a).

/Amy L. Peters/

Amy L. Peters (for Li Gao, Ph.D., Reg. No. 71,343)

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**02/28/2024 02:13:38 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	64482715	FILING DATE	02/08/2024
CUSTOMER #	91684	FIRST NAMED INVENTOR	Jo Ann Wilson
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Li Gao

Documents

TOTAL DOCUMENTS: 6

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs.pdf		18	-	702 KB
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-LET..pdf	(1-1)	1	Miscellaneous Incoming Letter	121 KB
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-PEFR.pdf	(2-2)	1	Applicant Response to Pre-Exam Formalities Notice	102 KB
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-REM.pdf	(3-3)	1	Applicant Arguments/Remarks Made in an Amendment	104 KB
2024-02-28_EX10-039C11-	(4-9)	6	Request for Corrected Filing	288 KB

US_Response_to_NTFMP_Docs-CFILE.pdf			Receipt	
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-ADS.pdf	(10-17)	8	Application Data Sheet	117 KB
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-LET..pdf	(18-18)	1	Miscellaneous Incoming Letter	95 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs.pdf	023F99F9FB4771954D70B6C0FC4CAB0BD4C1DD2BC99C3E61A2DACF25C761244F2A7AEF959A16A4BEF9E686A821188561633B40375E067C8A4C5A960E800176D7
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-LET..pdf	FAFF3D302558CDAFACAB86A6C0E19EB9E3FCD238DA03607C579BE3E6AA8CD8F325C5CD31B83B7931755E6645CC4F6ACCD93A5E4CB477AF35EF703883764A81A1
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-PEFR.pdf	2B9B554F2750D32A742478B8E8804681B12241109DC4CBB62CC72BDFB7815B33500F1D426A9442DC93DBEE38BB2557096276CA04914BF18AE3E9C4C64D6C2C8B
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-REM.pdf	08CF6792449C64D9EEFFE61D9000D2F1D58648AEEFC0B94F94C6F52E152D1E2734E11D2C62BA1A3FCF38494A0B5883BE7D63BB5A3255666CF40A5176C8679932
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-CFILE.pdf	8B7D3C0CC8B012CC9BF02E3EB94A3B5B9AA02014FF4E9B99F7832107BD0BA5E0B74C4C69C883D25CB5B109A70722B306AC94F8917ED2087583E2E9FD1C5B5A31
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-ADS.pdf	4EAD8C19B4DE500E6494026004DD30C9677FE096902E76F8B2FA8416230C354A19B433DAE299E8895FB975C3A05E332A0AE322DDA85E2B3ED6A5BD3EF2007B41
2024-02-28_EX10-039C11-US_Response_to_NTFMP_Docs-LET..pdf	655D88AAEE75ADF0EE6F85C5CE3B50A785E82EAFBB2FFAAD6E42E4CB8246A766CD955BEA6C538478D3A44FA09320CE4051337E55E46995A38CCAEF02ECB8D4FC

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 filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
18/436,836	02/08/2024		2220	224990/10-039C11US/543389	22	2

CONFIRMATION NO. 5374

FILING RECEIPT

91684
JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

Date Mailed: 02/27/2024

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Jo Ann Wilson, San Francisco, CA;
Khalid Shah, Half Moon Bay, CA;

Applicant(s)

Exelixis, Inc ., Alameda, CA;

Power of Attorney: The patent practitioners associated with Customer Number 91684

Domestic Priority data as claimed by applicant

This application is a CON of 18/462,739 09/07/2023
which is a CON of 17/679,634 02/24/2022 ABN
which is a CON of 17/170,275 02/08/2021 PAT 11,298,349
which is a CON of 17/152,394 01/19/2021 ABN
which is a CON of 16/706,323 12/06/2019 ABN
which is a DIV of 16/151,653 10/04/2018 PAT 10,543,206
which is a DIV of 15/348,716 11/10/2016 PAT 10,123,999
which is a DIV of 13/984,559 03/20/2014 PAT 9,717,720
which is a 371 of PCT/US2012/024591 02/10/2012
which claims benefit of 61/441,520 02/10/2011
and claims benefit of 61/441,527 02/10/2011

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 02/22/2024

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 18/436,836**

Projected Publication Date: 06/06/2024

Non-Publication Request: No

Early Publication Request: No

Title

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign

patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

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

NOT GRANTED

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

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 18/436,836

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	22 minus 20 =	* 2			OR	x 100 =	200
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x =	0
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	2020

APPLICATION AS AMENDED - PART II

AMENDMENT A

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

AMENDMENT B

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

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

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

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

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

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/436,836	02/08/2024	Jo Ann Wilson	224990/10-039C11US/543389

CONFIRMATION NO. 5374

91684
JONATHAN P. O"BRIEN, PH.D./Exelixis
HONIGMAN LLP
650 Trade Centre Way
Suite 200
Kalamazoo, MI 49002-0402

FORMALITIES LETTER

OC00000068760682

Date Mailed: 02/27/2024

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to the above-identified nonprovisional application. The item(s) indicated below, however, are missing.

Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- Additional claim fees of $**200** as an undiscounted entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

The fee(s) required (including the fees noted above) are as follows. No entity status discount is in effect. If applicant is qualified for small entity status, a written assertion of small entity status must be submitted to establish small entity status. (See 37 CFR 1.27). If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $**200** for 2 total claims over 20.
- $(**0**) previous unapplied payment amount.
- $**200** TOTAL FEE BALANCE DUE.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be addressed to:

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REPLY VIA ELECTRONIC FILING

A reply may be submitted via electronic filing only by registered users of the appropriate USPTO patent electronic filing system and must include:

- A separate document having the document description, "**Applicant response to Pre-Exam Formalities Notice**"; and
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NOTE: If the reply is not being submitted electronically, a copy of this notice must be included.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/jchen/

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Derrick Brent
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office

HONIGMAN

Li Gao, Ph.D.
Office: 517.377.0708
Mobile: 517.256.2694
lgao@honigman.com

Via Patent Center

February 8, 2024

Commissioner for Patents
United States Patent and Trademark Office
P. O. Box 1450
Alexandria, VA 22313

Re: US Patent Application No.: TBD
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024
Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds
Attorney Docket No.: 224990/10-039C11-US/543389

Dear Sir or Madam:

Enclosed for filing please find the following documents:

1. This Cover Letter to the Commissioner;
2. Utility Patent Application Transmittal form (PTO/AIA/15);
3. Application Data Sheet (PTO/AIA/14);
4. Specification, Claims, and Abstract;
5. Preliminary Amendment under 37 C.F.R. § 1.115;
6. Request for Prioritized Examination under 37 C.F.R. § 1.102(e);
7. Information Disclosure Statement by Applicant (PTO/SB/08a);
8. Non-Patent Literature (12 documents);
9. Fee Transmittal (PTO/SB/17);
10. Executed Inventor Declaration (2 sheets)(PTO/AIA/01);
11. Executed Power of Attorney with Transmittal (PTO/AIA/82A&B); and
12. Certificate of Transmission under 37 C.F.R. § 1.8(a).

This application is a continuation application of United States Serial Number 18/462,739, filed September 7, 2023, which is a continuation application of United States Serial Number 17/679,634, filed February 24, 2022, which is a continuation application of United States Serial Number 17/170,275, filed February 8, 2021, now United States Patent Number 11,298,349, which is a continuation application of United States Serial Number 17/152,394, filed January 19, 2021, which is a continuation of United States Application Serial Number 16/706,323, filed December 6, 2019, which is a division of United States Application Serial Number 16/151,653, filed October 4, 2018, now United States Patent Number 10,543,206, which is a division of United States Application Serial Number 15/348,716, filed November 10, 2016, now United States Patent Number 10,123,999, which is a division of United States Application Serial Number 13/984,559, filed March 20, 2014, now United States Patent Number 9,717,720, which

claims priority under 35 U.S.C. § 371 to Patent Cooperation Treaty Application Number PCT/US2012/024591, filed February 10, 2012, which claims the benefit of United States Provisional Application Number 61/441,520, filed February 10, 2011, and United States Provisional Application Number 61/441,527, filed February 10, 2011, the entire contents of which are incorporated herein by reference.

The Applicant also provides herewith a Request for Track One prosecution along with the pertinent processing and examination fees.

The Applicant notes that the filing of the enclosed Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement qualifies as prior art under 35 U.S.C. § § 102 or 103, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). It is believed that no fee is due pursuant to 37 C.F.R. § 1.97(b)(3). In accordance with 37 C.F.R. § 1.98(d), some copies of the cited references are not provided because they were previously provided to the Office in an earlier application. The Applicant will gladly provide the references to the Examiner, however, upon request.

It is believed that due with this submission is the Basic Utility Application Fee of $320.00 set forth in 37 C.F.R. § 1.16(a), the Utility Search Fee of $700.00 set forth in § 1.16(k), the Utility Examination Fee of $800.00 set forth in § 1.16(o), the processing fee of $140.00 set forth in 37 C.F.R. 1.17(i), the prioritized examination fee of $4,200.00 set forth in 37 C.F.R. § 1.17(c), and the $400.00 non-docx filing fee. The Applicant hereby authorizes the Patent Office to charge this total of $6,560.00 to Deposit Account No. 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Very truly yours,

HONIGMAN LLP

/Li Gao, Ph.D./

Li Gao, Ph.D.
Reg. No. 71,343

LXG/ayp
Enclosures

PTO/AIA/15 (10-17)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	224990/10-039C11-US/543389
First Named Inventor	Jo Ann Wilson
Title	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Con
Priority Mail Express® Label No.	

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [✔] **Fee Transmittal Form** (PTO/SB/17 or equivalent)
2. [ ] **Applicant asserts small entity status.** See 37 CFR 1.27
3. [ ] **Applicant certifies micro entity status.** See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
4. [✔] **Specification** [*Total Pages* 47] Both the claims and abstract must start on a new page. *(See MPEP § 608.01(a) for information on the preferred arrangement)*
5. [✔] **Drawing(s)** (35 U.S.C. 113) [*Total Sheets* 0]
6. **Inventor's Oath or Declaration** [*Total Pages* 2] *(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))*
   a. [ ] Newly executed (original or copy)
   b. [✔] A copy from a prior application (37 CFR 1.63(d))
7. [✔] **Application Data Sheet** ** See note below.* See 37 CFR 1.76 (PTO/AIA/14 or equivalent)
8. **CD-ROM or CD-R** in duplicate, large table, or Computer Program (*Appendix*)
   [ ] Landscape Table on CD
9. **Nucleotide and/or Amino Acid Sequence Submission** (*if applicable, items a. – c. are required*)
   a. [ ] Computer Readable Form (CRF)
   b. [ ] Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

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ACCOMPANYING APPLICATION PAPERS

10. [ ] **Assignment Papers** (cover sheet & document(s))
    Name of Assignee _____
11. [ ] **37 CFR 3.73(c) Statement** (*when there is an assignee*) [✔] **Power of Attorney**
12. [ ] **English Translation Document** (*if applicable*)
13. [✔] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of citations attached
14. [✔] **Preliminary Amendment**
15. [ ] **Return Receipt Postcard** (*MPEP § 503*) (*Should be specifically itemized*)
16. [ ] **Certified Copy of Priority Document(s)** (*if foreign priority is claimed*)
17. [ ] **Nonpublication Request** Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
18. [✔] **Other:** Cover Letter, Certificate of Transmission, Request for Prioritized Examination,

Note*: (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS

[✔] The address associated with Customer Number: 91684 **OR** [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email	

Signature	/Li Gao, Ph.D./	Date	February 8, 2024
Name (Print/Type)	Li Gao, Ph.D.	Registration No. (Attorney/Agent)	71,343

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

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

Secrecy Order 37 CFR 5.2:

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

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jo Ann		Wilson	

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

City	San Francisco	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	74 Seward Street		
Address 2			
City	San Francisco	State/Province	CA
Postal Code	94114	Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Khalid		Shah	

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

City	Half Moon Bay	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	281 Eagle Trace Drive		
Address 2			
City	Half Moon Bay	State/Province	CA
Postal Code	94019	Country	US

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

Correspondence Information:

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

☐ **An Address is being provided for the correspondence Information of this application.**			
Customer Number	91684		
Email Address	patent@honigman.com	Add Email	Remove Email

Application Information:

Title of the Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds		
Attorney Docket Number	224990/10-039C11US/543389	**Small Entity Status Claimed**	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

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

Representative Information:

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

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
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Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	18462739	2023-09-07
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
18462739	Continuation of	17679634	2022-02-24
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17679634	Continuation of	17170275	2021-02-08	11298349	2022-04-12

Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
17170275	Continuation of	17152394	2021-01-19
Prior Application Status	Abandoned		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
17152394	Continuation of	16706323	2019-12-06
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16706323	Division of	16151653	2018-10-04	10543206	2020-01-28

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16151653	Division of	15348716	2016-11-10	10123999	2018-11-13

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15348716	Division of	13984559	2014-03-20	9717720	2017-08-01

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
13984559	a 371 of international	PCT/US2012/024591	2012-02-10
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2012/024591	Claims benefit of provisional	61441520	2011-02-10
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
PCT/US2012/024591	Claims benefit of provisional	61441527	2011-02-10

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

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

			Remove
Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (02-18)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Applicant Information:

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

Applicant 1

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. [x]

Organization Name	Exelixis, Inc.

Mailing Address Information For Applicant:

Address 1	1851 Harbor Bay Parkway		
Address 2			
City	Alameda	**State/Province**	CA
Country	US	Postal Code	94502
Phone Number		Fax Number	
Email Address			

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

Assignee Information including Non-Applicant Assignee Information:

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Li Gao, Ph.D./			Date (YYYY-MM-DD)	2024-02-08
First Name	Li	Last Name	Gao, Ph.D.	Registration Number	71,343

Additional Signature may be generated within this form by selecting the Add button.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	224990/10-039C11US/543389
	Application Number	
Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds	

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

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 61/441,520, filed February 10, 2011, and 61/441,527, filed February 10, 2011, which are incorporated herein by reference

FIELD OF THE INVENTION

[0002] This disclosure relates to processes for preparing compounds useful for modulating protein kinase enzymatic activity. More specifically, this disclosure relates to processes for preparing quinolines that are useful for modulating cellular activities such as proliferation, differentiation, programmed cell death, migration, and chemo-invasion and to pharmaceutical compositions containing such compounds.

BACKGROUND OF THE INVENTION

[0003] Traditionally, dramatic improvements in the treatment of cancer are associated with identification of therapeutic agents acting through novel mechanisms. One mechanism that can be exploited in cancer treatment is the modulation of protein kinase activity because signal transduction through protein kinase activation is responsible for many of the characteristics of tumor cells. Protein kinase signal transduction is of particular relevance in, for example, renal, gastric, head and neck, lung, breast, prostate, and colorectal cancers; hepatocellular carcinoma; as well as in the growth and proliferation of brain tumor cells.

[0004] Protein kinases can be categorized as receptor type or non-receptor type. Receptor-type tyrosine kinases are comprised of a large number of transmembrane receptors with diverse biological activity. For a detailed discussion of the receptor-type tyrosine kinases, see Plowman et al., DN&P 7(6): 334-339, 1994. Since protein kinases and their ligands play critical roles in various cellular activities, deregulation of protein kinase enzymatic activity can lead to altered cellular properties, such as uncontrolled cell growth associated with cancer. In addition to oncological indications, altered kinase signaling is implicated in numerous other pathological diseases, including, for example, immunological disorders, cardiovascular diseases, inflammatory diseases, and degenerative diseases. Therefore, protein kinases are attractive targets for small molecule drug discovery. Particularly attractive targets for small-molecule modulation with respect to antiangiogenic

and antiproliferative activity include receptor type tyrosine kinases c-Met, KDR, c-Kit, Axl, flt-3, and flt-4.

[0005] The kinase c-Met is the prototypic member of a subfamily of heterodimeric receptor tyrosine kinases (RTKs) which include Met, Ron, and Sea. The endogenous ligand for c-Met is the hepatocyte growth factor (HGF), a potent inducer of angiogenesis. Binding of HGF to c-Met induces activation of the receptor via autophosphorylation, resulting in an increase of receptor dependent signaling, which promotes cell growth and invasion. Anti-HGF antibodies or HGF antagonists have been shown to inhibit tumor metastasis *in vivo* (See: Maulik et al Cytokine & Growth Factor Reviews 2002 13, 41-59). c-Met overexpression has been demonstrated on a wide variety of tumor types including breast, colon, renal, lung, squamous cell myeloid leukemia, hemangiomas, melanomas, astrocytomas, and glioblastomas. Additionally, activating mutations in the kinase domain of c-Met have been identified in hereditary and sporadic renal papilloma and squamous cell carcinoma. (See, e.g., Maulik et al., Cytokine & growth Factor reviews 2002 13, 41-59; Longati et al., Curr Drug Targets 2001, 2, 41-55; Funakoshi et al., Clinica Chimica Acta 2003 1-23).

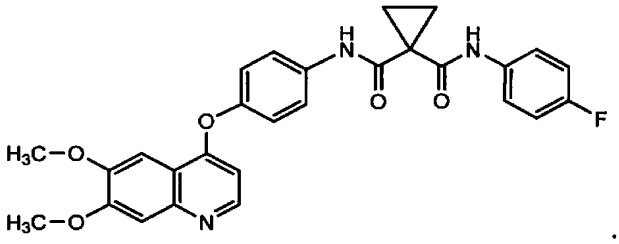
[0006] Inhibition of epidermal growth factor (EGF), vascular endothelial growth factor (VEGF), and ephrin signal transduction will prevent cell proliferation and angiogenesis, two key cellular processes needed for tumor growth and survival (Matter A., Drug Disc. Technol. 2001 6, 1005-1024). Kinase KDR (refers to kinase insert domain receptor tyrosine kinase) and flt-4 (fms-like tyrosine kinase-4) are both VEGF receptors. Inhibition of EGF, VEGF, and ephrin signal transduction will prevent cell proliferation and angiogenesis, two key cellular processes needed for tumor growth and survival (Matter A. Drug Disc. Technol. 2001 6, 1005-1024). EGF and VEGF receptors are desirable targets for small molecule inhibition. All members of the VEGF family stimulate cellular responses by binding to tyrosine kinase receptors (the VEGFRs) on the cell surface, causing them to dimerize and become activated through transphosphorylation. The VEGF receptors have an extracellular portion with immunoglobulin-like domains, a single transmembrane spanning region, and an intracellular portion containing a split tyrosine-kinase domain. VEGF binds to VEGFR-1 and VEGFR-2. VEGFR-2 is known to mediate almost all of the known cellular responses to VEGF.

[0007] Kinase c-Kit (also called stem cell factor receptor or steel factor receptor) is a type 3 receptor tyrosine kinase (RTK) belonging to the platelet-derived growth factor receptor subfamily. Overexpression of c-Kit and c-Kit ligand has been described in variety of human

diseases, including human gastrointestinal stromal tumors, mastocytosis, germ cell tumors, acute myeloid leukemia (AML), NK lymphoma, small-cell lung cancer, neuroblastomas, gynecological tumors, and colon carcinoma. Moreover, elevated expression of c-Kit may also relate to the development of neoplasia associated with neurofibromatosis type 1 (NF-1), mesenchymal tumors GISTs, and mast cell disease, as well as other disorders associated with activated c-Kit.

[0008] Kinase Flt-3 (fms-like tyrosine kinase-3) is constitutively activated via mutation, either in the juxtamembrane region or in the activation loop of the kinase domain, in a large proportion of patients with AML (Reilly, Leuk. Lymphoma, 2003, 44: 1-7).

[0009] Small-molecule compounds that specifically inhibit, regulate, and/or modulate the signal transduction of kinases, such as c-Met, VEGFR2, KDR, c-Kit, Axl, flt-3, and flt-4 described above, are particularly desirable as a means to treat or prevent disease states associated with abnormal cell proliferation and angiogenesis. One such small-molecule is compound IA, which has the chemical structure:



IA

WO2005/030140 describes the synthesis of compound IA (Table 2, Compound 12, Example 48) and also discloses the therapeutic activity of this molecule to inhibit, regulate, and/or modulate the signal transduction of kinases (Assays, Table 4, entry 289), the entire contents of which is incorporated herein by reference.

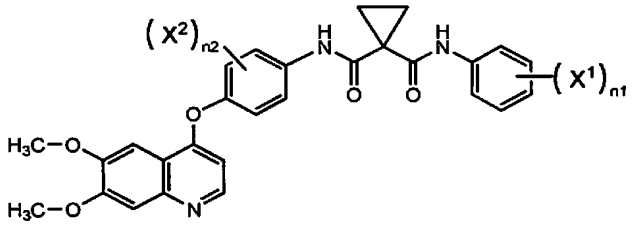
[0010] Although therapeutic efficacy is the primary concern for a therapeutic agent, the pharmaceutical composition can be equally important to its development. Generally, the drug developer endeavors to discover a pharmaceutical composition that possesses desirable properties, such as satisfactory water-solubility (including rate of dissolution), storage stability, hygroscopicity, and reproducibility, all of which can impact the processability, manufacture, and/or bioavailability of the drug.

[0011] Accordingly, there is a need for the discovery of new processes for making quinolines such as compound IA that minimize the formation of undesirable process contaminants or byproducts. There is also a need for new pharmaceutical compositions containing quinolines such as compound IA that are essentially free of process byproducts.

SUMMARY OF THE INVENTION

[0012] These and other needs are met by the present disclosure, which is directed to processes for making and compositions containing quinolines or pharmaceutically acceptable salts thereof.

[0013] In one aspect, the disclosure relates to processes for preparing a compound of formula I:



I

or a pharmaceutically acceptable salt thereof, wherein:

X^1 is H, Br, Cl, or F;

X^2 is H, Br, Cl, or F;

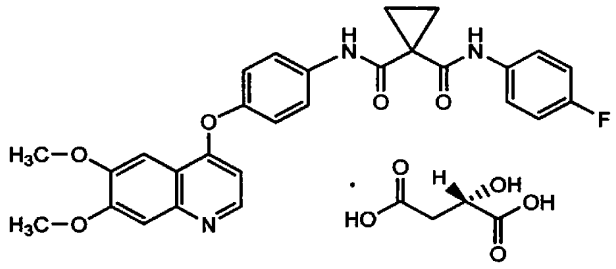
n1 is 1-2; and

n2 is 1-2.

[0014] Intermediates useful in preparing the above compounds are also disclosed.

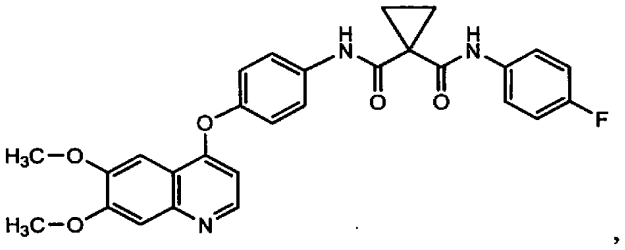
[0015] The compounds of formula I are useful as protein kinase modulators, and they inhibit various protein kinases including Ret and c-Met.

[0016] In another aspect, the disclosure provides a process for preparing compound IB:



IB

from compound IA:



IA,

comprising:

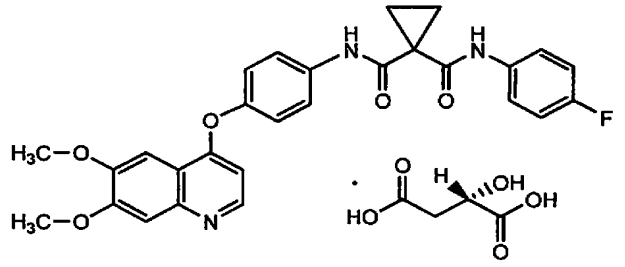
(a) heating and agitating a mixture comprising compound IA and L-malic acid, methylethyl ketone, and water;

(b) cooling the mixture;

(c) vacuum distilling the mixture successively; and

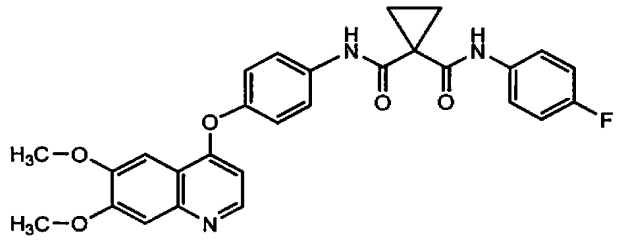
(d) isolating the compound of IB by filtration.

[0017] In another aspect, the disclosure provides a process for preparing compound IB:



IB

from compound IA:



IA,

comprising:

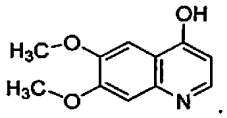
(a) heating and agitating a mixture comprising compound IA and L-malic acid, methylethyl ketone, and water;

(b) cooling the mixture;

(c) seeding the mixture with compound IB;

(d) vacuum distilling the mixture; and

(e) isolating compound IB by filtration.

[0018] In another aspect, the disclosure provides compound I, IA, or IB admixed with less than 100 ppm 6,7-dimethoxy-quinoline-4-ol, the structure of which is  .

[0019] In another aspect, the disclosure provides pharmaceutical compositions containing the compound of formula I, compound IA, or compound IB for oral administration.

[0020] In another aspect, the disclosure provides a pharmaceutical tablet composition according to Table 1.

Table 1

Ingredient	% w/w
Compound I	31.68
Microcrystalline Cellulose (MCC) (Avicel PH102)	38.85
Lactose anhydrous 60 M	19.42
Hydroxypropyl Cellulose, EXF	3.00
Croscarmellose Sodium	3.00
Total Intra-granular	**95.95**
Silicon dioxide, Colloidal PWD	0.30
Croscarmellose Sodium	3.00
Magnesium Stearate	0.75
Total	**100.00**

[0021] In another aspect, the disclosure provides a pharmaceutical tablet composition according to Table 2.

Table 2

Ingredient	(% w/w)
Compound I	25.0-33.3
Microcrystalline Cellulose, NF	q.s
Hydroxypropyl Cellulose, NF	3
Poloxamer, NF	0-3
Croscarmellose Sodium, NF	6.0
Colloidal Silicon Dioxide, NF	0.5
Magnesium Stearate, NF	0.5-1.0
Total	100

[0022] In another aspect, the disclosure provides a pharmaceutical tablet composition according to Table 2A.

Table 2A

Ingredient	**% w/w**
Compound IB (10 % drug load as Compound IA)	12.67
MCC	51.52
Lactose	25.76
Hydroxypropyl cellulose	3.0
Croscarmellose Sodium	6.0
Colloidal Silicon Dioxide	0.3
Magnesium Stearate	0.75
Total	**100**

[0023] In another aspect, the disclosure provides a pharmaceutical capsule composition according to Table 3.

Table 3

Ingredient	**mg/unit dose**
Compound IB (10 % drug load as Compound IA)	25
Silicified Microcrystalline Cellulose	196.75
Croscarmellose sodium	12.5
Sodium starch glycolate	12.5
Fumed Silica	0.75
Stearic acid	2.5
Total Fill Weight	250

[0024] In another aspect, the disclosure provides a pharmaceutical capsule composition according to Table 4.

Table 4

Ingredient	**mg/unit dose**
Compound IB (50 % drug load as Compound IA)	100
Silicified Microcrystalline Cellulose	75.40
Croscarmellose sodium	10.00
Sodium Starch Glycolate	10.00
Fumed silica	0.6
Stearic Acid	4.0
Total Fill Weight	200

[0025] In another aspect, the disclosure provides a pharmaceutical capsule composition according to Table 5, wherein the IB weight equivalents are provided.

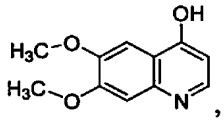
Table 5

	mg/unit dose
Ingredient	**50mg**
Compound IB	63.35
Microcrystalline Cellulose	95.39
Croscarmellose sodium	9.05
Sodium starch glycolate	9.05
Fumed Silica	0.54
Stearic acid	3.62
Total Fill Weight	181.00

[0026] In another aspect, the disclosure provides a pharmaceutical capsule composition according to Table 6, wherein the IB weight equivalents are provided.

Table 6

	mg/unit dose
Ingredient	**60mg**
Compound IB	73.95
Microcrystalline Cellulose	114.36
Croscarmellose sodium	10.85
Sodium starch glycolate	10.85
Fumed Silica	0.65
Stearic acid	4.34
Total Fill Weight	217.00

[0027] In another aspect, the invention is directed to a pharmaceutical composition comprising compound I, IA, or IB admixed with less than 100 ppm 6,7-dimethoxy-quinoline-4-ol, the structure of which is 

, and a pharmaceutically acceptable carrier.

[0028] There are many different aspects and embodiments of the disclosure described herein, and each aspect and each embodiment is non-limiting in regard to the scope of the disclosure. The terms "aspects" and "embodiments" are meant to be non-limiting regardless of where the terms "aspect" or "embodiment" appears in this specification. The transitional term "comprising," as used herein, which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements.

DETAILED DESCRIPTION OF THE INVENTION

Definitions

[0029] As used herein, the following words and phrases are generally intended to have the meanings as set forth below, except to the extent that the context in which they are used indicates otherwise or they are expressly defined to mean something different.

[0030] The word "can" is used in a non-limiting sense and in contradistinction to the word "must." Thus, for example, in many aspects of the invention a certain element is described as "can" having a specified identity, which is meant to convey that the subject element is permitted to have that identity according to the invention but is not required to have it.

[0031] If a group "R" is depicted as "floating" on a ring system, then unless otherwise defined, the substituent(s) "R" can reside on any atom of the ring system, assuming replacement of a depicted, implied, or expressly defined hydrogen from one of the ring atoms, so long as a stable structure is formed.

[0032] When there are more than one such depicted "floating" groups, such as where there are two groups; then, unless otherwise defined, the "floating" groups can reside on any atoms of the ring system, again assuming each replaces a depicted, implied, or expressly defined hydrogen on the ring.

[0033] "Pharmaceutically acceptable salts" include acid addition salts.

[0034] "Pharmaceutically acceptable acid addition salt" refers to those salts that retain the biological effectiveness of the free bases and that are not biologically or otherwise undesirable, formed with inorganic acids such as hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid, phosphoric acid, and the like, or mixtures thereof, as well as organic acids such as acetic acid, trifluoroacetic acid, propionic acid, glycolic acid, pyruvic acid, oxalic acid, maleic acid, malonic acid, succinic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, p-toluenesulfonic acid, salicylic acid, and the like, or mixtures thereof.

[0035] "Essentially free" as used in the phrase "essentially free of process byproducts or contaminants," means that a compound or composition as disclosed here in is admixed with 200 parts per million (ppm) or less of such byproducts or contaminants.

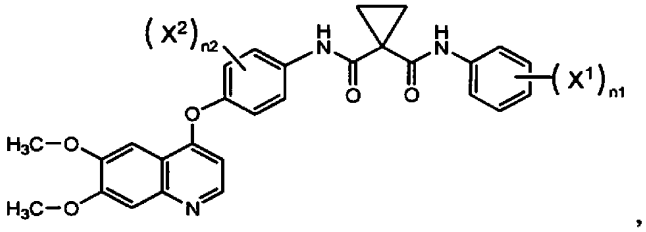
[0036] The disclosure is further illustrated by the following examples, which are not to be construed as limiting the disclosure in scope or spirit to the specific procedures described in them. Unless specified otherwise, the starting materials and various intermediates may be

obtained from commercial sources, prepared from commercially available organic compounds, or prepared using well-known synthetic processes.

Processes

Aspect 1: Processes for Making Compounds of Formula I

[0037] Aspect (1) of the invention relates to a process of preparing a compound of formula I:



I

or a pharmaceutically acceptable salt thereof, wherein:

X^1 is H, Br, Cl, or F;

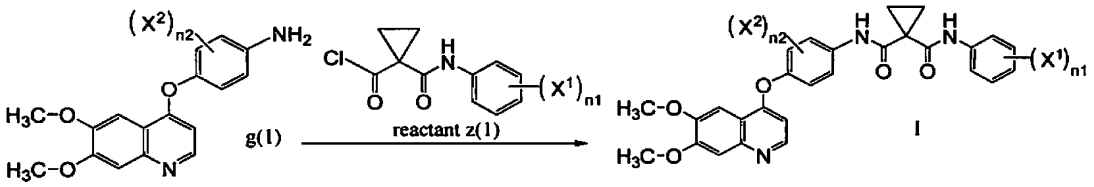
X^2 is H, Br, Cl, or F;

n1 is 1-2; and

n2 is 1-2;

the process comprising:

contacting the compound of formula g(1) with reactant z(1) to yield the compound of formula I:



[0038] The reaction is advantageously carried out under suitable reaction conditions. Non-limiting examples of suitable reaction conditions include using basic conditions. Non-limiting examples of basic conditions that can be used in Aspect (1) include the use of inorganic bases, such as aqueous KOH, NaOH, K_2CO_3, Na_2CO_3, K_3PO_4, Na_3PO_4, K_2HPO_4, Na_2HPO_4, and the like, or mixtures thereof. Other non-limiting examples of suitable reaction conditions include using suitable solvents. Non-limiting examples of suitable solvents that can be used include water miscible solvents, such as THF, acetone, ethanol, and the like, or mixtures thereof. Other non-limiting examples of suitable reaction conditions include using suitable temperatures. Suitable temperatures that may be used for the reaction include a

temperature at a range from about 10 °C to about 30 °C, or alternatively, at a range from about 15 °C to about 28 °C, or alternatively, at a range from about 20 °C to about 25 °C. The product formed by the reaction is in the free base form, and this free base form may be converted into a pharmaceutically acceptable salt thereof by processes known in the art. For example, the compound of formula I can be converted to the L-malate salt by the addition of L-malic acid and a suitable solvent.

[0039] Utilities of the compound of formula I are further described in WO 2005/030140 A2, which is incorporated herein by reference.

Embodiments of Aspect (1) Part A

[0040] In another embodiment of Aspect (1), X^1 is Cl or F.

[0041] In another embodiment of Aspect (1), X^2 is Cl or F.

[0042] In another embodiment of Aspect (1), X^1 is F.

[0043] In another embodiment of Aspect (1), X^2 is F.

[0044] In another embodiment of Aspect (1), X^1 is H.

[0045] In another embodiment of Aspect (1), X^2 is H.

[0046] In another embodiment of Aspect (1), n1 is 1.

[0047] In another embodiment of Aspect (1), n2 is 1.

[0048] In another embodiment of Aspect (1), n1 is 2.

[0049] In another embodiment of Aspect (1), n2 is 2.

[0050] All compounds of formula I for Aspect (1) disclosed above include any of the disclosed alternative embodiments in Part A for each of X^1, X^2, n1 or n2, in combination with any other of the disclosed alternative embodiments in Part A for each of X^1, X^2, n1, or n2, as well as a pharmaceutically acceptable salt of any such combination.

Embodiments of Aspect (1) Part B

[0051] In another embodiment of Aspect (1), n1 and n2 are each 1.

[0052] In another embodiment of Aspect (1), n1 and n2 are each 2.

[0053] In another embodiment of Aspect (1), n1 is 1; and n2 is 2.

[0054] In another embodiment of Aspect (1), n1 is 2 and n2 is 1.

[0055] In another embodiment of Aspect (1), X^1 is H; and X^2 is F.

[0056] In another embodiment of Aspect (1), X^1 is F; and X^2 is H.

[0057] In another embodiment of Aspect (1), X^1 and X^2 are each H.

[0058] In another embodiment of Aspect (1), X^1 and X^2 are each F.

[0059] In another embodiment of Aspect (1), X^1 is Cl; and X^2 is H.

[0060] In another embodiment of Aspect (1), X^1 is H; and X^2 is Cl.

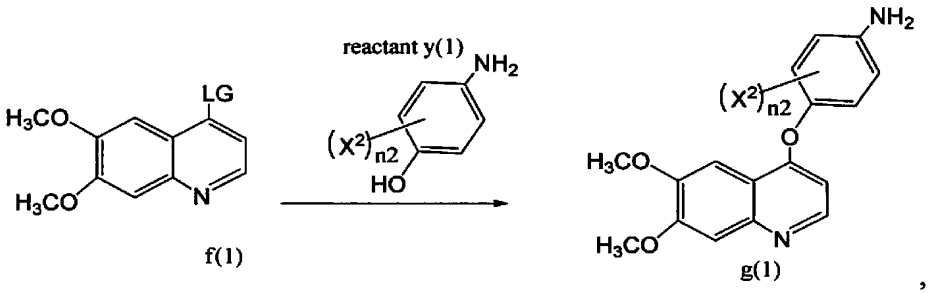
[0061] In another embodiment of Aspect (1), X^1 and X^2 are each Cl.

[0062] In another embodiment of Aspect (1), X^1 is Cl; and X^2 is F.

[0063] In another embodiment of Aspect (1), X^1 is F; and X^2 is Cl.

Embodiments of Aspect (1) Part C

[0064] In an embodiment of Aspect (1), the compound of formula g(1) can be made by reacting a compound of formula f(1) with reactant y(1) to yield the compound of g(1):



,

wherein LG represents a leaving group, and each of X^2, and n2 are as defined in Aspect (1), or as in any of the embodiments of Aspect (1) Part A. A non-limiting example of a leaving group includes a halo group such as Cl, Br, or F. Various compounds of reactant y(1) are commercially available, such as 2-fluoro-4-aminophenol and 4-aminophenol. Also, the skilled artisan would be able to make any variation of reactant y(1) using commercially available starting materials and by using known techniques to modify these commercially available starting materials to yield various compounds within the scope of reactant y(1).

[0065] The reaction in this embodiment is advantageously carried out under suitable reaction conditions. Non-limiting examples of suitable reaction conditions include using suitable solvents such as polar solvents. Non-limiting examples of polar solvents that can be used include tetrahydrofuran (THF), dimethylacetamide (DMA), dimethylsulfoxide (DMSO), dimethylformamide (DMF), ethyl acetate, N-methyl pyrrolidone (NMP), propylene carbonate, and the like, or mixtures thereof. In another embodiment, the polar solvent is dimethylacetamide (DMA). In another embodiment, the polar solvent is dimethylsulfoxide (DMSO). In another embodiment, the polar solvent is dimethylformamide (DMF). In another embodiment, the polar solvent is ethyl acetate. In another embodiment, the polar solvent is N-methyl pyrrolidone (NMP). In another embodiment, the polar solvent is propylene carbonate. In another embodiment, the solvent is a mixture of solvents, such as a mixture comprising THF and DMA.

[0066] The reactants f(1) and y(1) can be added together at a temperature ranging from about 10 °C to about 30 °C, or alternatively, from about 15 °C to about 28 °C, or alternatively, from about 20 °C to about 25 °C. The mixture is then heated to a temperature ranging from about 80 °C to about 125 °C, or alternatively, from about 95 °C to about 110 °C, or alternatively, from about 100 °C to about 105 °C, and the selected temperature is maintained until the reaction is complete.

[0067] Other non-limiting examples of suitable reaction conditions in this step of Aspect (1) include the use of a suitable base, such as a metal hydroxide or a non-nucleophilic base. Examples of metal hydroxides include sodium hydroxide or potassium hydroxide. Non-limiting examples of non-nucleophilic bases that can be used include lithium diisopropylamide, lithium tetramethylpiperidide, and alkali metal alkoxides such as sodium tert-butoxide, potassium tert-butoxide, sodium-pentoxide, and the like, or mixtures thereof. Preferably, the base is sodium tert-butoxide or sodium tert-pentoxide. In one embodiment, the base is sodium tert-pentoxide. Typically the sodium tert-pentoxide is commercially available as 35 weight percent solution of base in tetrahydrofuran, or as a 95 weight percent solid reagent. Preferably, the sodium tert-pentoxide is a 95 weight percent solid.

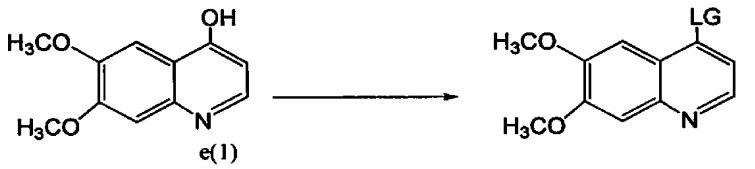
[0068] Typically, approximately 1.1 to 3.0 molar equivalents of base are used relative the moles of f(1) that are used. More preferably, 1.3 to 2.5 molar equivalents of base are used relative the moles of f(1) that are used. More preferably, 1.5 to 2.2 molar equivalents of base are used relative the moles of f(1) that are used. More preferably, 1.7 to 2.1 molar equivalents of base are used relative the moles of f(1) that are used.

[0069] Typically, the amount of molar equivalents of amino phenol that are used exceeds the molar equivalents of base that are used. In one embodiment, 1.1 to 2 molar equivalents of amino phenol are used relative to the molar equivalents of base that are used.

[0070] Once the reaction is substantially complete, the reaction mixture can be cooled to a temperature ranging from about 10 °C to about 25 °C. Precooled water can be charged at a rate to maintain a temperature that ranges from about 5 °C to about 35 °C. Alternatively, the precooled water can be charged at a rate to maintain a temperature that ranges from about 10 °C to about 25 °C. As a non-limiting example, the precooled water can be at a temperature ranging from about 0 °C to about 10 °C. As another non-limiting example, the precooled water can be at a temperature ranging from about 2 °C to about 7 °C. The precipitate can be collected by filtration under standard conditions and purified by standard purification techniques.

Embodiments of Aspect (1) Part D

[0071] In an embodiment of Aspect (1), the compound of formula f(1) can be made by converting a compound of formula e(1) to the compound of formula f(1):

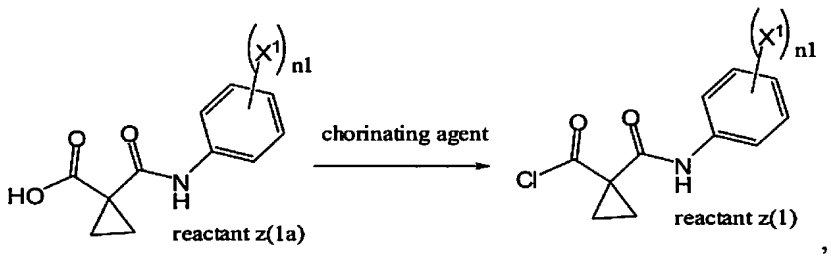


wherein LG represents a leaving group. Non-limiting examples of leaving groups that can be used include halo groups (e.g., Cl, Br, or F) that can be added by halogenating agents. Non-limiting examples of halogenating agents that can be used include chlorinating agents, such as $SOCl_2$, SO_2Cl_2, $COCl_2$, PCl_5, $POCl_3$, and the like.

[0072] The reaction is advantageously carried out under suitable reaction conditions. Non-limiting examples of suitable reaction conditions in Part D of Aspect (1) include the use of suitable solvents. Non-limiting example of suitable solvents that can be used during the halogenation of the compound of formula e(1) include a polar, aprotic solvent, such as CH_3CN, DMF, and the like, or mixtures thereof. In other embodiments, the chlorination can be carried out using $POCl_3$ in acetonitrile, $COCl_2$ in DMF, or $SOCl_2$ in DMF. The addition of the chlorination agent is advantageously carried out at a temperature ranging from about 60 °C to about 90 °C. In another embodiment, the addition of the chlorination agent can be carried out at a temperature ranging from about 70 °C to about 85 °C. In another embodiment, the addition of the chlorination agent can be carried out at a temperature ranging from about 74 °C to about 80 °C. The product can then be collected by filtration and purified using standard techniques.

Embodiments of Aspect (1) Part E

[0073] In an embodiment of Aspect (1), reactant z(1) can be made by reacting reactant z(1a) with a chlorinating agent to yield reactant z(1):

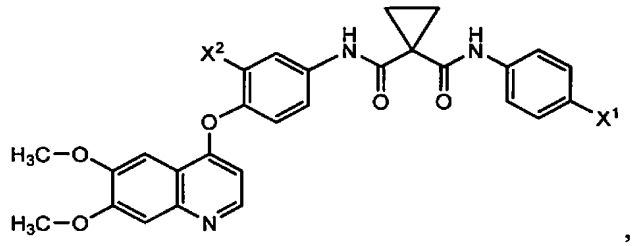


wherein X^1 is Br, Cl, or F; and n1 is 1-2. Compounds of reactant z(1a) can be made according to the process described in Example 25 of WO 2005/030140 A2, and the skilled artisan would be able to make any necessary substitutions using commercially available starting materials to come up with various compounds within the scope of reactant z(1a). Example 25 in WO 2005/030140 A2 is incorporated herein by reference.

[0074] The reaction is advantageously carried out under suitable reaction conditions. Non-limiting examples of suitable reaction conditions include using a chlorinating agent such as $POCl_3$, oxalyl chloride, and the like. In another embodiment, oxalyl chloride is used as a chlorinating agent. Non-limiting examples of suitable reaction conditions include carrying out the reaction at a temperature in the range from about 0 °C to about 25 °C, or alternatively at a temperature in the range from about 5 °C to about 20 °C. Other non-limiting examples of suitable reaction conditions include carrying out the reaction in a suitable solvent. Non-limiting examples of suitable solvents that can be used include polar aprotic solvents, such as halogenated hydrocarbons (e.g., dichloromethane and chloroform), ethers (e.g., Et_2O), dioxane, tetrahydrofuran (THF) containing catalytic DMF, and the like, or mixtures thereof. The resulting solution containing reactant z(1) can be used, without further processing, to make the compound of formula I.

Other Embodiments of Aspect (1)

[0075] In another embodiment of Aspect (1), the compound of formula I is a compound of formula IA-1:

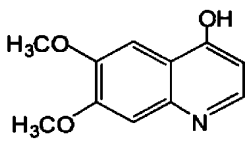


IA-1

or a pharmaceutically acceptable salt thereof, wherein:

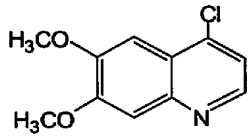
X^1 is H, Cl, Br, or F; and X^2 is H, Cl, Br, or F. Compound IA can be in the free base form or it can converted to a pharmaceutically acceptable salt thereof. Accordingly, compound IA can be converted to its L-malate salt by the addition of L-malic acid and a suitable solvent.

[0076] In another embodiment of Part D of Aspect (1), the compound of formula e(1) is compound e(2):



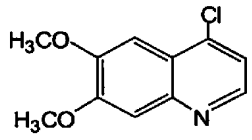
e(2) ;

and the compound of formula f(1) is compound f(2):



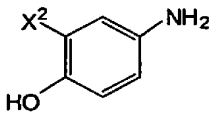
f(2) .

[0077] In another embodiment of Part C of Aspect (1), the compound of formula f(1) is compound f(2):



f(2) ;

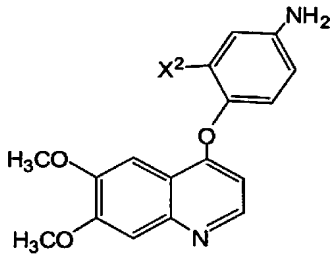
reactant y(1) is reactant (y)(2):



reactant (y)(2) ,

wherein X^2 is hydrogen or fluoro; and

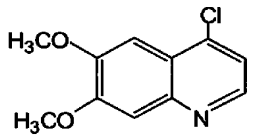
the compound of formula g(1) is of formula g(2):



g(2) .

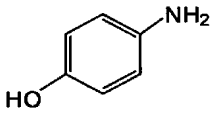
[0078] In a further embodiment, the reaction employs a non-nucleophilic base. In a further embodiment, the non-nucelophilic base is an alkali metal alkoxide; and the reaction is carried out in a polar solvent. In a further embodiment, the alkali metal alkoxide is sodium tert-butoxide, and the polar solvent is DMA.

[0079] In another embodiment of Part C of Aspect (1), the compound of formula f(1) is compound f(2):



f(2) ;

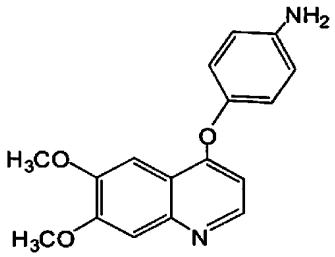
reactant y(1) is reactant (y)(3):



reactant (y)(3) ,

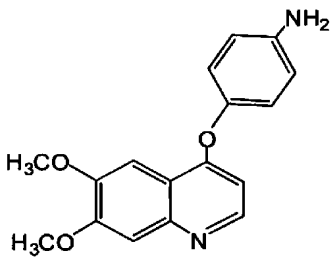
wherein X^2 is hydrogen or fluoro; and

the compound of formula g(1) is compound g(3):



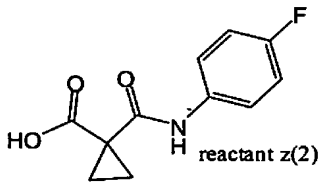
g(3) .

[0080] In another embodiment of Aspect (1) of this disclosure, the compound of formula g(1) is compound g(3):



g(3) ;

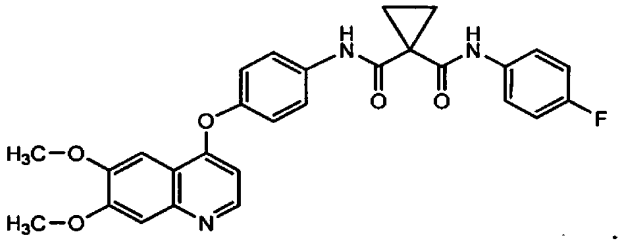
reactant z(1) is reactant (z)(2):



reactant z(2)

; and

the compound of formula I is compound IA:

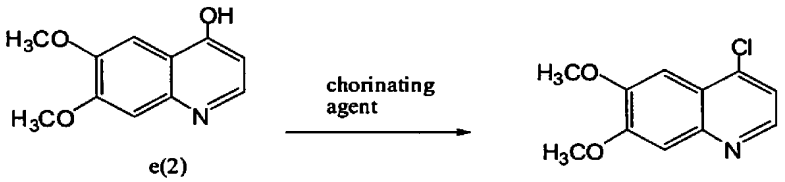


IA

[0081] In a further embodiment, the reaction is carried out in the presence of an inorganic base. In a further embodiment, the inorganic base is K_2CO_3, and the solvent employed in this reaction is a combination of THF and H_2O.

[0082] In another embodiment of Aspect (1) of this disclosure, X^1 and X^2 for each of formula g(1) and reactant z(1) are each selected from Cl or F. In another embodiment, X^1 and X^2 for each of formula g(2), and reactant z(1) are both F.

[0083] The compound of formula f(2),or a pharmaceutically acceptable salt thereof, can be made by converting the compound of formula e(2) to a compound of formula f(2) with a chlorinating agent in a suitable solvent:

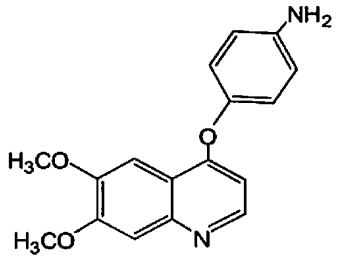


e(2) f(2)

The compound of formula f(2) can be in its free base form or converted to a pharmaceutically acceptable salt thereof. The reaction conditions that can be used in this aspect include any of the reaction conditions disclosed in Part E of Aspect (1).

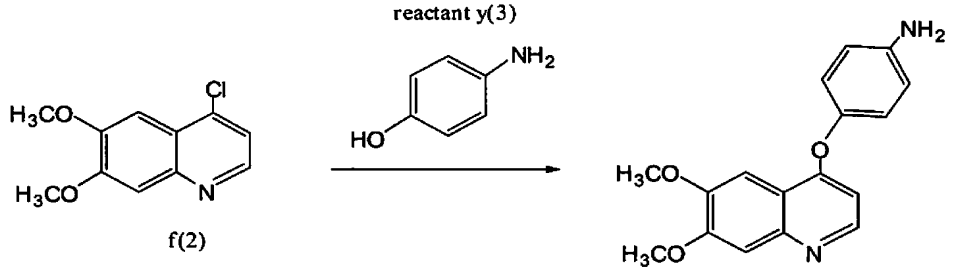
Aspect 2: Processes for Making Compounds of Formula g(2)

[0084] Aspect (2) of the disclosure relates to a process of preparing compound g(2):



g(2)

or a pharmaceutically acceptable salt thereof; the process comprising reacting compound f(2) with reactant y(3) under basic conditions (e.g., using 2,6-lutidine) in an appropriate solvent to yield compound g(3):



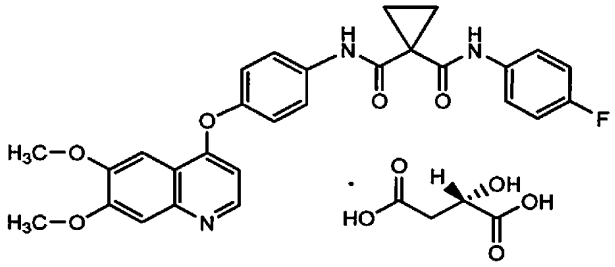
f(2) g(3)

The reaction conditions that can be used in this aspect include any of the reaction conditions disclosed in Part C of Aspect (1).

[0085] Alternative reaction conditions that can be used in this aspect include any of the reaction conditions disclosed in Parts C and D of Aspect (1).

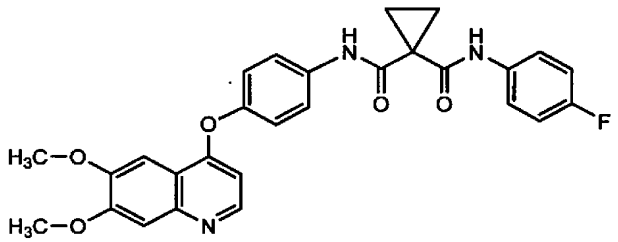
Aspect 3: Processes for Making Compounds of IB

[0086] As indicated above, in one aspect, the invention provides a process for preparing compound IB:



IB

from compound IA:



IA;

comprising:

(a) heating and agitating a mixture comprising compound IA and L-malic acid, methylethyl ketone, and water;

(b) cooling the mixture;

(c) vacuum distilling the mixture successively; and

(d) isolating the compound of IB by filtration.

[0087] In one embodiment of this aspect, compound IA is admixed with a sufficient amount of L-malic acid in a methylethyl ketone (MEK)/water (1:1) mixture. Alternatively, L-malic acid is added as a solution in water to a mixture of compound IA in methyl ethyl ketone. Generally the amount of L-malic is greater than 1 molar equivalent relative to compound IA. The mixture of compound IA and L-malic acid in MEK/water is heated at about 40-70 °C, and preferably at about 50-60 °C, and more preferably at about 55-60 °C with agitation, such as by stirring or the like, for about 1 to about 5 hours. At the end of the heating, the mixture is optionally clarified by filtering to give a clear solution. The resulting clear solution is then vacuum distilled from 1 to about 5 times at 150 to 200 mm Hg and a maximum jacket temperature of 55 °C to provide the desired crystalline compound of IB.

[0088] In one embodiment, L-malic acid is charged as a solution in water to compound IA. Generally the amount of L-malic is greater than 1 molar equivalent relative to compound IA. The mixture of compound IA and L-malic acid in MEK/water is heated at about 40-70 °C, and preferably at about 50-60 °C, and more preferably at about 55-60 °C with agitation, such as by stirring or the like, for about 1 to about 5 hours. At the end of the heating, the mixture is optionally clarified by filtering to give a clear solution which is at a temperature of about 30-40 °C, and more preferably at a temperature of about 33-37 °C. This clear solution is optionally seeded to facilitate crystallization. After seeding, the resulting mixture is vacuum distilled as provided above.

[0089] In one embodiment, compound IB is in the N-1 form. In another embodiment, compound IB is in the N-2 form. In another embodiment, compound IB is a mixture of the N-1 form and the N-2 form. Processes for preparing the N-1 and N-2 forms of compound IB

are disclosed in WO 2010/083414 (PCT/US2010021194), the entire contents of which are incorporated herein by reference.

[0090] In another embodiment, the disclosure relates to compound IA or IB admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment, the compound is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

[0091] In another embodiment, the disclosure relates to compound IA admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment, the compound is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

[0092] In another embodiment, the disclosure relates to compound IB admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment, the compound is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

[0093] In another embodiment, the disclosure relates to compound IB in the N-1 form admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment, the compound is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

[0094] In another embodiment, the disclosure relates to compound IB in the N-2 form admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment, the compound is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

[0095] In another embodiment, the disclosure relates to compound IB as a mixture of the N-1 form and the N-2 form admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment, the compound is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment, the compound is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

Pharmaceutical Compositions

[0096] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound I, IA, or IB. Various carriers used in formulating pharmaceutically acceptable compositions and known techniques for their bulk preparation and subsequent production into unit dosage forms are employed to make the pharmaceutical compositions disclosed herein and are described in Remington: The Science and Practice of Pharmacy, 21st edition, 2005, ed. D. B. Troy, Lippincott Williams & Wilkins, Philadelphia, and Encyclopedia of Pharmaceutical Technology, eds. J. Swarbrick and J. C. Boylan, 1988-1999, Marcel Dekker, New York. The amount of carriers and excipients used in a composition can be varied proportionally according to the amount of active ingredient used (that is, Compound I, IA or IB).

[0097] In one embodiment, the pharmaceutical composition is a tablet.

[0098] In another embodiment, the pharmaceutical composition is a capsule.

[0099] In another embodiment, the pharmaceutical composition comprises Compound IA.

[00100] In another embodiment, the pharmaceutical composition comprises Compound IB.

[00101] In another embodiment, the pharmaceutical composition comprises Compound IB. as the N-1 polymorph.

[00102] In another embodiment, the pharmaceutical composition comprises Compound IB as the N-2 polymorph.

[00103] In another embodiment, the pharmaceutical composition comprises Compound IB as a mixture of the N-1 form and the N-2 form.

[00104] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; one or more fillers; one or more disintergrants; one or more glidants; and one or more lubricants.

[00105] In this embodiment, the filler comprises microcrystalline cellulose.

[00106] In this embodiment, the disintegrant comprises croscarmellose sodium.

[00107] In this embodiment, the disintegrant comprises croscarmellose sodium and sodium starch glycolate.

[00108] In this embodiment, the glidant comprises fumed silica.

[00109] In this embodiment, the lubricant comprises stearic acid.

[00110] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; lactose; hydroxypropyl cellulose; croscarmellose sodium; colloidal silicon dioxide; and magnesium stearate.

[00111] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; hydroxypropyl cellulose; a surfactant; croscarmellose sodium; colloidal silicon dioxide; and magnesium stearate.

[00112] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; croscarmellose sodium; fumed silica; and stearic acid.

[00113] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; anhydrous lactose; hydroxypropyl cellulose; croscarmellose sodium; silicon dioxide; and magnesium stearate.

[00114] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; anhydrous lactose; hydroxypropyl cellulose; a surfactant; croscarmellose sodium; silicon dioxide; and magnesium stearate.

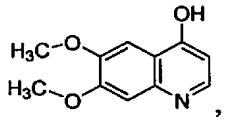
[00115] In another aspect, the disclosure provides a pharmaceutical composition according to Tables 1, 2, 2A, 3, 4, 5, and 6 as provided above. The compositions are prepared according to methods available to the skilled artisan. For example, the Tablet

formulations are prepared by combining, blending, and compacting the components of the tablet compositions. The capsule compositions are prepared by combining and blending the components and then placing the blend in a gelatin capsule.

[00116] For example, the 25 mg capsules (Table 3, 10 percent drug load formulation) are prepared as follows. The drug substance is delumped through a mill. The delumped drug substance is then co-screened with an equal volume Prosolv HD90. The excipients, except for stearic acid, are screened and charged to a blender along with the co-screened drug substance. The mixture is blended in a V-Blender. This process is repeated to manufacture a second sublot of unlubricated blend. The two sublots are then combined together in a V-blender and lubricated with stearic acid which has been co-screened with an equal volume of unlubricated blend. The final blend is then encapsulated into opaque, size 1 gelatin capsules using an automated capsule filling machine. The capsules are then weight sorted through an automatic weight sorter.

[00117] The 100-mg capsules (Table 4, 50% drug load formulation) are manufactured in two equal sublots of 5 kg of blend which are combined prior to lubricant blend The drug substance is delumped through a mill. The excipients, except for stearic acid, are screened and charged to the mixer along with the delumped drug substance. The mixture is blended with a high shear mixer. The process is repeated to manufacture a second sublot of unlubricated blend. The final blend is then encapsulated into Swedish oraopaque, size 1 gelatin capsules using an automated capsule filling machine. The capsuare then weight sorted through an automatic weight sorter.

[00118] The 50 and 60 mg capsules (Tables 5 and 6) are prepared in a similar fashion as the 25 and 100 mg capsules.

[00119] In another aspect, the disclosure relates to a pharmaceutical composition comprising a compound of Formula IA or IB and a pharmaceutically acceptable carrier admixed with less than 100 ppm of 6,7-dimethoxy-quinoline-4-ol. 6,7-dimethoxy-quinoline-4-ol, the structure of which is 

, can be used as reagent e(1) to make chloride f(1) and is a byproduct that may form during the synthesis of Compound IA or IB. Minimizing the concentration of contaminants or byproducts such as 6,7-dimethoxy-quinoline-4-ol in pharmaceutical compositions destined for human administration is desirable.

[00120] In one embodiment, the pharmaceutical composition as defined in any of the previous embodiments (for example, the pharmaceutical composition of Tables 1, 2, 2A, 3, 4, 5, and6) is admixed with 100 ppm 6,7-dimethoxy-quinoline-4-ol.

[00121] In another embodiment, the pharmaceutical composition as defined in any of the previous embodiments is admixed with 50 ppm 6,7-dimethoxy-quinoline-4-ol.

[00122] In another embodiment, the pharmaceutical composition as defined in any of the previous embodiments is admixed with 25 ppm 6,7-dimethoxy-quinoline-4-ol.

[00123] In another embodiment, the pharmaceutical composition as defined in any of the previous embodiments is admixed with 15 ppm 6,7-dimethoxy-quinoline-4-ol.

[00124] In another embodiment, the pharmaceutical composition as defined in any of the previous embodiments is admixed with 10 ppm 6,7-dimethoxy-quinoline-4-ol.

[00125] In another embodiment, the pharmaceutical composition as defined in any of the previous embodiments is admixed with 5 ppm 6,7-dimethoxy-quinoline-4-ol.

[00126] In another embodiment, the pharmaceutical composition as defined in any of the previous embodiments is admixed with 2.5 ppm 6,7-dimethoxy-quinoline-4-ol.

[00127] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; one or more fillers; one or more disintergrants; one or more glidants; and one or more lubricants admixed with 100 ppm or less 6,7-dimethoxy-quinoline-4-ol.

[00128] In this embodiment, the filler comprises microcrystalline cellulose.

[00129] In this embodiment, the disintegrant comprises croscarmellose sodium.

[00130] In this embodiment, the disintegrant comprises croscarmellose sodium and sodium starch glycolate.

[00131] In this embodiment, the glidant comprises fumed silica.

[00132] In this embodiment, the lubricant comprises stearic acid.

[00133] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; croscarmellose sodium; fumed silica; and stearic acid; admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment of this embodiment, the composition is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with

5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

[00134] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; anhydrous lactose; hydroxypropyl cellulose; a surfactant; croscarmellose sodium; silicon dioxide; and magnesium stearate; admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment of this embodiment, the composition is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

[00135] In another embodiment, the disclosure relates to a pharmaceutical composition comprising Compound IA or IB; microcrystalline cellulose; croscarmellose sodium; fumed silica; and stearic acid; ; admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In one embodiment of this embodiment, the composition is admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol. In another embodiment of this embodiment, the composition is admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

EXAMPLES

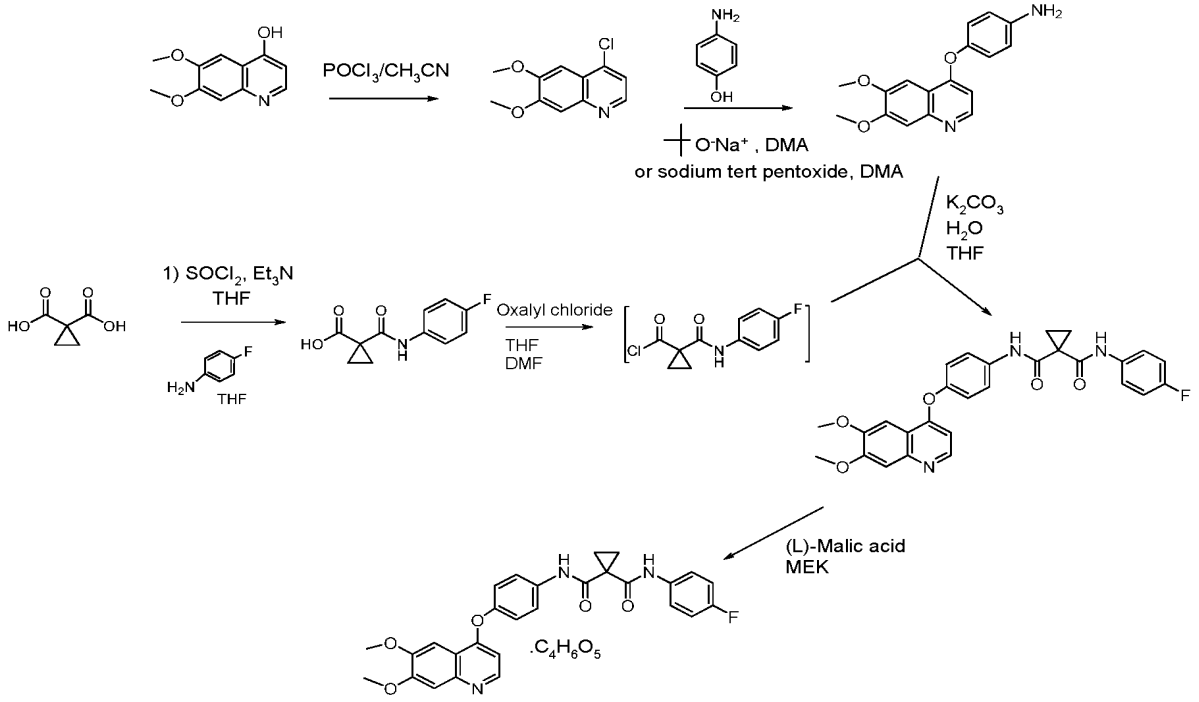
[00136] The invention is illustrated further by the following examples in Scheme 1 and the description thereof, which are not to be construed as limiting the invention in scope or spirit to the specific procedures described in them. Those having skill in the art will recognize that the starting materials may be varied and additional steps employed to produce compounds encompassed by the invention, as demonstrated by the following examples. Those skilled in the art will also recognize that it may be necessary to utilize different solvents or reagents to achieve some of the above transformations. Unless otherwise specified, all reagents and solvents are of standard commercial grade and are used without further purification. The

appropriate atmosphere to run the reaction under, for example, air, nitrogen, hydrogen, argon, and the like, will be apparent to those skilled in the art.

Preparation of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide and the (L)-malate salt thereof.

[00137] A synthetic route that can be used for the preparation of N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide and the (L)-malate salt thereof is depicted in Figure 1:

Figure 1



Preparation of 4-Chloro-6,7-dimethoxy-quinoline

[00138] A reactor was charged sequentially with 6,7-dimethoxy-quinoline-4-ol (47.0 kg) and acetonitrile (318.8 kg). The resulting mixture was heated to approximately 60 °C, and phosphorus oxychloride ($POCl_3$, 130.6 kg) was added. After the addition of $POCl_3$, the temperature of the reaction mixture was raised to approximately 77 °C. The reaction was deemed complete (approximately 13 hours) when less than 3% of the starting material remained (in-process high-performance liquid chromatography [HPLC] analysis). The reaction mixture was cooled to approximately 2 – 7 °C and then quenched into a chilled solution of dichloromethane (DCM, 482.8 kg), 26 % NH_4OH (251.3 kg), and water (900 L). The resulting mixture was warmed to approximately 20 – 25 °C, and phases were separated.

The organic phase was filtered through a bed of AW hyflo super-cel NF (Celite; 5.4 kg) and the filter bed was washed with DCM (118.9 kg). The combined organic phase was washed with brine (282.9 kg) and mixed with water (120 L). The phases were separated and the organic phase was concentrated by vacuum distillation with the removal of solvent (approximately 95 L residual volume). DCM (686.5 kg) was charged to the reactor containing organic phase and concentrated by vacuum distillation with the removal of solvent (approximately 90 L residual volume). Methyl t-butyl ether (MTBE, 226.0 kg) was then charged and the temperature of the mixture was adjusted to -20 to -25 °C and held for 2.5 hours resulting in solid precipitate which was then filtered and washed with n-heptane (92.0 kg), and dried on a filter at approximately 25 °C under nitrogen to afford the title compound. (35.6 kg).

Preparation of 4-(6,7-dimethoxy-quinoline-4-yloxy)-phenylamine

[00139] 4-Aminophenol (24.4 kg) dissolved in N,N-dimethylacetamide (DMA, 184.3 kg) was charged to a reactor containing 4-chloro-6,7-dimethoxyquinoline (35.3 kg), sodium t-butoxide (21.4 kg) and DMA (167.2 kg) at 20-25 °C. This mixture was then heated to 100-105 °C for approximately 13 hours. After the reaction was deemed complete as determined using in-process HPLC analysis (<2% starting material remaining), the reactor contents were cooled at 15 to 20 °C and water (pre-cooled, 2 to 7 °C, 587 L) charged at a rate to maintain 15 to 30 °C temperature . The resulting solid precipitate was filtered, washed with a mixture of water (47 L) and DMA (89.1 kg) and finally with water (214 L). The filter cake was then dried at approximately 25 °C on filter to yield crude 4-(6,7-dimethoxy-quinoline-4-yloxy)-phenylamine (59.4 kg wet, 41.6 kg dry calculated based on LOD). Crude 4-(6,7-dimethoxy-quinoline-4-yloxy)-phenylamine was refluxed (approximately 75 °C) in a mixture of tetrahydrofuran (THF, 211.4 kg) and DMA (108.8 kg) for approximately 1hour and then cooled to 0-5 °C and aged for approximately 1 h after which time the solid was filtered, washed with THF (147.6 kg) and dried on a filter under vacuum at approximately 25 °C to yield 4-(6,7-dimethoxy-quinoline-4-yloxy)-phenylamine (34.0 kg).

Alternative Preparation of 4-(6,7-dimethoxy-quinoline-4-yloxy)-phenylamine

[00140] 4-chloro-6,7-dimethoxyquinoline (34.8 kg) and 4-aminophenol (30.8 kg) and sodium tert pentoxide (1.8 equivalents) 88.7 kg, 35 wt percent in THF) were charged to a reactor, followed by N,N-dimethylacetamide (DMA, 293.3 kg). This mixture was then heated to 105-115 °C for approximately 9 hours. After the reaction was deemed complete as

determined using in-process HPLC analysis (<2% starting material remaining), the reactor contents were cooled at 15 to 25 °C and water (315 kg) was added over a two hour period while maintaining the temperature between 20 and 30 °C. The reaction mixture was then agitated for an additional hour at 20 to 5 °C. The crude product was collected by filtration and washed with a mixture of 88 kg water and 82.1 kg DMA, followed by 175 kg water. The product was dried on a filter drier for 53 hours. The LOD showed less than 1% w/w.

[00141] In an alternative procedure, 1.6 equivalents of sodium tert-pentoxide were used and the reaction temperature was increased from 110-120 °C. In addition , the cool down temperature was increased to 35-40 °C and the starting temperature of the water addition was adjusted to 35-40 °C, with an allowed exotherm to 45 °C.

Preparation of 1-(4-fluoro-phenylcarbamoyl)-cyclopropanecarboxylic acid

[00142] Triethylamine (19.5 kg) was added to a cooled (approximately 5 C) solution of cyclopropane-1,1-dicarboxylic acid (24.7 kg) in THF (89.6 kg) at a rate such that the batch temperature did not exceed 5 °C. The solution was stirred for approximately 1.3 hours, and then thionyl chloride (23.1 kg) was added, keeping the batch temperature below 10 °C. When the addition was complete, the solution was stirred for approximately 4 h keeping temperature below 10 °C. A solution of 4–fluoroaniline (18.0 kg) in THF (33.1 kg) was then added at a rate such that the batch temperature did not exceed 10 °C. The mixture was stirred for approximately 10 hours after which the reaction was deemed complete. The reaction mixture was then diluted with isopropyl acetate (218.1 kg). This solution was washed sequentially with aqueous sodium hydroxide (10.4 kg, 50 % dissolved in 119 L of water) further diluted with water (415 L), then with water (100 L) and finally with aqueous sodium chloride (20.0 kg dissolved in 100 L of water). The organic solution was concentrated by vacuum distillation (100 L residual volume) below 40 °C followed by the addition of n-heptane (171.4 kg), which resulted in the precipitation of solid. The solid was recovered by filtration and washed with n-Heptane (102.4 kg) resulting in wet crude, 1-(4-fluoro-phenylcarbamoyl)-cyclopropanecarboxylic acid (29.0 kg). The crude, 1-(4-fluoro-phenylcarbamoyl)-cyclopropanecarboxylic acid was dissolved in methanol (139.7 kg) at approximately 25 °C followed by the addition of water (320 L) resulting in slurry which was recovered by filtration, washed sequentially with water (20 L) and n-heptane (103.1 kg) and then dried on the filter at approximately 25 °C under nitrogen to afford the title compound (25.4 kg).

Preparation of 1-(4-Fluoro-phenylcarbamoyl)-cyclopropanecarbonyl chloride

[00143] Oxalyl chloride (12.6 kg) was added to a solution of 1-(4-fluoro-phenylcarbamoyl)-cyclopropanecarboxylic acid (22.8 kg) in a mixture of THF (96.1 kg) and N, N-dimethylformamide (DMF; 0.23 kg) at a rate such that the batch temperature did not exceed 25 °C. This solution was used in the next step without further processing.

Alternative Preparation of 1-(4-Fluoro-phenylcarbamoyl)-cyclopropanecarbonyl chloride

[00144] A reactor was charged with 1-(4-fluoro-phenylcarbamoyl)-cyclopropanecarboxylic acid (35 kg), 344 g DMF, and 175kg THF. The reaction mixture was adjusted to 12-17 °C and then to the reaction mixture was charged 19.9 kg of oxalyl chloride over a period of 1 hour. The reaction mixture was left stirring at 12-17 °C for 3 to 8 hours. This solution was used in the next step without further processing.

Preparation of cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinoline-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide (Compound IA)

[00145] The solution from the previous step containing 1–(4–fluoro–phenylcarbamoyl)–cyclopropanecarbonyl chloride was added to a mixture of compound 4-(6,7-dimethoxy-quinoline-4-yloxy)-phenylamine (23.5 kg) and potassium carbonate (31.9 kg) in THF (245.7 kg) and water (116 L) at a rate such that the batch temperature did not exceed 30 °C. When the reaction was complete (in approximately 20 minutes), water (653 L) was added. The mixture was stirred at 20-25 °C for approximately 10 hours, which resulted in the precipitation of the product. The product was recovered by filtration, washed with a pre-made solution of THF (68.6 kg) and water (256 L), and dried first on a filter under nitrogen at approximately 25 °C and then at approximately 45 °C under vacuum to afford the title compound (41.0 kg, 38.1 kg, calculated based on LOD).

Alternative Preparation of cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinoline-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide

[00146] A reactor was charged with 4-(6,7-dimethoxy-quinoline-4-yloxy)-phenylamine (35.7 kg, 1 equivalent), followed by 412.9 kg THF. To the reaction mixture was charged a solution of 48.3 K_2CO_3 in 169 kg water. The acid chloride solution of described in the Alternative Preparation of 1-(4–Fluoro-phenylcarbamoyl)-cyclopropanecarbonyl chloride above was transferred to the reactor containing 4-(6,7-dimethoxy-quinoline-4-yloxy)-

phenylamine while maintaining the temperature between 20-30 °C over a minimum of two hours. The reaction mixture was stirred at 20-25 °C for a minimum of three hours. The reaction temperature was then adjusted to 30-25 °C and the mixture was agitated. The agitation was stopped and the phases of the mixture were allowed to separate. The lower aqueous phase was removed and discarded. To the remaining upper organic phase was added 804 kg water. The reaction was left stirring at 15-25 °C for a minimum of 16 hours.

[00147] The product precipitated. The product was filtered and washed with a mixture of 179 kg water and 157.9 THF in two portions. The crude product was dried under a vacuum for at least two hours. The dried product was then taken up in 285.1 kg THF. The resulting suspension was transferred to reaction vessel and agitated until the suspension became a clear (dissolved) solution, which required heating to 30-35 °C for approximately 30 minutes. 456 kg water was then added to the solution, as well as 20 kg SDAG-1 ethanol (ethanol denatured with methanol over two hours. The mixture was agitated at 15-25 °C for at least 16 hours. The product was filtered and washed with a mixture of 143 kg water and 126.7 THF in two portions. The product was dried at a maximum temperature set point of 40 °C.

[00148] In an alternative procedure, the reaction temperature during acid chloride formation was adjusted to 10-15 °C. The recrystallization temperature was changed from 15-25 °C to 45-50 °C for 1 hour and then cooled to 15-25 °C over 2 hours.

Preparation of cyclopropane–1,1–dicarboxylic acid [4–(6,7–dimethoxy– quinoline–4–yloxy)–phenyl]–amide (4–fluoro–phenyl)–amide, (L) malate salt (Compound IB)

[00149] Cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinoline-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide (1-5; 13.3 kg), L-malic acid (4.96 kg), methyl ethyl ketone (MEK; 188.6 kg) and water (37.3 kg) were charged to a reactor and the mixture was heated to reflux (approximately 74 °C) for approximately 2 hours. The reactor temperature was reduced to 50 to 55 °C and the reactor contents were filtered. These sequential steps described above were repeated two more times starting with similar amounts of 1-5 (13.3 kg), L-Malic acid (4.96 kg), MEK (198.6 kg) and water (37.2 kg). The combined filtrate was azeotropically dried at atmospheric pressure using MEK (1133.2 kg) (approximate residual volume 711 L; KF $\leq$ 0.5 % w/w) at approximately 74 °C. The temperature of the reactor contents was reduced to 20 to 25 °C and held for approximately 4 hours resulting in solid precipitate which was filtered, washed with MEK (448 kg) and dried under vacuum at 50°C to afford the title compound (45.5 kg).

Alternative Preparation of cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinoline-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide, (L) malate salt

[00150] Cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinoline-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide (47.9 kg), L-malic acid (17.2), 658.2 kg methyl ethyl ketone, and 129.1 kg water (37.3 kg) were charged to a reactor and the mixture was heated 50-55 °C for approximately 1-3 hours, and then at 55-60 °C for an addition al 4-5 hours. The mixture was clarified by filtration through a 1 μm cartridge. The reactor temperature was adjusted to 20-25 °C and vacuum distilled with a vacuum at 150-200 mm Hg with a maximum jacket temperature of 55 °C to the volume range of 558-731 L.

[00151] The vacuum distillation was performed two more times with the charge of 380 kg and 380.2 kg methyl ethyl ketone, respectively. After the third distillation, the volume of the batch was adjusted to 18 v/w of Cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinoline-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide by charging 159.9 kg methyl ethyl ketone to give a total volume of 880L. An addition al vacuum distillation was carried out by adjusting 245.7 methyl ethyl ketone. The reaction mixture was left with moderate agitation at 20-25 °C for at least 24 hours. The product was filtered and washed with 415.1 kg methyl ethyl ketone in three portions. The product was dried under a vacuum with the jacket temperature set point at 45 °C.

[00152] In an alternative procedure, the order of addition was changed so that a solution of 17.7 kg L-malic acid dissolved in 129.9 kg water was added to Cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinoline-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide (48.7 kg) in methyl ethyl ketone (673.3 kg).

Preparation of Compound IB, Form N-1

[00153] A solution was prepared by adding tetrahydrofuran (12 mL/g-bulk-LR (limiting reagent); 1.20 L) and N-(4-{[6,7-bis(methyloxy)-quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, (100 g; 1.00 equiv; 100.00 g) and (L)-malic acid (1.2 equiv (molar); 32.08 g) to a 1 L reactor. Water (0.5317 mL/g-bulk-LR; 53.17 mL) was added and the solution was heated to 60 °C and maintained at that temperature for one hour until the solids were fully dissolved. The solution was passed through a Polish Filter.

[00154] At 60 °C, acetonitrile (12 mL/g-bulk-LR; 1.20 L) was added over a period of 8 hours. The solution was held at 60 °C for 10 hours. The solution was then cooled to 20 °C and held for 1 hour. The solids were filtered and washed with acetonitrile (12 mL/g-bulk-LR;

1.20 L). The solids were dried at 60 °C (25 mm Hg) for 6 hours to afford compound (I), Form N-1 (108 g; 0.85 equivalent; 108.00 g; 85.22% yield) as a white crystalline solid.

Alternate Preparation of Compound IB, Form N-1

[00155] A solution was prepared with 190 mL tetrahydrofuran (110 mL), methyl isobutyl ketone, and 29 mL water. Next, 20 mL of this solution were transferred into an amber bottle, and then saturated by adding N-(4-{[6,7-bis(methyloxy)-quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, (L)-malate until a thick slurry formed, and aging for at least 2 hours with stirring at room temperature. The solids were removed by filtration through a Buchner funnel, rendering a clear saturated solution.

[00156] Separately, a powder blend was made with known amounts of two batches of compound IB: (1) 300 mg of batch 1, which contained approximately 41% compound IB, Form N-1 and 59% compound IB, Form N-2 by Raman spectroscopy analysis, and (2) 200 mg of batch 2, which had a XPRD pattern similar to compound IB, Form N-2.

[00157] The compound IB, Form N-1 and compound (I), Form N-2 powder blend was added into the saturated solution, and the slurry was aged under magnetic stirring at room temperature for 25 days. The slurry was then sampled and filtered through a Buchner funnel to obtain 162 mg of wet cake. The wet cake was dried in a vacuum oven at 45 °C to afford 128 mg of crystalline compound IB in the N-1 form.

Preparation of Crystalline Compound IB, Form N-2

Preparation of Crystalline Compound IB, Form N-2 Seed Crystals

[00158] A solution was prepared by combining 20 ml of acetone and 300 mg of compound IA (N-(4-{[6,7-bis(methyloxy)quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide) in a 25ml screw capped vial. Next, 0.758ml of a 0.79M (L)-malic acid stock solution was added to the vial with magnetic stirring. The solution was then left stirring for 24 hours at ambient temperature. The sample was then suction filtered with 0.45μm PTFE filter cartridge and dried *in vacuo* at ambient temperature overnight.

Preparation of Crystalline Compound IB, Form N-2.

[00159] To a reactor were added N-(4-{[6,7-bis(methyloxy)-quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide (48 g; 1.00 equiv; 48.00 g) and tetrahydrofuran (16.5 mL/g-bulk-LR; 792.00 mL). The water content was adjusted to 1 wt% water. The solution was heated to 60 °C. Once dissolved, the solution was passed through a polish filter to provide the first solution.

[00160] In a separate reactor, (L)-malic acid (1.2 equiv (molar); 15.40 g) was dissolved into methyl isobutyl ketone (10 mL/g-bulk-LR; 480.00 mL) and tetrahydrofuran (1 mL/g-bulk-LR; 48.00 mL). Next, 50 mL of the (L)-malic acid solution was added to the first solution at 50 °C. Seed crystals were added (1%, 480 mg) and the malic acid solution was added at 50 °C dropwise via an addition funnel (1.3 ml/min over 3 hours). The slurry was held at 50 °C for 18 hours and then was cooled to 25 °C over 30 minutes. The solids were filtered, and washed with 20% tetrahydrofuran/methyl isobutyl ketone (10V, 480 mL). The solids were dried under vacuum at 60 °C for 5 hours to afford compound IB (55.7 g; 0.92 equivalent; 55.70 g; 91.56% yield) as an off-white crystalline solid.

Stability Studies of Pharmaceutical Compositions

[00161] The pharmaceutical capsule compositions of Tables 3 and 4 were prepared by mixing the ingredients according to processes known in the art.

Table 3

Ingredient	**mg/unit dose**
Compound IB (10 % drug load as Compound IA)	25
Microcrystalline Cellulose	196.75
Croscarmellose sodium	12.5
Sodium starch glycolate	12.5
Fumed Silica	0.75
Stearic acid	2.5
Total Fill Weight	250

Table 4

Ingredient	**mg/unit dose**
Compound IB (50 % drug load as Compound IA)	100
Silicified Microcrystalline Cellulose	75.40
Croscarmellose sodium	10.00
Sodium Starch Glycolate	10.00
Fumed silica	0.6
Stearic Acid	4.0
Total Fill Weight	200

[00162] The capsule compositions were subjected to stability studies to monitor the formation of 6,7-dimethoxy-quinoline-4-ol at various temperatures and relative humidities over time. The results are summarized in Tables 7A and 7B and Tables 8A and 8B.

Table 7A: Stability of 25 Mg Capsules (Table 3)

	Conditions	Bottle A1	Bottle A2	Bottle A3	Bottle A4
		PPM of 6,7-dimethoxy-quinoline-4-ol			
Initial T=0	25 °C/60% RH	2	2	3	3
1 Month	25 °C/60% RH	3	4	5	NA
	30 °C/75% RH	4	4	NA	NA
	40 °C/75% RH	9	9	10	NA
3 Months	25 °C/60% RH	5	5	7	NA
	30 °C/75% RH	7	6	NA	NA
	40 °C/75% RH	22	23	24	NA
6 Months	25 °C/60% RH	6	6	7	7 (3M in blister)
	30 °C/75% RH	9	9	NA	NA
	40 °C/75% RH	40	44	43	27 (3M in blister)
9 Months	25 °C/60% RH	7	7	9	8 (6M in blister)
	30 °C/75% RH	13	12	NA	NA
	40 °C/75% RH	NA	NA	68	60 (6M in blister)

M=Months; NA=Not Applicable; RH= Relative Humidity; PPM= Parts per Million. A portion of Bottle A4 was repackaged in a blister pack after being stored in bottles for 3 months.

Table 7B: Stability of 25 Mg Capsules (Table 3)

	Conditions	Bottle B1	Bottle B	Bottle B3	Bottle B4
		PPM of 6,7-dimethoxy-quinoline-4-ol			
Initial T=0	25 °C/60% RH	3	1	2	2
1 Month	25 °C/60% RH	<2	<2	<2	NA
	30 °C/75% RH	<2	<2	NA	NA
	40 °C/75% RH	2	<2	<2	NA
3 Months	25 °C/60% RH	2	<2	<2	NA
	30 °C/75% RH	2	<2	NA	NA
	40 °C/75% RH	3	<2	<2	NA
6 Months	25 °C/60% RH	<2	<2	<2	<2 (3M in blister)
	30 °C/75% RH	2	<2	NA	NA
	40 °C/75% RH	4	<2	3	3 (3M in blister)
9 Months	25 °C/60% RH	<2	<2	<2	<2 (6M in blister)
	30 °C/75% RH	3	<2	NA	NA
	40 °C/75% RH	NA	NA	5	4 (6M in blister)

A portion of Bottle B4 was repackaged in a blister pack after being stored in bottles for 3 months.

Table 8A: Stability of 100 Mg Capsules (Table 4)

	Conditions	Bottle A1	Blister A2	Bottle A3
		PPM of 6,7-dimethoxy-quinoline-4-ol		
Initial T=0	25 °C/60% RH	4	4	6
1 Month	25 °C/60% RH	4	4	6
	30 °C/75% RH	4	NA	6
	40 °C/75% RH	6	6	9
3 Months	25 °C/60% RH	5	5	7
	30 °C/75% RH	6	NA	7
	40 °C/75% RH	10	10	12
6 Months	25 °C/60% RH	5	5	
	30 °C/75% RH	6	NA	
	40 °C/75% RH	11	17	

M=Months; NA=Not Applicable; RH= Relative Humidity; PPM= Parts per Million.

Table 8B: Stability of 100 Mg Capsules (Table 4)

	Conditions	Bottle B1	Blister B2	Bottle B3
		PPM of 6,7-dimethoxy-quinoline-4-ol		
Initial T=0	25 °C/60% RH	1	1	2
1 Month	25 °C/60% RH	<2	<2	<2
	30 °C/75% RH	<2	<2	2
	40 °C/75% RH	<2	<2	2
3 Months	25 °C/60% RH	<2	<2	<2
	30 °C/75% RH	<2	NA	<2
	40 °C/75% RH	<2	<2	2
6 Months	25 °C/60% RH	<2	<2	
	30 °C/75% RH	<2	NA	
	40 °C/75% RH	2	2	

M=Months; NA=Not Applicable; RH= Relative Humidity; PPM= Parts per Million.

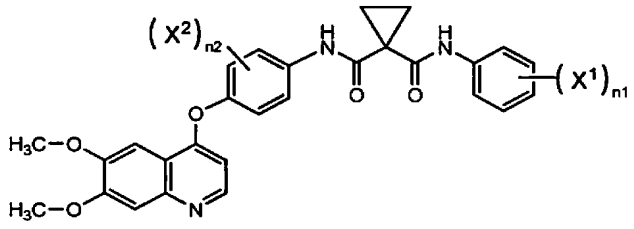
[00163] The results summarized in Tables 7A and 7B and 8A and 8B indicate that formation of 6,7-dimethoxy-quinoline-4-ol was minimized to 50 ppm or less over time in the capsule formulations.

[00164] The foregoing disclosure has been described in some detail by way of illustration and example, for purposes of clarity and understanding. The invention has been described with reference to various specific and preferred embodiments and techniques. However, it should be understood that many variations and modifications can be made while remaining within the spirit and scope of the invention. It will be obvious to one of skill in the art that

changes and modifications can be practiced within the scope of the appended claims. Therefore, it is to be understood that the above description is intended to be illustrative and not restrictive. The scope of the invention should, therefore, be determined not with reference to the above description, but should instead be determined with reference to the following appended claims, along with the full scope of equivalents to which such claims are entitled. All references cited herein are incorporated by reference in their entirety.

CLAIMS

1. A process for preparing a compound of formula I:



I

or a pharmaceutically acceptable salt thereof, wherein:

X^1 is H, Br, Cl, or F;

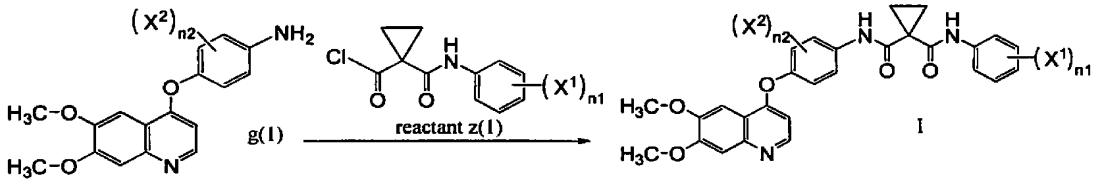
X^2 is H, Br, Cl, or F;

n1 is 1-2; and

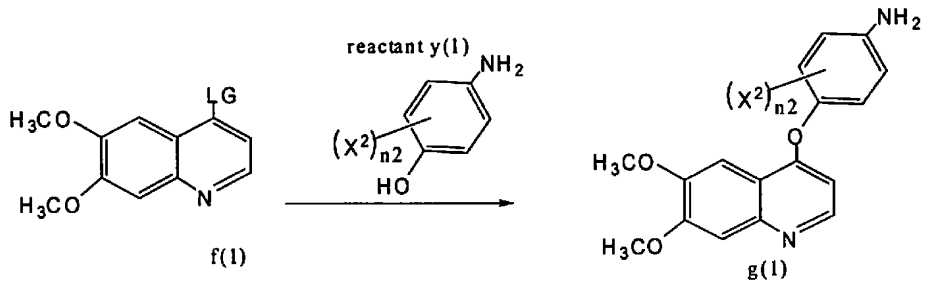
n2 is 1-2;

the process comprising:

contacting the compound of formula g(1) with reactant z(1) to yield the compound of formula I:

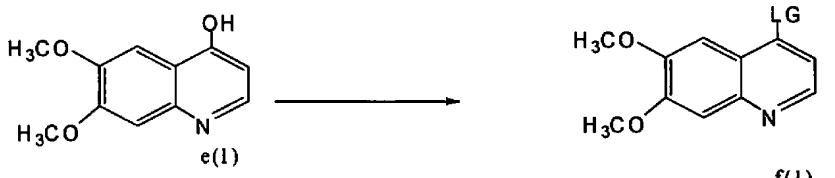


2. The process according to claim 1, wherein the compound of formula g(1) is made by reacting a compound of formula f(1) with reactant y(1) to yield the compound of formula g(1):



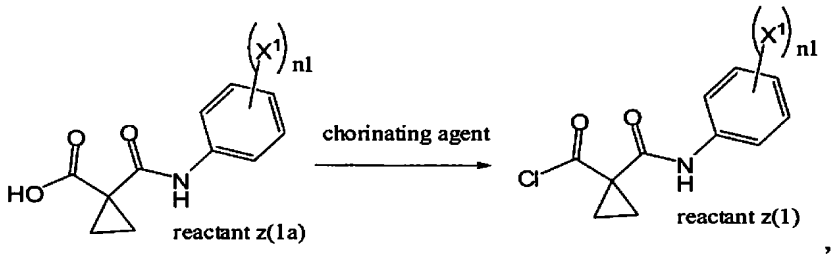
wherein LG represents a leaving group, and each X^2 and n2 are as defined in claim 1.

3. The process according to claim 2, wherein the compound of formula f(1) is made by converting compound e(1) to the compound of formula f(1):



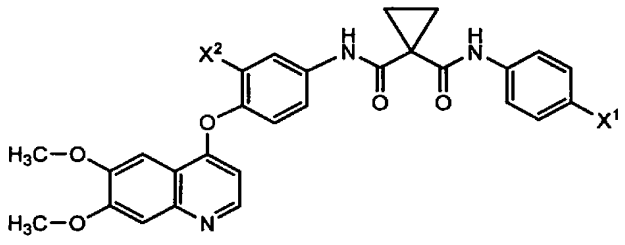
wherein LG represents a leaving group.

4. The process according to claim 1, wherein reactant z(1) is made by reacting reactant z(1a) with a chlorinating agent to yield reactant z(1):



wherein X^1 is Br, Cl, or F; and n1 is 1-2.

5. The process according to claim 1, wherein the compound of formula I is compound IA-1:



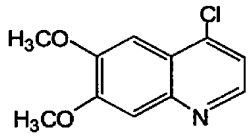
IA

or a pharmaceutically acceptable salt thereof, wherein:

X^1 is H, Cl, Br, or F; and

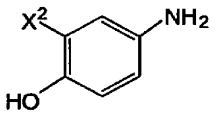
X^2 is H, Cl, Br, or F.

6. The process according to claim 5, wherein the compound of formula f(1) is compound f(2):



f(2) ;

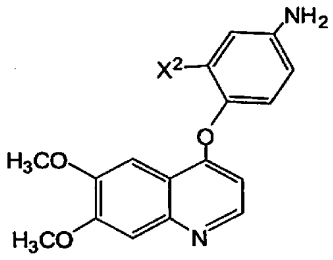
reactant y(1) is reactant (y)(2):



reactant (y)(2) ,

wherein X^2 is hydrogen or fluoro; and

the compound of formula g(1) is of formula g(2):



g(2) .

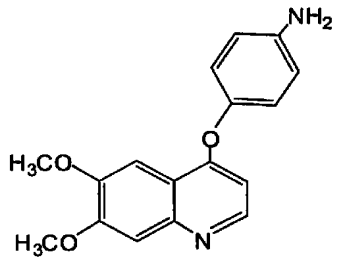
7. The process according to claim 6, wherein the reaction employs a non-nucleophilic base.

8. The process according to claim 7, wherein the non-nucleophilic base is an alkali metal alkoxide; and the reaction is carried out in a polar solvent.

9. The process according to claim 8, wherein the alkali metal alkoxide is sodium tert-butoxide, and the polar solvent is DMA.

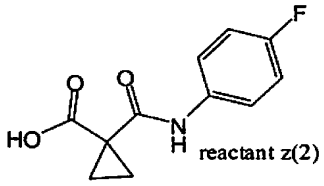
10. The process according to claim 8, wherein the alkali metal alkoxide is sodium tert-pentoxide, and the polar solvent is DMA.

11. The process according to claim 1, wherein the compound of formula g(1) is of compound g(3):



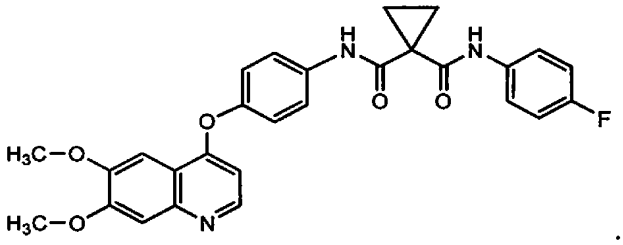
g(3) ;

reactant z(1) is reactant (z)(2):



reactant z(2) ; and

the compound of formula I is compound IA:

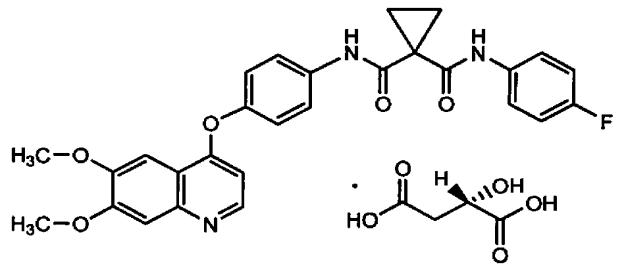


IA

12. The process according to claim 11, wherein the reaction is carried out in the presence of an inorganic base.

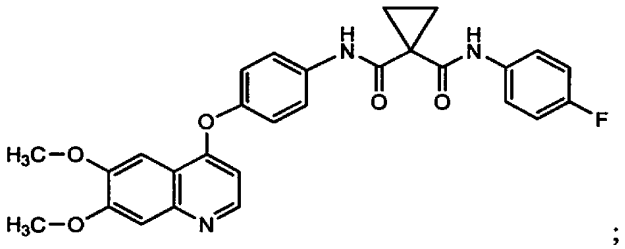
13. The process according to claim 12, wherein the inorganic base is K_2CO_3, and the solvent employed in this reaction is a combination of THF and H_2O.

14. A process for preparing compound IB:



IB

from compound IA:



;

IA

comprising:

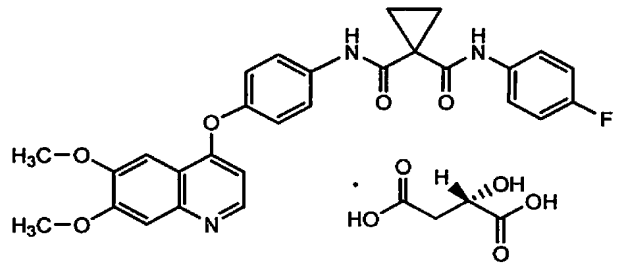
(a) heating and agitating a mixture comprising compound IA and L-malic acid, methylethyl ketone, and water;

(b) cooling the mixture;

(c) vacuum distilling the mixture successively; and

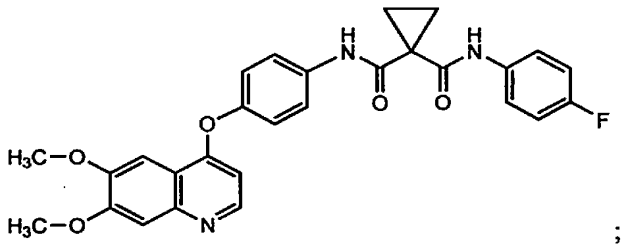
(d) isolating the compound of IB by filtration.

15. A process for preparing compound IB:



IB

from compound IA:



;

IA

comprising:

(a) heating and agitating a mixture comprising compound IA and L-malic acid, methylethyl ketone, and water;
(b) cooling the mixture;
(c) seeding the mixture with the compound of IB;
(d) vacuum distilling the mixture; and
(e) isolating the compound of IB by filtration.

16. Compound IA or IB admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

17. Compound IB admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

18. Compound IB in the N-1 form admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

19. Compound IB in the N-2 form admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

20. Compound IB as a mixture of the N-1 form and N-2 form admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

21. A pharmaceutical composition according to Table 1.

Table 1

Ingredient	% w/w
Compound I	31.68
Microcrystalline Cellulose (Avicel PH102)	38.85
Lactose anhydrous 60 M	19.42
Hydroxypropyl Cellulose, EXF	3.00
Croscarmellose Sodium	3.00
Total Intra-granular	**95.95**
Silicon dioxide, Colloidal PWD	0.30
Croscarmellose Sodium	3.00
Magnesium Stearate	0.75
Total	**100.00**

22. A pharmaceutical composition according to Table 2.

Table 2

Ingredient	(% w/w)
Compound I	25.0-33.3
Microcrystalline Cellulose, NF	q.s
Hydroxypropyl Cellulose, NF	3
Poloxamer, NF	0-3
Croscarmellose Sodium, NF	6.0
Colloidal Silicon Dioxide, NF	0.5
Magnesium Stearate, NF	0.5-1.0
Total	100

23. A pharmaceutical composition according to Table 2A.

Table 2A

Ingredient	% w/w
Compound IB (10 % drug load as Compound IA)	12.67
MCC	51.52
Lactose	25.76
Hydroxypropyl cellulose	3.0
Croscarmellose Sodium	6.0
Colloidal Silicon Dioxide	0.3
Magnesium Stearate	0.75
Total	**100**

24. A pharmaceutical composition according to Table 3.

Table 3

Ingredient	mg/unit dose
Compound IB (10 % drug load as Compound IA)	25
Silicified Microcrystalline Cellulose	196.75
Croscarmellose sodium	12.5
Sodium starch glycolate	12.5
Fumed Silica	0.75
Stearic acid	2.5
Total Fill Weight	250

25. A pharmaceutical composition according to Table 4.

Table 4

Ingredient	mg/unit dose
Compound IB (50 % drug load as Compound IA)	100
Silicified Microcrystalline Cellulose	75.40
Croscarmellose sodium	10.00
Sodium Starch Glycolate	10.00
Fumed silica	0.6
Stearic Acid	4.0
Total Fill Weight	200

26. A pharmaceutical composition according to Table 5.

Table 5

	mg/unit dose
Ingredient	**50mg**
Compound IB (10 % drug load as Compound IA)	63.35
Microcrystalline Cellulose	95.39
Croscarmellose sodium	9.05
Sodium starch glycolate	9.05
Fumed Silica	0.54
Stearic acid	3.62
Total Fill Weight	181.00

27. A pharmaceutical composition according to Table 6.

Table 6

	mg/unit dose
Ingredient	**60mg**
Compound IB	73.95
Microcrystalline Cellulose	114.36
Croscarmellose sodium	10.85
Sodium starch glycolate	10.85
Fumed Silica	0.65
Stearic acid	4.34
Total Fill Weight	217.00

28. The pharmaceutical composition of claims 20-27 admixed with 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

29. The pharmaceutical composition of claims 20-27 admixed with 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

30. The pharmaceutical composition of claims 20-27 admixed with 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

31. The pharmaceutical composition of claims 20-27 admixed with 15 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

32. The pharmaceutical composition of claims 20-27 admixed with 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

33. The pharmaceutical composition of claims 20-27 admixed with 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

34. The pharmaceutical composition of claims 20-27 admixed with 2.5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 August 2012 (16.08.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/109510 A1

(51) International Patent Classification:
C07D 215/227 (2006.01) *A61P 35/00* (2006.01)
A61K 31/47 (2006.01)

(21) International Application Number:
PCT/US2012/024591

(22) International Filing Date:
10 February 2012 (10.02.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/441,520 10 February 2011 (10.02.2011) US
61/441,527 10 February 2011 (10.02.2011) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, 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.

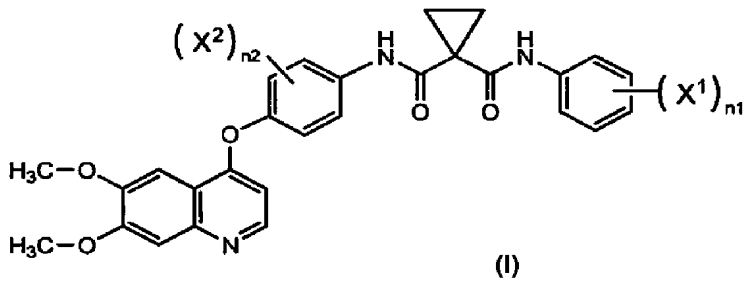
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

WO 2012/109510 A1

(54) Title: PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS



(I)

(57) Abstract: The present invention is directed to processes for making and compositions containing quinolines such as formula I or pharmaceutically acceptable salts thereof wherein: X1 is H, Br, CI, or X2 is H, Br, CI, or n1 is 1-2; and n2 is 1-2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: To be Determined
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: To be Determined
Examiner: To be Determined
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: To be Determined

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

Commissioner for Patents
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PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115

Dear Sir or Madam:

Prior to examination of the present Application, the Applicant respectfully requests that the application be amended as follows.

Amendments to the claims begin on page 2.

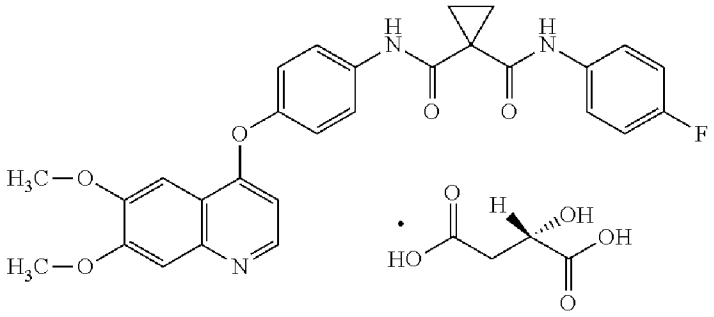
Amendments to the specification begin on page 5.

Remarks begin on page 6.

AMENDMENTS TO THE CLAIMS

1-34. Canceled.

35. (New) A pharmaceutical composition for oral administration comprising Compound IB:



IB

and a pharmaceutically acceptable carrier, wherein the pharmaceutical composition is a tablet or a capsule, and wherein the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

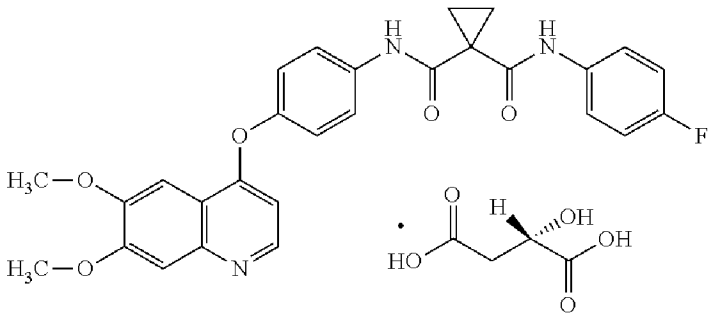
36. (New) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition contains 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

37. (New) The pharmaceutical composition of claim 2, wherein the pharmaceutical composition contains 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

38. (New) The pharmaceutical composition of claim 3, wherein the pharmaceutical composition contains 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

39. (New) The pharmaceutical composition of claim 4, wherein the pharmaceutical composition contains 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

40. (New) A method of treating cancer, comprising administering to a subject in need thereof a pharmaceutical composition comprising Compound IB:



IB

and a pharmaceutically acceptable carrier, wherein the pharmaceutical composition is a tablet or a capsule, and wherein the pharmaceutical composition contains 100 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

41. (New) The method of claim 6, wherein the pharmaceutical composition contains 50 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

42. (New) The method of claim 7, wherein the pharmaceutical composition contains 25 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

43. (New) The method of claim 8, wherein the pharmaceutical composition contains 10 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

44. (New) The method of claim 9, wherein the pharmaceutical composition contains 5 ppm or less of 6,7-dimethoxy-quinoline-4-ol.

45. (New) The method of claim 6, wherein the cancer is renal cancer.

46. (New) The method of claim 6, wherein the cancer is prostate cancer.

47. (New) The method of claim 6, wherein the cancer is hepatocellular carcinoma.

48. (New) The method of claim 7, wherein the cancer is renal cancer.

49. (New) The method of claim 7, wherein the cancer is prostate cancer.

50. (New) The method of claim 7, wherein the cancer is hepatocellular carcinoma.

51. (New) The method of claim 8, wherein the cancer is renal cancer.

52. (New) The method of claim 8, wherein the cancer is prostate cancer.

53. (New) The method of claim 8, wherein the cancer is hepatocellular carcinoma.

54. (New) The method of claim 9, wherein the cancer is renal cancer.

55. (New) The method of claim 9, wherein the cancer is prostate cancer.

56. (New) The method of claim 9, wherein the cancer is hepatocellular carcinoma.

AMENDMENTS TO THE SPECIFICATION

Please replace paragraph number [0001] under the heading "Cross-Reference to Related Applications" at page 1 with the replacement paragraph provided below:

[0001] This application is a continuation application of United States Serial Number 18/462,739, filed September 7, 2023, which is a continuation application of United States Serial Number 17/679,634, filed February 24, 2022, which is a continuation application of United States Serial Number 17/170,275, filed February 8, 2021, now United States Patent Number 11,298,349, which is a continuation application of United States Serial Number 17/152,394, filed January 19, 2021, which is a continuation of United States Application Serial Number 16/706,323, filed December 6, 2019, which is a division of United States Application Serial Number 16/151,653, filed October 4, 2018, now United States Patent Number 10,543,206, which is a division of United States Application Serial Number 15/348,716, filed November 10, 2016, now United States Patent Number 10,123,999, which is a division of United States Application Serial Number 13/984,559, filed March 20, 2014, now United States Patent Number 9,717,720, which claims priority under 35 U.S.C. § 371 to Patent Cooperation Treaty Application Number PCT/US2012/024591, filed February 10, 2012, which claims the benefit of United States Provisional Application Number 61/441,520, filed February 10, 2011, and United States Provisional Application Number 61/441,527, filed February 10, 2011, the entire contents of which are incorporated herein by reference.

REMARKS

Claim Status

Claims 1-34 are canceled.

Claims 35-56 are new. The new claims are supported by the specification and claims as originally filed and do not introduce new matter.

Thus, claims 35-56 are currently pending.

The Applicant reserves the right to file divisional applications or take such other appropriate action as deemed necessary to protect the subject matter restricted, canceled, or withdrawn from this application.

AMENDMENTS TO THE SPECIFICATION

Under the heading "Cross-Reference to Related Applications", paragraph [0001] of the specification has been amended to state that this application is a continuation application of United States Serial Number 18/462,739, filed September 7, 2023, which is a continuation application of United States Serial Number 17/679,634, filed February 24, 2022, which is a continuation application of United States Serial Number 17/170,275, filed February 8, 2021, now United States Patent Number 11,298,349, which is a continuation application of United States Serial Number 17/152,394, filed January 19, 2021, which is a continuation of United States Application Serial Number 16/706,323, filed December 6, 2019, which is a division of United States Application Serial Number 16/151,653, filed October 4, 2018, now United States Patent Number 10,543,206, which is a division of United States Application Serial Number 15/348,716, filed November 10, 2016, now United States Patent Number 10,123,999, which is a division of United States Application Serial Number 13/984,559, filed March 20, 2014, now United States Patent Number 9,717,720, which claims priority under 35 U.S.C. § 371 to Patent Cooperation Treaty Application Number PCT/US2012/024591, filed February 10, 2012, which claims the benefit of United States Provisional Application Number 61/441,520, filed February 10, 2011, and United States Provisional Application Number 61/441,527, filed February 10, 2011, the entire contents of which are incorporated herein by reference.

USPTO TRACK ONE

The Applicant submits herewith as a large entity a Track One prosecution request and submits the processing fee set forth in 37 C.F.R. 1.17(i) in the amount of $140.00 as well as the prioritized examination fee set forth in 37 C.F.R. 1.17(c) in the amount of $4,200.00. Twenty-two new claims are presented by the Applicant for examination, none of which are multiply dependent claims. Thus, the claims are in compliance with Track One claim requirements, including: (i) no more than thirty claims in total; (ii) no more than four independent claims; and (iii) no multiply depdendent claims. The Applicant therefore respectfully requests Track One status for the captioned application.

INFORMATION DISCLOSURE STATEMENT

The Applicant notes that the filing of the enclosed Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement qualifies as prior art under 35 U.S.C. § § 102 or 103, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). It is believed that no fee is due pursuant to 37 C.F.R. § 1.97(b)(3). In accordance with 37 C.F.R. § 1.98(d), some copies of the cited references may not be provided because they were previously provided to the Office in an earlier application. The Applicant will gladly provide the references to the Examiner, however, upon request.

OTHER C-MET INHIBITOR CASES

The Applicant wishes to make the Examiner aware of the Applicant's other applications related to c-Met inhibitors and their use in the treatment of cancer. For the Examiner's convenience, the Applicant is providing a list of the Applicant's applications directed to the treatment of cancer using c-Met inhibitors. The Applicant understands the Examiner has electronic access to these applications and to the Office Actions that have issued in these applications, and has therefore not included copies with this Response. The Applicant will gladly provide the applications and Office Actions to the Examiner, however, upon request.

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
10/573,336	09/18/2006		Koontz, Tammy J.	Abandoned
11/571,140	12/21/2006	7977345	Moore, Susanna	Expired

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
11/586,751	10/26/2006	9174947	Ward, Paul V.	Issued
11/753,462	05/24/2007	8178532	Ward, Paul V.	Issued
11/753,503	05/24/2007	8476298	Ward, Paul V.	Expired
11/753,514	05/24/2007	8067436	Bernhardt, Emily A.	Issued
12/393,806	02/26/2009	7579473	Seaman, D. Margaret M.	Issued
12/911,442	10/25/2010		Ward, Paul, V.	Abandoned
13/087,094	04/14/2011		Chickos, Sarah, J.	Abandoned
13/129,183	05/13/2011		Seaman, D. Margaret M.	Abandoned
13/132,650	06/03/2011		Seaman, D. Margaret M.	Abandoned
13/145,054	10/20/2011	8877776	Carter, Kendra D	Issued
13/249,815	09/30/2011	8497284	Bernhardt, Emily A.	Issued
13/384,451	07/12/2012	8673912	Anderson, Rebecca L.	Issued
13/389,266	07/12/2012		Perreira, Melissa Jean	Abandoned
13/427,093	03/22/2012		Ward, Paul V.	Abandoned
13/438,964	04/04/2012		Brown-Pettigrew, Angela C.	Abandoned
13/634,275	09/12/2012		Anderson, Rebecca L.	Abandoned
13/753,031	01/29/2013		Pagonakis, Anna	Abandoned
13/753,146	01/29/2013		Pagonakis, Anna	Abandoned
13/810,537	08/26/2013	9724342	Pallay, Michael B.	Issued
13/810,546	08/27/2013		Branson, Daniel L.	Abandoned
13/876,290	11/05/2013		Stone, Christopher R.	Abandoned
13/876,306	11/08/2013		Lee, Andrew P.	Abandoned
13/876,318	10/25/2013		Karol, Jody Lynn	Abandoned
13/888,592	05/07/2013		Ward, Paul V.	Abandoned
13/928,977	06/27/2013		Bernhardt, Emily A.	Abandoned
13/984,559	03/20/2014	9717720	Rozof, Timothy R.	Issued
14/021,614	09/09/2013		Matos Negron, Taina Del Mar	Abandoned
14/115,236	02/28/2014		Anderson, James D.	Abandoned
14/166,545	01/28/2014		Not Yet Assigned	Abandoned
14/173,973	02/06/2014		Johannsen, Diana B.	Abandoned
14/340,871	07/25/2014	9809549	Carter, Kendra D.	Issued
14/346,570	03/21/2014	10166225	Wang, Shengjun	Issued
14/353,251	04/21/2014	9365516	Murray, Jeffrey H.	Issued
14/356,927	05/08/2014		Baek, Bong-Sook	Abandoned
14/356,938	05/08/2014		Cerioni, Daniel Lee	Abandoned
14/398,188	10/31/2014	9861624	Henley III, Raymond J.	Issued
14/426,580	03/06/2015		Jean-Louis, Samira J.M.	Abandoned
14/518,733	10/20/2014		Wright, Sarah C.	Abandoned
14/668,312	03/25/2015		Brown-Pettigrew, Angela C.	Abandoned
14/699,683	04/29/2015		Perreira, Melissa Jean	Abandoned

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
14/776,337	09/14/2015	10273211	Badio, Barbara P.	Issued
14/782,493	10/05/2015		Saeed, Kamal A.	Abandoned
14/782,537	10/05/2015	11564915	Alley, Genevieve S.	Issued
14/843,480	09/02/2015		Shen, Wu Cheng Winston	Abandoned
14/847,801	09/08/2015		Ward, Paul V.	Abandoned
14/933,801	11/05/2015		Brown-Pettigrew, Angela C.	Abandoned
15/066,872	03/10/2016		Ward, Paul V.	Abandoned
15/118,738	08/12/2016	10501418	Chandrakumar, Nizal S.	Issued
15/126,767	09/16/2016	10159666	Solola, Taofiq A.	Issued
15/133,708	04/20/2016	9969692	Murray, Jeffrey H.	Issued
15/305,854	10/21/2016		McMillian, Kara Renita	Abandoned
15/348,716	11/10/2016	10123999	Rozof, Timothy R.	Issued
15/500,312	01/30/2017	11124481	Seaman, D. Margaret M.	Issued
15/501,582	02/03/2017	11065240	Seaman, D. Margaret M.	Issued
15/426,804	02/07/2017	10039757	Pallay, Michael B.	Issued
15/612,703	06/02/2017	10034873	Pallay, Michael B.	Issued
15/617,725	06/08/2017		Neagu, Irina	Abandoned
15/618,593	06/09/2017		Carter, Kendra D.	Abandoned
15/621,527	06/13/2017		Carter, Kendra D.	Abandoned
15/688,310	08/28/2017	11124482	Ward, Paul V.	Issued
15/955,246	04/17/2018		Not Yet Assigned	Abandoned
16/026,708	07/03/2018	10548888	Pallay, Michael B.	Issued
16/093,426	10/12/2018	11141413	Weddington, Kevin E.	Issued
16/095,221	10/19/2018		Saeed, Ali S.	Abandoned
16/142,691	09/26/2018	11116759	Howell, Theodore R.	Issued
16/151,653	10/04/2018	10543206	Rozof, Timothy R.	Issued
16/190,869	11/14/2018		Solola, Taofiq A.	Abandoned
16/230,267	12/21/2018		Kantamneni, Shobha	Pending
16/251,617	01/18/2019	10736886	Perreira, Melissa Jean	Issued
16/336,724	03/26/2019		Sharon X. Wen	Abandoned
16/362,863	03/25/2019		Reese, Heidi L.	Abandoned
16/479,143	07/18/2019	11198731	Lu, Cheng	Issued
16/671,834	11/01/2019	10851061	Chandrakumar, Nizal S.	Issued
16/617,352	11/26/2019	11279675	Seaman, D. Margaret M.	Issued
16/620,379	12/06/2019	11504362	Oh, Taylor V.	Issued
16/706,323	12/06/2019		Rozof, Timothy R.	Abandoned
16/722,563	12/20/2019	11123338	Pallay, Michael B.	Issued
16/776,139	01/29/2020		Solola, Taofiq A.	Abandoned
16/787,212	02/11/2020	11504363	Anderson, James D.	Issued
16/796,250	02/20/2020		Neagu, Irina	Abandoned

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
16/905,307	06/18/2020	11612597	Timothy R. Rozof	Issued
16/919,562	07/02/2020	11433064	Perreira, Melissa Jean	Issued
16/921,542	07/06/2020		Ward, Paul V.	Abandoned
17/031,196	09/24/2020		Solola, Taofiq A.	Pending
17/070,514	10/14/2020	11091439	Rozof, Timothy R.	Issued
17/070,790	10/14/2020		Seaman, D. Margaret M.	Abandoned
17/084,312	10/29/2020	11724986	Chandrakumar, Nizal S.	Issued
17/149,365	01/14/2021	11091440	Rozof, Timothy R.	Issued
17/152,394	01/19/2021		Not Yet Assigned	Abandoned
17/170,275	02/08/2021	11298349	Seaman, D. Margaret M.	Issued
17/171,752	02/09/2021	11098015	Rozof, Timothy R.	Issued
17/212,851	03/25/2021	11760726	Chandrakumar, Nizal S.	Issued
17/371,372	07/09/2021		Rozof, Timothy R.	Abandoned
17/425,661	07/23/2021		Not Yet Assigned	Pending
17/409,098	08/23/2021		Not Yet Assigned	Abandoned
17/466,328	09/03/2021		Seaman, D. Margaret M.	Abandoned
17/468,103	09/07/2021		Kevin E. Weddington	Pending
17/497,201	10/08/2021		Seaman, D. Margaret M.	Abandoned
17/505,275	10/19/2021		Rozof, Timothy R.	Abandoned
17/505,307	10/19/2021		Pallay, Michael B.	Abandoned
17/519,327	11/04/2021		Lu, Cheng	Pending
17/538,310	11/30/2021		Not Yet Assigned	Abandoned
17/668,098	02/09/2022	11731941	Seaman, D. Margaret M.	Issued
17/679,634	02/24/2022		Seaman, D. Margaret M.	Abandoned
17/869,427	07/20/2022		Not Yet Assigned	Abandoned
17/873,918	07/26/2022		Not Yet Assigned	Pending
17/888,356	08/15/2022		Weddington, Kevin E.	Abandoned
17/957,505	09/30/2022		Not Yet Assigned	Abandoned
17/965,529	10/13/2022		James D. Anderson	Pending
17/975,765	10/28/2022		Oh, Taylor V.	Pending
18/059,840	11/29/2022		Not Yet Assigned	Abandoned
18/069,467	12/21/2022		Not Yet Assigned	Abandoned
18/112,214	02/21/2023		Rozof, Timothy R.	Pending
18/157,568	01/20/2023		Not Yet Assigned	Abandoned
18/176,604	03/01/2023		Not Yet Assigned	Abandoned
18/344,267	06/29/2023		Timothy R. Rozof	Pending
18/359,214	07/26/2023		Not Yet Assigned	Pending
18/363,994	08/02/2023		Not Yet Assigned	Pending
18/462,739	09/07/2023		Not Yet Assigned	Pending
18/463,412	09/08/2023		Not Yet Assigned	Pending

Application Number	Filing or 371 Date	Patent Number	Examiner	Status
18/465,462	09/12/2023		Not Yet Assigned	Pending
18/490,248	10/19/2023		Not Yet Assigned	Pending
18/491,407	10/20/2023		Not Yet Assigned	Pending
18/423,824	01/26/2024		Not Yet Assigned	Pending

CO-PENDING APPLICATION, SERIAL NO. 18/462,739

The Applicant has paid a three-month extension of time fee under 37 C.F.R. § 1.136 in co-pending application, Serial No. 18/462,739 ("the '739 application"). The Applicant notes that the present application claims priority to the '739 application and, for the avoidance of doubt, the Applicant's payment of the extension fee in the '739 application ensures co-pendency with the present application.

CONCLUSION & FEES DUE

It is believed that due with this submission is the Basic Utility Application Fee of $320.00 set forth in 37 C.F.R. § 1.16(a), the Utility Search Fee of $700.00 set forth in § 1.16(k), the Utility Examination Fee of $800.00 set forth in § 1.16(o), the processing fee of $140.00 set forth in 37 C.F.R. 1.17(i), the prioritized examination fee of $4,200.00 set forth in 37 C.F.R. § 1.17(c), and the $400.00 non-docx filing fee. The Applicant hereby authorizes the Patent Office to charge this total of $6,560.00 to Deposit Account No. 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389. It is believed that no other fees are due at this time. However, if there are any additional charges for this submission, or any credits, please apply them to Deposit Account Number 503145, referencing Attorney Docket Number 224990/10-039C11-US/543389.

Respectfully submitted,

HONIGMAN LLP

/Li Gao, Ph.D./

Dated: February 8, 2024

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Lansing, MI 48933-1800
Telephone: (517) 377-0708

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jo Ann Wilson	Nonprovisional Application Number (if known):	
Title of Invention:	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Li Gao, Ph.D./	Date 2024-02-08
Name (Print/Typed) Li Gao, Ph.D.	Practitioner Registration Number 71343

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2024-02-08
First Named Inventor	Jo Ann Wilson
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	224990/10-039C11US/543389

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	9724342		2017-08-08	WILSON, et al.	
	2	9809549		2017-11-07	BROWN, et al.	
	3	7579473		2009-08-25	EXELIXIS, INC.	
	4	7977345		2011-07-12	EXELIXIS, INC.	
	5	7999006		2011-08-16	EXELIXIS, INC.	
	6	8067436		2011-11-29	EXELIXIS, INC.	
	7	8178532		2012-05-15	EXELIXIS, INC.	
	8	8314232		2012-11-20	EXELIXIS, INC.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	9	8476298		2013-07-02	EXELIXIS, INC.	
	10	8497284		2013-07-30	EXELIXIS, INC.	
	11	8673912		2014-03-18	EXELIXIS, INC.	
	12	8877776		2014-11-04	EXELIXIS, INC.	
	13	9174947		2015-11-03	EXELIXIS, INC.	
	14	9365516		2016-06-14	EXELIXIS, INC.	
	15	7166722		2007-01-23	MATSUNAGA, et al.	
	16	7169789		2007-01-30	KUBO, et al.	
	17	5358941		1994-10-25	BECHARD, et al.	
	18	9717720		2017-08-01	WILSON, et al.	
	19	9969692		2018-05-15	WILSON, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	20	10034873		2018-07-31	WILSON, et al.	
	21	10039757		2018-09-08	WILSON, et al.	
	22	10166225		2019-01-01	AFTAB, et al.	
	23	10123999		2018-11-13	WILSON, et al.	

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

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20080161305		2008-07-03	FORSYTH, et al.	
	2	20110077233		2011-03-31	BANNEN, et al.	
	3	20120252840		2012-10-04	AFTAB, et al.	
	4	20140066444		2014-03-26	SMITH, et al.	
	5	20150057310		2015-02-26	BROWN, et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	6	20150202196		2015-07-23	BANNEN, et al.	
	7	20160000772		2016-01-07	AFTAB, et al.	
	8	20160051532		2016-02-25	AFTAB, et al.	
	9	20160229805		2016-08-11	WILSON, et al.	
	10	20170143689		2017-05-25	WILSON, et al.	
	11	20170266178		2017-09-21	WILSON, et al.	
	12	20170275251		2017-09-28	BROWN, et al.	
	13	20180002289		2018-01-04	BROWN, et al.	
	14	20180037552		2018-02-08	BROWN, et al.	
	15	20090274693		2009-11-05	EXELIXIS, INC.	
	16	20110077233		2011-03-31	EXELIXIS, INC.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	17	20120070368		2012-03-22	EXELIXIS, INC.	
	18	20120184523		2012-07-19	EXELIXIS, INC.	
	19	20120252840		2012-10-04	EXELIXIS, INC.	
	20	20120282179		2012-11-08	EXELIXIS, INC.	
	21	20130030172		2013-01-31	EXELIXIS, INC.	
	22	20130142790		2013-01-31	EXELIXIS, INC.	
	23	20130143881		2013-01-31	EXELIXIS, INC.	
	24	20130150363		2013-06-06	EXELIXIS, INC.	
	25	20130197230		2013-06-06	EXELIXIS, INC.	
	26	20130252940		2013-06-13	EXELIXIS, INC.	
	27	20130252956		2013-08-01	EXELIXIS, INC.	

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	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	28	20130330377		2013-09-26	EXELIXIS, INC.	
	29	20130337015		2013-09-26	EXELIXIS, INC.	
	30	20140057943		2013-12-12	EXELIXIS, INC.	
	31	20140057908		2013-12-19	EXELIXIS, INC.	
	32	20140066444		2014-02-27	EXELIXIS, INC.	
	33	20140155396		2014-02-27	EXELIXIS, INC.	
	34	20140179736		2014-03-06	EXELIXIS, INC.	
	35	20070054928		2007-03-08	BANNEN, et al.	
	36	20140200242		2014-06-05	EXELIXIS, INC.	
	37	20140228401		2014-06-26	EXELIXIS, INC.	
	38	20140302012		2014-07-17	EXELIXIS, INC.	

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	39	20140323522		2014-08-14	EXELIXIS, INC.	
	40	20150057310		2014-10-09	EXELIXIS, INC.	
	41	20150196545		2014-10-30	EXELIXIS, INC.	
	42	20150202196		2015-02-26	EXELIXIS, INC.	
	43	20150376133		2015-07-16	EXELIXIS, INC.	
	44	20160000772		2015-07-23	EXELIXIS, INC.	
	45	20160051532		2015-12-31	EXELIXIS, INC.	
	46	20160185725		2016-01-07	EXELIXIS, INC.	
	47	20050209247		2005-09-22	CHIRON CORPORATION	
	48	20070078159		2007-04-05	MATSUSHIMA, et al.	
	49	20110059081		2011-03-10	QUINTILES TRANSNATIONAL CORP.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	50	20140256938		2014-09-11	WISON, et al.	
	51	20160220554		2016-08-04	SMITH, et al.	
	52	20080004273		2008-01-03	RAEPPEL, et al.	
	53	20140121239		2014-05-01	AFTAB, et al.	
	54	20140221372		2014-08-07	KULKARNI, et al.	
	55	20150133494		2015-05-14	AFTAB, et al.	
	56	20150238477		2015-08-27	AFTAB, Dana T.	
	57	20160031818		2016-02-04	AFTAB, et al.	
	58	20160082019		2016-03-24	SWEENEY, et al.	
	59	20170087143		2017-03-30	AFTAB, et al.	
	60	20090203729		2009-08-13	INOUE, et al.	

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	Examiner Name	TBD
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	61	20190030021		2019-01-31	WILSON, et al.	
	62	20170057921		2017-03-02	WILSON, et al.	
	63	20170355678		2017-12-14	BANNEN, et al.	
	64	20180230100		2018-08-16	WILSON, et al.	
	65	20180311229		2018-11-01	WILSON, et al.	
	66	20190151302		2019-05-23	AFTAB, et al.	
	67	20190091215		2019-03-28	AFTAB, et al.	
	68	20050049267		2005-03-03	SUTO, et al.	

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	2009136663	WO		2009-11-12	TAKEDA PHARMACEUTICAL COMPANY LIMITED		☐

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
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	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	2	2005030140	WO		2005-04-07	EXELIXIS, INC.		☐
	3	2010083414	WO		2010-07-22	EXELIXIS, INC.		☐
	4	2011017639	WO		2011-02-10	EXELIXIS, INC.		☐
	5	2012009722	WO		2012-01-19	EXELIXIS, INC.		☐
	6	2012109510	WO		2012-06-16	WILSON, Jo Ann		☐
	7	2010113183	WO		2010-10-07	MSN LABORATORIES LIMITED		☐

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Kurzrock R et al. "379 POSTER A phase I study of XL 184, a MET, VEGFR2, and RET kinase inhibitor, administered orally to patients (pts) with advanced malignancies, including a subgroup of pts with medullary thyroid cancer (MTC)." Eropean journal of cancer. supplement, vol 6, no 12, 2008-10-01, 119.	☐
	2	European Medicines Agency, "Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: chemical substances", May 2000.	☐
	3	Sigma-Aldrich Corporation, "Cabozantinib Material Safety Data Sheet", Version 5.0, October 20, 2014, retrieved from the internet at http://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=CDS009101&brand=ALDRICH&PageToGoToURL=http%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fproduct%2Faldrich%2Fcds009101%3Flang%3Den on October 1, 2015.	☐

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	First Named Inventor	Jo Ann Wilson
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	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

	4	United States Department of Health and Human Services, "Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products", Revision 2, November 2003, retrieved from the internet at www.fda.gov/downloads/drugs/guidancecomplianceregulatory information/guidances/ucm073369.pdf on October 1, 2015.	☐
	5	International Search Report for PCT/US2012/024591, mailed May 25, 2012.	☐
	6	KIBBE, A.H. Handbook of Pharmaceutical Excipients, 3rd edition: American Pharmactical Association and Pharmaceutical Press, ISBN 0-85369-381-1, 2000 (pages 110,244,305,143,102,501,534,386,160).	☐
	7	Li, Lubricants, 2014, Vol 2, 21-43. (Year: 2014).	☐
	8	"Overview of PHarmaceutical Excipients Used in Tablets and Capsules", 2008, Drug Topics, https://www.drugtopics.com/view/ overview-pharmaceutical-excipients-used-tablets-and-capsules. (Year: 2008).	☐
	9	Pingali, Int J Pharm, 2011, Vol 409(0), 269-277. (Year: 2011).	☐
	10	United States Department of Health and Human Services, "Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products", Revision 2, November 2003, retrieved from the internet at https://www.fda.gov/media/71707/download on January 19, 2022.	☐
	11	United States Department of Health and Human Services, "Guidance for Industry Q3B(R2) Impurities in New Drug Products", Revision 2, August 2006, retrieved from the internet at https://www.fda.gov/media/71733/download on January 19, 2022.	☐
	12	ZHANG, Y., et al., "XL-184, a MET, VEGFR-2 and RET kinase inhibitor for the treatment of thyroid cancer, clioblastoma multiforme and NSCLC", Idrugs, Vol. 13, No. 2, pp. 112-121, February 2010.	☐
	13	WILLHAUCK, M. J., "Neue Therapieoptionen bei fortgeschrittenen Schilddrusenkarzinomen" Deutsche Medizinische Wochenschrift 2011, 136, 1165-1168.	☐
	14	NCT00704288, Study of XL184 in Adults with Glioblastoma Multiformel, view April 7, 2010, ClinicalTrials.gov. https://clinicaltrials.gov/ct2/history/NCT00704288?A=10&B-10.	☐

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	15	NCT00704730, Efficacy Study of XL184 in Adults with Medullary Thyroid Cancer, view May 28, 2010, ClinicalTrials.gov. https://clinicaltrials.gov/ct2/history/NCT00704730?A=57&B=57.	☐
	16	MOLOGNI, L., "Development of RET Kinase Inhibitors for Targeted Cancer Therapy" Current Medicinal Chemistry 2011,18, 162-175.	☐
	17	KURZROCK, R., et al., "Activity of XL184 (Cabozantinib), an oral tyrosine kinase inhibitor, in patients with medullary thyroid cancer", Journal of Clinical Oncology, Vol. 29, No. 19, pp. 2660-2666, July 1, 2011. Retrieved from the Internet: URL:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3646303/.	☐
	18	ARKO, et al., "Experimental approaches for the treatment of malignant gliomas" Pharmacology & Therapeutics 2010, 128, 1-36.	☐
	19	Handbook of Pharmaceutical Excipients" Pharmaceutical Press, 2006 pages 137, 188, 211, 701, 737 and 738.	☐
	20	Commission Decision dated February 6, 2009.	☐
	21	Michael Aulton e Kevin Taylor, Pharmaceutics: The Science of Dosage Form Design, 2nd Edition, pages 1 to 679 (Publication Year: 2001).	☐
	22	ROWE, Raymond C., et al., Handbook of Pharmaceutical Excipients, 6th Edition, Pharmaceutical Press and American Pharmacists Association, ISBN 9781582121352 (USA) (Publication Year: 2009).	☐
	23	Ravi Salgia et al., "A phase 1 dose-escalation study of the safety and pharmacokinetics (PK) of XL184, a VEGFR and MET kinase inhibitor, administered orally to patients (pts) with advanced malignancies", Mol Cancer Ther (2007) 6 (11_Supplement): A152 (Publication Date: November 1, 2007).	☐

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
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	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

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

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	Filing Date	2024-02-08
	First Named Inventor	Jo Ann Wilson
	Art Unit	TBD
	Examiner Name	TBD
	Attorney Docket Number	224990/10-039C11US/543389

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Li Gao, Ph.D./	Date (YYYY-MM-DD)	2024-02-08
Name/Print	Li Gao, Ph.D.	Registration Number	71343

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

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FEE TRANSMITTAL

Complete if known	
Application Number	
Filing Date	February 8, 2024
First Named Inventor	Jo Ann Wilson
Examiner Name	TBD
Art Unit	TBD
Practitioner Docket No.	224990/10-039C10-US/543389

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

TOTAL AMOUNT OF PAYMENT ($) 6,560.00

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 503145 Deposit Account Name: Honigman LLP

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayment of fee(s)

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES (U = undiscounted fee; S = small entity fee; M = micro entity fee)

	FILING FEES			SEARCH FEES			EXAMINATION FEES			
Application Type	**U ($)**	**S ($)**	**M ($)**	**U ($)**	**S ($)**	**M ($)**	**U ($)**	**S ($)**	**M ($)**	**Fees Paid ($)**
Utility	320	160*	80	700	350	175	800	400	200	$1,820.00
Design	220	110	55	160	80	40	640	320	160	$0
Plant	220	110	55	440	220	110	660	330	165	$0
Reissue	320	160	80	700	350	175	2,320	1,160	580	$0
Provisional	300	150	75	0	0	0	0	0	0	$0

* The $160 small entity status filing fee for a utility application is further reduced to $80 for a small entity status applicant who files the application via EFS-Web.

2. EXCESS CLAIM FEES

Fee Description	**Undiscounted Fee ($)**	**Small Entity Fee ($)**	**Micro Entity Fee ($)**
Each claim over 20 (including Reissues)	100	50	25
Each independent claim over 3 (including Reissues)	480	240	120
Multiple dependent claims	860	430	215

Total Claims		**Extra Claims**		**Fee ($)**		**Fee Paid ($)**
_____	-20 or HP =	_____	x	_____	=	$0

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		**Extra Claims**		**Fee ($)**		**Fee Paid ($)**
_____	-3 or HP =	_____	x	_____	=	$0

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	**Fee ($)**	**Fee Paid ($)**
	_____	$0

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $420 ($210 for small entity) ($105 for micro entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**		**Fee ($)**		**Fee Paid ($)**
47	- 100 =	0	/ 50 =	0 (round **up** to a whole number)	x	0	=	$0

4. OTHER FEE(S)

	Fees Paid ($)
Non-English specification, $140 fee ($70 for small entity) ($35 for micro entity)	$0
Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, $400 fee ($200 small or micro entity)	$0
Other (e.g., late filing surcharge): Prioritized Examination Fee, Processing Fee, Non-Docx Filing Fee	$4,740.00

SUBMITTED BY

Signature	/Li Gao, Ph.D./	Registration No. (Attorney/Agent) 71343	Telephone 517.377.0708
Name (Print/Type)	Li Gao, Ph.D.		Date February 8, 2024

This collection of information is required by 37 CFR 1.136. 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 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 16/151,653 filed on October 4, 2018

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Khalid Shah Date (Optional) 14 June 2019

Signature: [signature]

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/348,716 filed on November 10, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

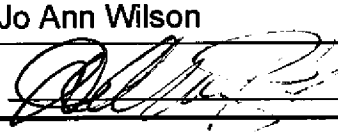
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Jo Ann Wilson Date (Optional): _____

Signature: 

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/82A (07-13)
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	TBD
Filing Date	February 8, 2024
First Named Inventor	Jo Ann Wilson
Title	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds
Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	224990/10-039C11-US/543389

SIGNATURE of Applicant or Patent Practitioner

Signature	/Li Gao, Ph.D./	Date (Optional)	February 8, 2024
Name	Li Gao, Ph.D.	Registration Number	71343
Title (if Applicant is a juristic entity)	Attorney for applicant		
Applicant Name (if Applicant is a juristic entity)	Exelixis, Inc.		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
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POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above.

91684

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Exelixis, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	7/26/19
Name	Jeffrey Hasselkiel		
Title	Executive Vice President and General Counsel		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: To be Determined
Inventors: Jo Ann Wilson et al.
Filing Date: February 8, 2024

Art Unit: To be Determined
Examiner: To be Determined
Attorney Docket No.: 224990/10-039C11-US/543389
Conf. No.: To be Determined

Title: Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8(a)

The undersigned hereby certifies that the following documents are being submitted in accordance with 37 C.F.R. § 1.6(a)(4) on the 8th day of February 2024.

1. Cover Letter to the Commissioner;
2. Utility Patent Application Transmittal form (PTO/AIA/15);
3. Application Data Sheet (PTO/AIA/14);
4. Specification, Claims, and Abstract;
5. Preliminary Amendment under 37 C.F.R. § 1.115;
6. Request for Prioritized Examination under 37 C.F.R. § 1.102(e);
7. Information Disclosure Statement by Applicant (PTO/SB/08a);
8. Non-Patent Literature (12 documents);
9. Fee Transmittal (PTO/SB/17);
10. Executed Inventor Declaration (2 sheets)(PTO/AIA/01);
11. Executed Power of Attorney with Transmittal (PTO/AIA/82A&B); and
12. This Certificate of Transmission under 37 C.F.R. § 1.8(a).

/Amy L. Peters/

Amy L. Peters (for Li Gao, Ph.D., Reg. No. 71,343)

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Jo Ann Wilson	Nonprovisional Application Number (if known):	
Title of Invention:	Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Li Gao, Ph.D./	Date 2024-02-08
Name (Print/Typed) Li Gao, Ph.D.	Practitioner Registration Number 71343

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**02/08/2024 04:59:00 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	64263903	FILING DATE	-
CUSTOMER #	91684	FIRST NAMED INVENTOR	Jo Ann Wilson
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Li Gao

Documents

TOTAL DOCUMENTS: 37

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
NPL20_Commission Decision.pdf	2	Non Patent Literature	30 KB
NPL19_Handbook of Pharmaceutical Excipients.pdf	8	Non Patent Literature	349 KB
NPL21_Part5.pdf	82	Non Patent Literature	3996 KB
NPL22_Part1.pdf	200	Non Patent Literature	4869 KB
NPL21_Part2.pdf	150	Non Patent Literature	6336 KB
NPL21_Part1.pdf	150	Non Patent Literature	6482 KB
NPL22_Part5.pdf	88	Non Patent Literature	840 KB

NPL21_Part4.pdf		150	Non Patent Literature	7729 KB
NPL21_Part3.pdf		150	Non Patent Literature	8343 KB
NPL23_Salgia.pdf		2	Non Patent Literature	410 KB
NPL12_Zhang.pdf		16	Non Patent Literature	548 KB
NPL13_Willhauck.pdf		4	Non Patent Literature	236 KB
NPL14_NCT00704288.pdf		6	Non Patent Literature	102 KB
NPL22_Part2.pdf		200	Non Patent Literature	4581 KB
NPL15_NCT00704730.pdf		12	Non Patent Literature	197 KB
NPL22_Part3.pdf		200	Non Patent Literature	3894 KB
NPL17_KURZROCK.pdf		8	Non Patent Literature	373 KB
NPL16_MOLOGNI.pdf		14	Non Patent Literature	608 KB
NPL22_Part4.pdf		200	Non Patent Literature	6028 KB
NPL18_ARKO.pdf		36	Non Patent Literature	2202 KB
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2024-02-08_EX10-039C11-US_Application_Filing_Docs-LET..pdf	(1-2)	2	Miscellaneous Incoming Letter	125 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-TRNA.pdf	(3-3)	1	Transmittal of New Application	111 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-ADS.pdf	(4-11)	8	Application Data Sheet	117 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-SPEC.pdf	(12-48)	37	Specification	2030 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-CLM.pdf	(49-57)	9	Claims	172 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-ABST.pdf	(58-58)	1	Abstract	51 KB
2024-02-08_EX10-039C11-US_Application_Filing_Doc	(59-59)	1	Preliminary Amendment	108 KB

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2024-02-08_EX10-039C11-US_Application_Filing_Docs-CLM.pdf	(60-62)	3	Claims	114 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-SPEC.pdf	(63-63)	1	Specification	109 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-REM.pdf	(64-69)	6	Applicant Arguments/Remarks Made in an Amendment	136 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-TRACK1.REQ.pdf	(70-70)	1	Track One Request	69 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-IDS.pdf	(71-84)	14	Information Disclosure Statement (IDS) Form (SB08)	77 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-TRAN.LET.pdf	(85-85)	1	Transmittal Letter	100 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-OATH.pdf	(86-87)	2	Oath or Declaration filed	220 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-PA...pdf	(88-89)	2	Power of Attorney	356 KB
2024-02-08_EX10-039C11-US_Application_Filing_Docs-LET..pdf	(90-90)	1	Miscellaneous Incoming Letter	96 KB
track1 request.pdf		1	Track One Request	71 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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2024-02-08_EX10-039C11-US_Application_Filing_Docs-REM.pdf	FE31ACEE695E7CD2F398ED5F15EB1F0ABA89F156520A5411CD04B70C2B78042F3A5C90B14EE9E821B191204DE2EF46946F3023AD7455E683CC1D9041CCE1A9E3
2024-02-08_EX10-039C11-US_Application_Filing_Docs-TRACK1.REQ.pdf	90444259B2E3821409A111E5B5C633C1CD4B9BDC7831FDCB25BCCC045BBE58EFF04C3AA7CD5598649CAC6AA16C02484F9BAF9BA74F677C2FC039F5D93DC0A934
2024-02-08_EX10-039C11-US_Application_Filing_Docs-IDS.pdf	ABFAD74003A20EB45B4FF34E629AA95B87F5F235064BB68393F4E97657B82721E701DEFE7A3BA67EFD5EEE807ED16E0EBF6002418B2C158F312789178703D66C
2024-02-08_EX10-039C11-US_Application_Filing_Docs-TRAN.LET.pdf	6E909E3C4CFCC8466680BF86EDBC67D57D61343EB51D450495E5840E99773EF2369C540244F515EAE6EA87A5443E68804800F22637BBE7DF887A4037DB037047
2024-02-08_EX10-039C11-US_Application_Filing_Docs-OATH.pdf	1854F912468421437758AC78903D5151990CB67F5976171320C7640DEB181A8704821547301C0AA8263749BC27FF40DE9DF008BCF2152C244DB3D2A9B234C687
2024-02-08_EX10-039C11-US_Application_Filing_Docs-PA...pdf	40447F20BAF7FDD1D91B7FC81279E22D63138387840C670A61FE5339CE77B4FF218737B64A68F3BC0120615A2B07FEC42DC1E34844A1BDE7EC255215FB3A532F
2024-02-08_EX10-039C11-US_Application_Filing_Docs-LET..pdf	B8AB300792897EC901FC06E05B9D8BB297C1FDE94890605EF5AAEF678F0BF857E5630BD4776F8B96964DC258925A2A41D0D70CAB6B8A104F381248CCBD2D185D
track1 request.pdf	2239C56331118347D7109700E2CAD4A831E1241294AD4CE5B9914791DD19DE7C0932EF4950126F7BAFB96A2EF12B4C13905A6B789BBA2A7947B3A800DE34DAB6

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES
PATENT AND TRADEMARK OFFICE

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/436,836	**02/08/2024 04:59:00 PM Z ET**	**224990/10-039C11US/543389**

Title of Invention

PROCESSES FOR PREPARING QUINOLINE COMPOUNDS AND PHARMACEUTICAL COMPOSITIONS CONTAINING SUCH COMPOUNDS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	5374	FILED BY	Amy Peters
PATENT CENTER #	64263903	AUTHORIZED BY	Li Gao
CUSTOMER #	91684	FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jo Ann Wilson

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 503145	**E202428H00325363**	**Amy Peters**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1830	PROCESSING FEE, EXCEPT IN PROVISIONAL APPLICATIONS	140.00	1	140.00
1817	REQUEST FOR PRIORITIZED EXAMINATION	4200.00	1	4200.00
1111	UTILITY PATENT APPL. SEARCH FEE	700.00	1	700.00
1011	BASIC FILING FEE - UTILITY (PAPER FILING ALSO REQUIRES NON-ELECTRONIC FILING FEE UNDER 1.16(T))	320.00	1	320.00
1311	PATENT APPL. EXAMINATION FEE	800.00	1	800.00
1054	Non-DOC-X Filing Surcharge	400.00	1	400.00

TOTAL AMOUNT:	**$6,560.00**

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