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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/986,310	01/07/2011	Nicholas S. Bodor	20009904-0067	6100

13974 7590 06/25/2014

DENTONS US LLP
P.O. BOX 061080
Chicago, IL 60606-1080

EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1673	

NOTIFICATION DATE	DELIVERY MODE
06/25/2014	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):

martin.bruehs@dentons.com
patents.us@dentons.com

Merck 2047
TWi v Merck
IPR2023-00050

Response to Rule 312 Communication	Application No.	Applicant(s)
	12/986,310	BODOR ET AL.
	Examiner	Art Unit
	Jonathan S. Lau	1673

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

1. ☒ The amendment filed on *12 June 2014* under 37 CFR 1.312 has been considered, and has been:

a) ☐ entered.

b) ☒ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.

Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

The specification is amended to omit that which is well-known to those skilled in the art. Therefore this amendment is directed to matters of form not affecting the scope of the invention.

/SHAOJIA ANNA JIANG/ Supervisory Patent Examiner, Art Unit 1673	/Jonathan S Lau/ Examiner, Art Unit 1673

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
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CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

13974 7590 03/13/2014
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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.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/986,310	01/07/2011	Nicholas S. Bodor	20009904-0067	6100

TITLE OF INVENTION: ORAL FORMULATIONS OF CLADRIBINE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	06/13/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
LAU, JONATHAN S	1673	514-046000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 DENTONS US LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: ARES TRADING S.A.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): AUBONNE, SWITZERLAND

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

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
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4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 19-3140 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /MARTIN A. BRUEHS/ Date JUNE 13, 2014
Typed or printed name MARTIN A. BRUEHS Registration No. 45635

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	12986310
Filing Date:	07-Jan-2011
Title of Invention:	ORAL FORMULATIONS OF CLADRIBINE
First Named Inventor/Applicant Name:	Nicholas S. Bodor
Filer:	Martin A. Bruehs/Louie Malloy
Attorney Docket Number:	20009904-0067

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Printed Copy of Patent - No Color	8001	4	3	12
		Total in USD ($)		**972**

Electronic Acknowledgement Receipt

EFS ID:	19296893
Application Number:	12986310
International Application Number:	
Confirmation Number:	6100
Title of Invention:	ORAL FORMULATIONS OF CLADRIBINE
First Named Inventor/Applicant Name:	Nicholas S. Bodor
Customer Number:	13974
Filer:	Martin A. Bruehs/Louie Malloy
Filer Authorized By:	Martin A. Bruehs
Attorney Docket Number:	20009904-0067
Receipt Date:	13-JUN-2014
Filing Date:	07-JAN-2011
Time Stamp:	11:55:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$972
RAM confirmation Number	9528
Deposit Account	
Authorized User	

File Listing:

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

1	Issue Fee Payment (PTO-85B)	0067IssueFee.pdf	138250 2eb3403798e7695bcf1f5c91bac8a384bf3f2c9f	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31792 51ca62ba91c449063c4ba5d750bf4cf06af2f90f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	170042		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Nicholas S. BODOR et al.	)	**MAIL STOP ISSUE FEE**
Application No.: 12/986,310	)	Examiner: Jonathan S. LAU
Filed: January 7, 2011	)	Group Art Unit: 1623
Title: ORAL FORMULATIONS OF CLADRIBINE	)	Confirmation No.: 6100

REPLY AND AMENDMENT PURSUANT TO 37 C.F.R. § 1.312

In response to the Notice to File Corrected Application Papers dated April 17, 2014, Applicants hereby submit the following amendment and remarks pursuant to 37 C.F.R. §1.312.

AMENDMENTS TO THE SPECIFICATION:

Please replace page 23 of the as-filed specification with the attached new page 23, which deleted the final sentence in the paragraph at lines 7-29.

Attached: Marked-Up and Clean Copies of Page 23

REMARKS

After allowance of this application, it was noted that page 23 of the as-filed specification contained references to applications for which no application numbers were given. These were provisional applications which were abandoned without the filing of non-provisional applications based thereon. Further, they were not for inventions of the present inventors and belonged to a former assignee. They were not made available to the public. In the parent case, now patented (Application No. 12/986, 310), the sentence in question was deleted during prosecution, by an amendment made October 3, 2008. Accordingly, page 23 of the specification has been amended to delete the final sentence on page 23, consistent with the parent.

This amendment was not proposed sooner because it was not realized that the error had not been corrected until after allowance. This amendment does not raise any new issues and thus is appropriate at this time. Entry is respectfully requested.

Respectfully submitted,

DENTONS US LLP

Date: June 12, 2014

/Mary Katherine Baumeister/
Mary Katherine Baumeister
Registration No. 26254

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Dentons US LLP
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Washington, D.C. 20005
Phone: 202-408-9186
Fax: 202-408-6399

Physicians, Vol. 111, No. 1, 35-44 (1999); Selby et al., *The Canadian Journal of Neurological Sciences*, 25, 295-299 (1998); Tortorella et al., *Current Opinion in Investigational Drugs*, 2 (12), 1751-1756 (2001); Rice et al., *Neurology*, 54, 1145-1155 (2000); and Karlsson et al., *British Journal of Haematology*, 116, 538-548 (2002); all of which are incorporated by reference herein in their entireties and relied upon.

Moreover, the route of administration for which the therapeutically effective dosages are taught in the literature should be taken into consideration. While the instant compositions optimize the bioavailability of cladribine following oral administration, it will be appreciated that even optimal bioavailability from oral dosage forms is not expected to approach bioavailability obtain after intravenous administration, particularly at early time points. Thus, it is often appropriate to increase a dosage suggested for intravenous administration to arrive at a suitable dosage for incorporation into a solid oral dosage form. At the present time, it is envisioned that, for the treatment of multiple sclerosis, 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment. Alternatively the patient would be treated with 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant dosage form once per day for a period of five to seven days per month for a total of six months, followed by eighteen months of no treatment. ~~For further dosing information, see also U.S. Provisional Patent Application No. _____ [IVAX0021-P-USA/Attorney Docket No. 033935-011], and U.S. Provisional Patent Application No. _____ [IVAX0022-P-USA/Attorney Docket No. 033935-012], both entitled "Cladribine Regimen for Treating Multiple Sclerosis", both filed on March 25, 2004 and incorporated by reference herein in their entireties.~~

Physicians, Vol. 111, No. 1, 35-44 (1999); Selby et al., *The Canadian Journal of Neurological Sciences*, 25, 295-299 (1998); Tortorella et al., *Current Opinion in Investigational Drugs*, 2 (12), 1751-1756 (2001); Rice et al., *Neurology*, 54, 1145-1155 (2000); and Karlsson et al., *British Journal of Haematology*, 116, 538-548 (2002); all of which are incorporated by reference herein in their entireties and relied upon.

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Electronic Acknowledgement Receipt

EFS ID:	19292491
Application Number:	12986310
International Application Number:	
Confirmation Number:	6100
Title of Invention:	ORAL FORMULATIONS OF CLADRIBINE
First Named Inventor/Applicant Name:	Nicholas S. Bodor
Customer Number:	13974
Filer:	Mary Katherine Baumeister/Rebecca Brimmer
Filer Authorized By:	Mary Katherine Baumeister
Attorney Docket Number:	20009904-0067
Receipt Date:	12-JUN-2014
Filing Date:	07-JAN-2011
Time Stamp:	18:18:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		312-Amendment.pdf	189700 1aaf1c6d1026e3403772a0cb4aacbef87c0939d9	yes	5

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Specification	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
	Specification	4	5

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