Application No.: 13/308,658 **Office Action Dated:** May 8, 2012

$$\left(H-N\right)$$

form a 5 to 7 membered ring containing a total of 2 to 4 heteroatoms selected from N, O, S, SO, or SO₂;

or optionally R¹ and R³ together with

$$\left(\begin{array}{c} I \\ I \\ I \end{array}\right)$$

form a 4 to 8 membered cycloheteroalkyl ring wherein the cycloheteroalkyl ring has an optional aryl ring fused thereto or an optional 3 to 7 membered cycloalkyl ring fused thereto;

with the proviso that where x is 1 and y is 0, X is H, n is o, and one of R^1 and R^2 is H and the other is alkyl, then R^3 is other than pyridyl or substituted pyridyl;

including all stereoisomers thereof;

<u>or [and]</u> a pharmaceutically acceptable salt thereof[, or a prodrug ester thereof], and all stereoisomers thereof.

Amend claim 12 as follows:

12. A pharmaceutical combination comprising a [DP4 inhibitor] compound as defined in claim 1 and an antidiabetic agent other than a DP4 inhibitor for treating diabetes and related diseases, an anti-obesity agent and/or a lipid-modulating agent.

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Amend claim 13 as follows:

13. The pharmaceutical combination as defined in claim 12 comprising said [DP4 inhibitor] compound as defined in claim 1 and [an] the antidiabetic agent other than a DP4 inhibitor.

Amend claim 16 as follows:

16. The combination as defined in claim 13 wherein the compound <u>as defined in claim 1</u> is present in a weight ratio to the antidiabetic agent within the range from about 0.01 to about 100:1.

Amend claim 17 as follows:

17. The combination as defined in claim 12 wherein the anti-obesity agent is a beta 3 adrenergic agonist, a lipase inhibitor, [a serotonin (and dopamine) reuptake inhibitor,] a thyroid receptor beta compound, an anorectic agent, and/or a fatty acid oxidation upregulator.

Amend claim 21 as follows:

21. The combination as defined in claim 19 wherein the <u>compound as defined in claim 1 [DP4 inhibitor]</u> is present in a weight ratio to the lipid-modulating agent within the range from about 0.01 to about 100:1.

Amend claim 22 as follows:

22. A pharmaceutical combination comprising a [DP4 inhibitor] compound as defined in claim 1 and an agent for treating infertility, an agent for treating polycystic ovary syndrome, an agent for treating a growth disorder and/or frailty, an anti-arthritis agent, an agent for preventing <u>or</u> inhibiting allograft rejection in transplantation, an agent for treating autoimmune disease, an anti-AIDS agent, an agent for treating inflammatory bowel disease/syndrome, an agent for treating anorexia nervosa, an anti-osteoporosis agent and/or an anti-obesity agent.

Amend added claim 29 to read as follows:

29. The composition of claim 27 or 28 further comprising an antidiabetic agent other than a DP4 inhibitor.

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Amend added claim 30 to read as follows:

30. The composition of claim 29 wherein the antidiabetic agent is metformin.

Amend added claim 31 to read as follows:

31. The composition of claim 29 wherein the antidiabetic agent is a SGLT2 inhibitor.

Cancel added claims 36 and 37.

Amend added claim 38 to read as follows:

38. The method of any one of claims 32, 33, 34, or 35, wherein the pharmaceutical composition further comprises an antidiabetic agent other than a DP4 inhibitor.

Amend added claim 39 to read as follows:

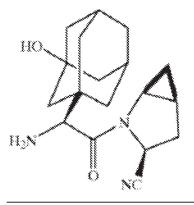
39. The method of claim 38 wherein the antidiabetic agent is metformin.

Amend added claim 40 to read as follows:\

40. The method of claim 38 wherein the antidiabetic agent is a SGLT2 inhibitor.

Add new claims 41 to 45 to read as follows:

41. A method for treating type II diabetes in a mammal comprising administering to the mammal a pharmaceutical composition comprising a compound that is



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or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier therefor.

42. The method of claim 41, wherein the pharmaceutically acceptable salt is the hydrochloride salt.

- 43. The method of any one of claims 41 or 42, wherein the pharmaceutical composition further comprises an antidiabetic agent other than a DP4 inhibitor.
 - 44. The method of claim 43, wherein the antidiabetic agent is metformin.
 - 45. The method of claim 43, wherein the antidiabetic agent is a SGLT2 inhibitor.

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Complete Listing of Claims As Amended (including status identifiers):

1. (Amended) A compound having the structure

$$H \xrightarrow{\mathbb{R}^3} \mathbb{R}^2 \mathbb{R}^1 \xrightarrow{(\bigcap_S)} \mathbb{N}$$

wherein x is 0 or 1 and y is 0 or 1, provided that

x=1 when y=0 and

x=0 when y=1; and wherein

n is 0 or 1;

X is H or CN;

R¹, R², R³ and R⁴ are the same or different and are independently selected from hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, bicycloalkyl, tricycloalkyl, alkylcycloalkyl, hydroxyalkylcycloalkyl, hydroxycycloalkyl, hydroxybicycloalkyl, hydroxytricycloalkyl, bicycloalkylalkyl, alkylthioalkyl, arylalkylthioalkyl, cycloalkenyl, aryl, aralkyl, heteroaryl, heteroarylalkyl, cycloheteroalkyl or cycloheteroalkylalkyl; all optionally substituted through available carbon atoms with 1, 2, 3, 4 or 5 groups selected from hydrogen, halo, alkyl, polyhaloalkyl, alkoxy, haloalkoxy, polyhaloalkoxy, alkoxycarbonyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, polycycloalkyl, heteroarylamino, arylamino, cycloheteroalkyl, cycloheteroalkylalkyl, hydroxy, hydroxyalkyl, nitro,

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cyano, amino, substituted amino, alkylamino, dialkylamino, thiol, alkylthio, alkylcarbonyl, acyl, alkoxycarbonyl, aminocarbonyl, alkynylaminocarbonyl, alkylaminocarbonyl, alkylcarbonyloxy, alkylcarbonylamino, arylcarbonylamino, alkylsulfonylamino, alkylsulfonyl, aminosulfinyl, aminosulfonyl, alkylsulfinyl, sulfonamido or sulfonyl;

and R¹ and R³ may optionally be taken together to form (CR⁵R⁶)_m where m is 2 to 6, and R⁵ and R⁶ are the same or different and are independently selected from hydroxy, alkoxy, H, alkyl, alkenyl, alkynyl, cycloalkyl, halo, amino, substituted amino, cycloalkylalkyl, cycloalkenyl, aryl, arylalkyl, heteroaryl, heteroarylalkyl, cycloheteroalkylalkyl, alkylcarbonylamino, arylcarbonylamino, alkoxycarbonylamino, aryloxycarbonyl, or alkylaminocarbonylamino, or R¹ and R⁴ may optionally be taken together to form (CR⁷R⁸)_p wherein p is 2 to 6, and R⁷ and R⁸ are the same or different and are independently selected from hydroxy, alkoxy, cyano, H, alkyl, alkenyl, alkynyl, cycloalkyl, cycloalkylalkyl, cycloalkenyl, halo, amino, substituted amino, aryl, arylalkyl, heteroaryl, heteroarylalkyl, cycloheteroalkyl, cycloheteroalkylalkyl, alkylcarbonylamino, arylcarbonylamino, alkoxycarbonyl, or alkylaminocarbonylamino, or optionally R¹ and R³ together with

$$\left(H-N\right)_{\mathbb{R}^4}$$

form a 5 to 7 membered ring containing a total of 2 to 4 heteroatoms selected from N, O, S, SO, or SO₂;

or optionally R¹ and R³ together with

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form a 4 to 8 membered cycloheteroalkyl ring wherein the cycloheteroalkyl ring has an optional aryl ring fused thereto or an optional 3 to 7 membered cycloalkyl ring fused thereto;

with the proviso that where x is 1 and y is 0, X is H, n is o, and one of R¹ and R² is H and the other is alkyl, then R³ is other than pyridyl or substituted pyridyl;

including all stereoisomers thereof;

or [and] a pharmaceutically acceptable salt thereof], or a prodrug ester thereof], and all stereoisomers thereof.

2. (Original) The compound as defined in claim 1 having the structure:

$$\begin{array}{c|c}
R^3 & R^2 & R^1 \\
N & N & N \\
R^4 & O & X
\end{array}$$

3. (Original) The compound as defined in claim 1 having the structure:

$$\begin{array}{c|c}
R^3 & R^2 & R^1 \\
N & N & N \\
N & N & N
\end{array}$$

4. (Original) The compound as defined in claim 1 having the structure: **DOCKET NO.:** BMS-2856 **Application No.:** 13/308,658

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$$H \xrightarrow{R^3} R^1$$

$$R^4 \qquad O$$

$$NC$$

5. (Original) The compound as defined in claim 1 having the structure:

6. (Original) The compound as defined in claim 1 wherein:

R³ is H, R¹ is H, alkyl, cycloalkyl, bicycloalkyl, tricycloalkyl, alkylcycloalkyl, hydroxyalkyl, hydroxyalkylcycloalkyl, hydroxycycloalkyl hydroxybicycloalkyl, or hydroxytricycloalkyl,

R² is H or alkyl, n is 0,

X is CN.

7. (Original) The compound as defined in claim 1 wherein the cyclopropyl fused to the pyrrolidine has the configuration:

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A compound having the structure: 8. (Original)

or a pharmaceutically acceptable salt thereof.

- 9. The compound as defined in claim 8 wherein the pharmaceutically (Original) acceptable salt is the hydrochloride salt or the trifluoroacetic acid salt.
 - 10. (Original) A compound which is

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wherein R¹ is alkyl, cycloalkyl, bicycloalkyl, tricycloalkyl, alkylcycloalkyl, hydroxyalkyl, hydroxycycloalkyl, hydroxyalkylcycloalkyl, hydroxybicycloalkyl, or hydroxytricycloalkyl,

or

wherein R¹ is alkyl, cycloalkyl, bicycloalkyl, tricycloalkyl, alkylcycloalkyl, hydroxyalkyl, hydroxycycloalkyl, hydroxyalkylcycloalkyl, hydroxybicycloalkyl, or hydroxytricycloalkyl.

- 11. (Original) A pharmaceutical composition comprising a compound as defined in claim 1 and a pharmaceutically acceptable carrier therefor.
- 12. (Amended) A pharmaceutical combination comprising a [DP4 inhibitor] compound as defined in claim 1 and an antidiabetic agent other than a DP4 inhibitor for treating diabetes and related diseases, an anti-obesity agent and/or a lipid-modulating agent.
- 13. (Twice Amended) The pharmaceutical combination as defined in claim 12 comprising said [DP4 inhibitor] compound <u>as defined in claim 1</u> and [an] <u>the antidiabetic agent other than a DP4 inhibitor</u>.
- 14. (Original) The combination as defined in claim 13 wherein the antidiabetic agent is 1, 2, 3 or more of a biguanide, a sulfonyl urea, a glucosidase inhibitor, a PPAR agonist, a PPAR / dual agonist, an SGLT2 inhibitor, an aP2 inhibitor, a glycogen phosphorylase inhibitor, an AGE inhibitor, an insulin sensitizer, a glucagon-like peptide-1 (GLP-1) or mimetic thereof, insulin and/or a meglitinide.

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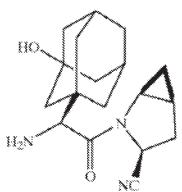
15. (Original) The combination as defined in Claim 14 wherein the antidiabetic agent is 1, 2, 3 or more of metformin, glyburide, glimepiride, glipyride, glipizide, chlorpropamide, gliclazide, acarbose, miglitol, pioglitazone, troglitazone, rosiglitazone, insulin, Gl-262570, isaglitazone, JTT-501, NN-2344, L895645, YM-440, R-119702, AJ9677, repaglinide, nateglinide, KAD1129, AR-HO39242, GW-409544, KRP297, AC2993, Exendin-4, LY307161, NN2211, and/or LY315902.

- 16. (Amended) The combination as defined in claim 13 wherein the compound <u>as</u> <u>defined in claim 1</u> is present in a weight ratio to the antidiabetic agent within the range from about 0.01 to about 100:1.
- 17. (Amended) The combination as defined in claim 12 wherein the anti-obesity agent is a beta 3 adrenergic agonist, a lipase inhibitor, [a serotonin (and dopamine) reuptake inhibitor,] a thyroid receptor beta compound, an anorectic agent, and/or a fatty acid oxidation upregulator.
- 18. (Original) The combination as defined in claim 17 wherein the anti-obesity agent is orlistat, ATL-962, AJ9677, L750355, CP331648, sibutramine, topiramate, axokine, dexamphetamine, phentermine, phenylpropanolamine, famoxin, and/or mazindol.
- 19. (Original) The combination as defined in claim 12 wherein the lipid modulating agent is an MTP inhibitor, an HMG CoA reductase inhibitor, a squalene synthetase inhibitor, a fibric acid derivative, an upregulator of LDL receptor activity, a lipoxygenase inhibitor, an ACAT inhibitor, a cholesteryl ester transfer protein inhibitor, or an ATP citrate lyase inhibitor.
- 20. (Original) The combination as defined in claim 19 wherein the lipid modulating agent is pravastatin, lovastatin, simvastatin, atorvastatin, cerivastatin, fluvastatin, nisvastatin, visastatin, fenofibrate, gemfibrozil, clofibrate, implitapide, CP-529,414, avasimibe, TS-962, MD-700, and/or LY295427.

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21. (Amended) The combination as defined in claim 19 wherein the <u>compound as</u> <u>defined in claim 1 [DP4 inhibitor]</u> is present in a weight ratio to the lipid-modulating agent within the range from about 0.01 to about 100:1.

- 22. (Amended) A pharmaceutical combination comprising a [DP4 inhibitor] compound as defined in claim 1 and an agent for treating infertility, an agent for treating polycystic ovary syndrome, an agent for treating a growth disorder and/or frailty, an anti-arthritis agent, an agent for preventing <u>or</u> inhibiting allograft rejection in transplantation, an agent for treating autoimmune disease, an anti-AIDS agent, an agent for treating inflammatory bowel disease/syndrome, an agent for treating anorexia nervosa, an anti-osteoporosis agent and/or an anti-obesity agent.
 - 23. (Canceled)
 - 24. (Canceled)
 - 25. (New) A compound that is



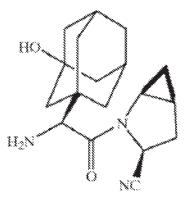
; or a pharmaceutically acceptable salt thereof.

- 26. (New) The compound as defined in claim 25, wherein the pharmaceutically acceptable salt is the hydrochloride salt.
- 27. (New) A pharmaceutical composition comprising the compound of claim 25 and a pharmaceutically acceptable carrier therefor.

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28. (New) A pharmaceutical composition comprising the compound of claim 26 and a pharmaceutically acceptable carrier therefor.

- 29. (New/Amended) The composition of claim 27 or 28 further comprising an antidiabetic agent other than a DP4 inhibitor.
- 30. (New/Amended) The composition of claim 29 wherein the antidiabetic agent is metformin.
- 31. (New/Amended) The composition of claim 29, wherein the antidiabetic agent is a SGLT2 inhibitor.
- 32. (New) A method for treating diabetes, insulin resistance, hyperglycemia, hyperinsulinemia, impaired glucose homeostasis, or impaired glucose tolerance in a mammal comprising administering to the mammal a pharmaceutical composition comprising a compound that is



or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier therefor.

- 33. (New) The method of claim 32, wherein the pharmaceutically acceptable salt is the hydrochloride salt.
 - 34. (New) The method of claim 32, for treating diabetes.

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35. (New) The method of claim 33, for treating diabetes.

36. (Canceled)

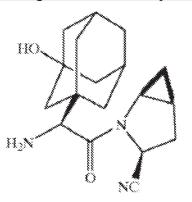
37. (Canceled)

38. (New/Amended) The method of any one of claims 32, 33, 34, or 35 wherein the pharmaceutical composition further comprises an antidiabetic agent other than a DP4 inhibitor.

39. (New/Amended) The method of claim 38, wherein the antidiabetic agent is metformin.

40. (New/Amended) The method of claim 38, wherein the antidiabetic agent is a SGLT2 inhibitor.

41. (New) A method for treating type II diabetes in a mammal comprising administering to the mammal a pharmaceutical composition comprising a compound that is



or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier therefor.

42. (New) The method of claim 41, wherein the pharmaceutically acceptable salt is the hydrochloride salt.

43. (New) The method of any one of claims 41 or 42, wherein the pharmaceutical composition further comprises an antidiabetic agent other than a DP4 inhibitor.

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44. (New) The method of claim 43, wherein the antidiabetic agent is metformin.

45. (New) The method of claim 43, wherein the antidiabetic agent is a SGLT2 inhibitor.

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REMARKS

Claims 1, 12, 13, 16, 17, 21, 22, 29, 30, 31, 38, 39, and 40 are amended herein. Claims 36 and 37 are canceled and new claims 41 to 45 are added herein. Support for each of the new claims and/or amendments is implicit in the prior versions of the claims, or is set forth in the chart that was submitted with the preliminary amendment filed December 1, 2011. No new matter is added.

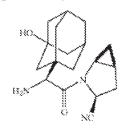
After entry of the present amendments, claims 1-22, 25-35, and 38-45 will remain pending.

Summary of the Interview

The undersigned thanks Examiners Polansky and Anderson for the courtesy of the telephonic interview conducted on May 22, 2012. The pending claims were discussed, as well as the objections and alleged rejections set forth in the May 8, 2012 Office Action. In particular, the undersigned thanks the Examiners for clarifying the objections to the Applicants' reissue declaration, the incorporation of corrections provided in the Certificates of Correction for the original patent, and the procedures to be followed to remedy any perceived errors.

Reissue Oath/Declaration

The Office alleges that the reissue declaration is defective because it fails to identify at least one specific error which is relied upon to support the reissue application. Without conceding the propriety of this assertion and in the interest of advancing prosecution of the application, a supplemental declaration is filed herewith, which states that the specific error relied upon is that, while the patent included claims encompassing the compound below, the patentee failed to include claims that are specifically directed to the compound:



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or a pharmaceutical salt thereof, as set forth in added claims 25 to 35 and 38 to 45.

The supplemental declaration also sets forth the mailing addresses and residences of the inventors. Patent Owner asserts that the supplemental reissue declaration complies with 37 C.F.R. 1.175.

Certificates of Correction

The Office has noted that changes to the specification and claims made via the Certificates of Correction for the original patent should be incorporated into the reissue patent. Said changes have been effected by the Patent Owner according to the procedure described in the Office Action. *See* MPEP 1453.VI.(C).

Claim Objections

The Office objects to added claim 38 for reciting, "The method of any one of claims 32, 33, 34, 25, 26, or 37..." Added claim 38 has been amended to recite "The method of any one of claims 32, 33, 34, or 35 ..." Withdrawal of the objection is requested.

The Office objects to claim 38 for reciting "an agent for preventing inhibiting allograft rejection in transplantation..." As discussed in the telephonic interview, claim 22, not claim 38, recites the identified language. Claim 22 has accordingly been amended to recite, "an agent for preventing <u>or</u> inhibiting allograft rejection in transplantation." Withdrawal of the objection is requested.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-7, 11-22, 29-31, and 38-40 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In light of the present claim amendments, withdrawal of the rejections is requested.

Claim 1 has been amended to more clearly identify pharmaceutically acceptable salts as an alternative, *i.e.*, "or a pharmaceutically acceptable salt thereof." The rejection of claim 1 therefore is considered moot.

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Claim 12 has been amended to recite "a [DP4 inhibitor] compound as defined in claim 1." Claim 13 has been similarly amended. The rejection of claims 12 and 13 is considered moot.

Claim 22 has been amended to recite "A pharmaceutical combination comprising a [DP4 inhibitor] compound as defined in claim 1." The rejection of claim 22 is considered moot. Patent Owner notes that claim 21 has been amended to recite, "The combination as defined in claim 19 wherein the compound as defined in claim 1 [DP4 inhibitor] is present in a weight ratio to the lipid-modulating agent within the range from about 0.01 to about 100:1." Claim 16 has been amended similarly to claim 21.

Claim 17 has been amended to delete the limitation, "a serotonin (and dopamine) reuptake inhibitor." The rejection of claim 17 is considered moot.

Claim 29 has been amended to recite, "The composition of claim 27 or 28 further comprising <u>an</u> antidiabetic agent other than a DP4 inhibitor." The rejection of claim 29 is considered moot. Dependent claims 30 and 31 have been amended to recite, "wherein the antidiabetic agent is . . ."

Claim 38 has been amended to recite, "The method of any one of claims 32, 33, 34, or 35." The rejection is considered moot. Claim 38 has also been amended to recite, "wherein the pharmaceutical composition further comprises an antidiabetic agent other than a DP4 inhibitor." Dependent claims 39 and 40 have been amended to recite "wherein the antidiabetic agent is..." Dependent claim 40 has also been amended to recite "The method of claim 38..."

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-7 and 11-22 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not complying with the written description requirement for reciting the "prodrug esters" of the compounds of claim 1. While not conceding the propriety of the rejection, the term "prodrug ester thereof" has been deleted from claim 1 to advance prosecution. Withdrawal of the rejection is requested.

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CONCLUSION

Patent Owner believes that the foregoing addresses all issues raised in the Office Action dated May 8, 2012, and that the application is now in condition for allowance. If any further issues remain, the Examiner is invited to contact Patent Owner's undersigned representative at the contact number listed below.

Date: August 8, 2012 /S. Maurice Valla/ S. Maurice Valla

Registration No. 43,966

Woodcock Washburn LLP Cira Centre 2929 Arch Street, 12th Floor Philadelphia, PA 19104-2891 Telephone: (215) 568-3100

Facsimile: (215) 568-3439

Electronic Paten	ıt App	lication Fee	Transmit	tal		
Application Number:	13308658					
Filing Date:	01-Dec-2011					
Title of Invention:		Cyclopropyl-Fused Pyrrolidine-Based Inhibitors Of Dipeptidyl Peptidase IV And Method				
First Named Inventor/Applicant Name:	Jeffrey A. Robl					
Filer:	SAN	ЛUEL VALLA/D. Мс	Carty			
Attorney Docket Number:	BM	S-2856				
Filed as Large Entity						
Utility under 35 USC 111(a) Filing Fees						
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)	
Basic Filing:	1					
Pages:						
Claims:						
Claims in excess of 20		1202	3	60	180	
Miscellaneous-Filing:						
Petition:						
Patent-Appeals-and-Interference:						
Post-Allowance-and-Post-Issuance:						
Extension-of-Time: Sun-Amneal-IPR2016-	01104	- Ex. 1006. P	art 2, p. 290	6 of 373		

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
	Total in USD (\$)		180	

Electronic Acknowledgement Receipt			
EFS ID:	13444151		
Application Number:	13308658		
International Application Number:			
Confirmation Number:	7781		
Title of Invention:	Cyclopropyl-Fused Pyrrolidine-Based Inhibitors Of Dipeptidyl Peptidase IV And Method		
First Named Inventor/Applicant Name:	Jeffrey A. Robl		
Customer Number:	23377		
Filer:	SAMUEL VALLA/D. McCarty		
Filer Authorized By:	SAMUEL VALLA		
Attorney Docket Number:	BMS-2856		
Receipt Date:	08-AUG-2012		
Filing Date:	01-DEC-2011		
Time Stamp:	11:20:56		
Application Type:	Utility under 35 USC 111(a)		

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$180
RAM confirmation Number	8914
Deposit Account	233050
Authorized User	

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1. F. (Patent application and reexamination processing fees)

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

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

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

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	1 Transmittal Letter	BMS-2856-Transmittal-reply-	262560 no		2
	Transmittal Eciter	to-05-08-12.PDF	f5c75d475478a99889c129e8444656fa3c18 9c57		2
Warnings:					
Information:					
2		BMS-2856-reply-to-05-08-12.	359181	yes	36
-		PDF	85b8b25bcf56ed3f67b7e901298ecc99f2ee cdee	yes	30
	Multip	oart Description/PDF files in	zip description		
	Document De	scription	Start	E	nd
	Amendment/Req. Reconsiderati	ion-After Non-Final Reject	1 1		1
	Claims	2	2 32		
	Applicant Arguments/Remarks	33	36		
Warnings:					
Information:					
3	Oath or Declaration filed	BMS-2856-Supplemental-	86103	no	4
	Oath of Declaration med	Declaration.PDF	d141ce311b111da19ff431467fc6fd89f40c7 77f	110	
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	30247	no	2
Tee Worksheet (3000)		lee iiio.pai	a92269519b1df66b248102c534e402d4b53 0cadc	110	2
Warnings:					
Information:					
		Total Files Size (in bytes)	73	38091	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Olider tile Fat	Jerwork Rec	uction Act of 1995	. no berson	Application Number	13/308,65		uniess it	displays a valid OMB control number.
ТР	ANGN	IITTAL		Filing Date	Decembe			<u>'</u>
	FOF			First Named Inventor	Jeffrey A.	,		
	FOR	ZIVI		Art Unit	1629	NODI		
				Examiner Name				
(to be used for a	all correspo	ndence after initial	filing)		Gregg Po	lansky		
Total Number of	Pages in Th	nis Submission		Attorney Docket Number	BMS-285	BMS-2856		
			ENC	LOSURES (Check a	ll that appl	y)		
Fee Trans	smittal Forr	n		Drawing(s)				Allowance Communication to TC
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Amendme	ent/Reply		_	Petition Petition to Convert to a			(Appea	Il Communication to TC Il Notice, Brief, Reply Brief)
│	ter Final		│ Ш	Provisional Application Power of Attorney, Revocati	ion		Propri	etary Information
L Af	fidavits/de	claration(s)		Change of Correspondence				Letter
Extension	of Time R	equest	∐ -	Terminal Disclaimer		V	Other below	Enclosure(s) (please Identify):
Express A	Abandonme	ent Request		Request for Refund Su		Supp	pplemental Reissue Declaration	
Informatio	n Disclosu	re Statement		CD, Number of CD(s)				
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Incomplet	e Applicati	on						
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		SIGNA	TURE C	OF APPLICANT, ATTO	ORNEY, (OR AG	ENT	
Firm Name	Woodcoc	k Washburn, LLI	-					
Signature	/S. Mauri	ce Valla/						
Printed name	S. Mauric	e Valla						
Date August 8, 2012			Reg. No.	43,966	3			
					2101/24			
		C	EKIIFI	CATE OF TRANSMISS	SION/MA	ILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:								
Signature								
							Data	
Typed or printed r	name						Date	

This collection of information is required by 37 CFR 1.5. 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 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

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

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

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/SB/52 (05-08)

Approved for use through 08/31/2013. OMB 0651-0033 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. Docket Number (optional) REISSUE APPLICATION DECLARATION BY THE ASSIGNEE BMS-2856 I hereby declare that: The residence, mailing address and citizenship of the inventors are stated below. I am authorized to act on behalf of the following assignee: _____Bristol-Myers Squibb Company and the title of my position with said assignee is: Assistant General Counsel The entire title to the patent identified below is vested in said assignee. Citizenship United States Inventor Jeffrey A. Robl Residence/Mailing Address 7 Tulip Drive, Newtown, PA 18940 Inventor Richard B. Sulsky Citizenshlp **United States** Residence/Mailing Address 311 Pennington-Rocky Hill Road, Pennington, NJ 08534 Additional Inventors are named on separately numbered sheets attached hereto. 7 Patent Number 6,395,767 Date of Patent Issued May 28, 2002 I believe said inventor(s) to be the original and first inventor(s) of the subject matter which is described and claimed in said patent, for which a relssue patent is sought on the invention entitled: Cyclopropyl-Fused Pyrrolidine-Based Inhibitors of Dipeptidyl Peptidase IV and Method the specification of which is attached hereto. December 1, 2011 _ as reissue application number 13 308,658 was filed on . 12/1/2011 and 8/8/2012 and was amended on (If applicable) I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b). Attached is form PTO/SB/02B (or equivalent) listing the foreign applications. I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.) by reason of a defective specification or drawing. by reason of the patentee claiming more or less than he had the right to claim in the patent. by reason of other errors.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.175. 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 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.

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

PTO/SB/52 (05-08)
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REISSUE APPLICATION DECLARATION BY THE ASSIGNATION BY THE BY T

REISSUE	REISSUE APPLICATION DECLARATION BY THE ASSIGNEE Docket Number (Optional) BMS-285				
At least one error upon which relssue is based is described as follows:					
See attached	sheet				
		itional sheets, if needed,			
I hereby appoin	ected in this reissue application arose	without any deceptive i	ntention on the	part of the applicant.	
	ers associated with Customer Number:	23377			
OR Practition	er(s) named below:				
	Name		Registration N	Number	
		•			
	*			-1.	
as my/our attorn	ney(s) or agent(s) to prosecute the application	ation identified above, an	d to transact all t	ousiness in the United	
	nd Trademark Office connected therewith				
Correspondenc	e Address: Direct all communications abo	out the application to:			
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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. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed. Signature Pathorization forms PTO-2038 submitted for payment purposes are not publication, any patent issuing thereon, or any patent to which this declaration is directed.					
Address of Assignee Bristol-Myers Squibb Co.; Patent Department; P.O. Box 4000; Princeton, NJ 08543-4000					

[Page 2 of 2]

Supplemental Declaration Additional Sheet

At least one error upon which reissue is based is described as follows:

While the patent included claims encompassing the compound below, the patent failed to include

claims that are specifically directed to the compound thereof, as set forth in added claims 25 to 35 and 38 to 45.

or a pharmaceutical salt

ADDITIONAL INVENTORS Page 1 of 1

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2012-08-13

WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891

Paper No.

Application No.:	13/308,658	Date Mailed:	2012-08-13
First Named Inventor:	Robl, Jeffrey, A.	Examiner:	POLANSKY, GREGG
Attorney Docket No.:	BMS-2856	Art Unit:	1629
Confirmation No.:	7781	Filing Date:	2011-12-01

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

Commissioner for Patents

PTO-90c (Rev.08-06)

Application No. Applicant(s) 13/308,658 ROBL ET AL. **Notice of Non-Compliant Amendment** (37 CFR 1.121) Art Unit 1700 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --The amendment document filed on <u>08 August</u>, <u>2012</u> is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required. THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT: 1. Amendments to the specification: A. Amended paragraph(s) do not include markings. ☐ B. New paragraph(s) should not be underlined. C. Other . 2. Abstract: ☐ A. Not presented on a separate sheet. 37 CFR 1.72. B. Other ____ ☐ 3. Amendments to the drawings: A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d). ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required. □ C. Other _____. 4. Amendments to the claims: A. A complete listing of all of the claims is not present. ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims) C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended). D. The claims of this amendment paper have not been presented in ascending numerical order. ☐ E. Other: . 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4): For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714. TIME PERIODS FOR FILING A REPLY TO THIS NOTICE: 1. Applicant is given no new time period if the non-compliant amendment is an after-final amendment or an amendment filed after allowance, or a drawing submission (only) If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the entire corrected amendment must be resubmitted. 2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a Quayle action. If any of above boxes 1 to 4 are checked, the correction required is only the corrected section of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

Legal Instruments Examiner (LIE), if applicable /BRUCE HARRISON/ Telephone No: (571)272-1016

U.S. Patent and Trademark Office

PTOL-324 (04-06)

Notice of Non-Compliant Amendment (37 CFR 1.121)

Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 308 of 373

Part of Paper No. 20120809-1



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2012-08-21

WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891

Paper No.

Application No.:	13/308,658	Date Mailed:	2012-08-21
First Named Inventor:	Robl, Jeffrey, A.	Examiner:	POLANSKY, GREGG
Attorney Docket No.:	BMS-2856	Art Unit:	1629
Confirmation No.:	7781	Filing Date:	2011-12-01

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

Commissioner for Patents

PTO-90c (Rev.08-06)

Letter Withdrawing a Notice of	Application No.: 13/308,658	Applicant(s): ROBL ET AL.
Non-Compliant Amendment		Art Unit: 1700
The Notice of Non-Compliant Amendment mailed		
withdrawn. The application is being forwarded to apply to any Notice of Non-Compliant Amendment		
Legal Instruments Examiner (LIE):	Telephone N	umber:
/BRUCE HARRISON/	(571)272-10	16

U.S. Patent and Trademark Office

Part of Paper No. 20120816-1

Letter Withdrawing a Notice of Non-Compliant Amendment $\,$ (Rev. 6/04 $\,$)

Application No.: 13/308,658 **Office Action Dated:** May 8, 2012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jeffrey A. Robl

Confirmation No.: 7781

Application No.: 13/308,658 Group Art Unit: 1629

Filing Date: December 1, 2011 Examiner: Gregg Polansky

For: Cyclopropyl-Fused Pyrrolidine-Based Inhibitors of Dipeptidyl Peptidase IV and

Method

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

Dear Commissioner:

 \boxtimes

SUPPLEMENTAL REPLY PURSUANT TO 37 CFR § 1.111

In further response to the Official Action dated May 8, 2012, reconsideration is respectfully requested in view of the amendments and/or remarks as indicated below:

	of Correction begin on page 2 of this paper.
	Amendments to the Claims are reflected in the listing of the claims which begins on page of this paper.
	Amendments to the Drawings begin on page of this paper and include an attached replacement sheet.
\boxtimes	Remarks begin on page 6 of this paper.
	The Commissioner is hereby authorized to charge any fee deficiency, charge any additional fees, or credit any overpayment of fees, associated with this application in connection with this filing, or any future filing, submitted to the U.S. Patent and Trademark Office during the pendency of this application, to Deposit Account No. 23-3050.

A Listing of Prior Changes to U.S. 6,395,767 ("the 767 patent") Made By Certificate

Application No.: 13/308,658 **Office Action Dated:** May 8, 2012

Changes to 767 Patent Previously Entered by Certificate of Correction

1. As indicated by the Certificate of Correction, please substitute the following paragraph for the paragraph at col. 14, lines 13-54 of the 767 patent:

Unless otherwise indicated, the term "heteroaryl" as used herein alone or as part of another group refers to a 5- or 6- membered aromatic ring which includes 1, 2, 3 or 4 hetero atoms such as nitrogen, oxygen or sulfur, and such rings fused to an aryl, cycloalkyl, heteroaryl or cycloheteroalkyl ring (e.g. benzothiophenyl, indolyl), and includes possible N-oxides. The heteroaryl group may optionally include 1 to 4 substituents such as any of the substituents set out above for alkyl. Examples of heteroaryl groups include the following:

and the like.

DOCKET NO.: BMS-2856 PATENT

Application No.: 13/308,658 **Office Action Dated:** May 8, 2012

2. As indicated by the Certificate of Correction, please substitute the following paragraph for the paragraph at col. 14, lines 55-58 of the 767 patent:

The term "cycloheteroalkylalkyl" as used herein alone or as part of another group refers to cycloheteroalkyl groups as defined above linked through a C atom or heteroatom to a (CH₂)_r chain.

3. As indicated by the Certificate of Correction, please substitute the following paragraph for the paragraph at col. 43, lines 20-38 of the 767 patent:

To a flame-dried 500-mL round-bottomed flask containing cyclopentylideneacetic acid ethyl ester (17.5 g, 113 mmol) in 100 mL anhydrous toluene at -78°C under argon was added DIBAL-H (189 mL of a 1.5 M solution in toluene, 284 mmol, 2.50 equiv) dropwise over a 30 min period through an addition funnel, and the mixture was then allowed to warm to rt, stirring for 18 h. The reaction mixture was then recooled to -78°C, and quenched by the careful addition of 30 mL anhydrous MeOH. Upon warming to rt, 1 N Rochelle's salt (100 mL) was added, and the mixture was stirred 90 min. The biphasic reaction mixture was then diluted with Et₂O (200 mL) in a separatory funnel, and the layers were separated. The organic layer was then washed with brine (100 mL), dried (Na₂SO₄), and concentrated under reduced pressure. Purification by flash column chromatography (silica gel, CH₂Cl₂ / EtOAc, 10:1) gave 11.6 g (92%) of the desired allylic alcohol as a colorless oil.

4. As indicated by the Certificate of Correction, please substitute the following Scheme 7 for the Scheme 7 at col. 52, line 37- col. 53, line 25 of the 767 patent:

DOCKET NO.: BMS-2856 PATENT

Application No.: 13/308,658 **Office Action Dated:** May 8, 2012

Scheme 7 General Method E, Examples 45 47

a.OsO4, THF:H2O, 1:1; NalO4; workup,then NaBH4, MeOH, RT. 56% b. TFA:CH2Cl2, 1:2, 0 degrees C to RT.

Step 1

DOCKET NO.: BMS-2856 **Application No.:** 13/308,658 **Office Action Dated:** May 8, 2012 **PATENT**

5. As indicated by the Certificate of Correction, please substitute the following paragraph for the paragraph at col. 70, lines 55-65 of the 767 patent:

EXAMPLE 67

Step 1

6. As indicated by the Certificate of Correction, please substitute the following Table 5 for the Table 5 at col. 84, lines 23-42 of the 767 patent:

TABLE 5

$$H_2N$$
 R
 N
 CN

Example #	Cycloalkane	R	MS Data M+H
79	cyclohexane	Methyl	262
80	cyclohexane	Ethyl	276
81	cyclopentane	Methyl	248
82	cyclopentane	Allyl	274
83	cyclopentane	Propyl	276
84	cyclobutane	Methyl	234

DOCKET NO.: BMS-2856 PATENT

Application No.: 13/308,658 **Office Action Dated:** May 8, 2012

REMARKS

The Patent Owner thanks the examiner for the courtesy of the telephonic interview conducted on January 10, 2013 with Stephanie A. Barbosa, attorney for Patent Owner. Examiner Polansky requested that the Patent Owner file a supplemental response that addresses certain changes to U.S. 6,395,767 that were previously entered by certificate of correction. In particular, Examiner Polansky identified that all changes must be set forth *via* entire paragraph, scheme, and table replacements rather than single line replacements. This supplemental response also includes the changes from the Certificate of Correction for col. 14, lines 55-58 and col. 43, lines 20-38 to correct typographical errors from the previous reply. This supplemental paper is filed in response to the Examiner's request.

Date: January 18, 2013 /S. Maurice Valla/ S. Maurice Valla

Registration No. 43,966

Woodcock Washburn LLP Cira Centre 2929 Arch Street, 12th Floor Philadelphia, PA 19104-2891 Telephone: (215) 568-3100

Facsimile: (215) 568-3439

Electronic Acl	Electronic Acknowledgement Receipt					
EFS ID:	14735292					
Application Number:	13308658					
International Application Number:						
Confirmation Number:	7781					
Title of Invention:	Cyclopropyl-Fused Pyrrolidine-Based Inhibitors Of Dipeptidyl Peptidase IV And Method					
First Named Inventor/Applicant Name:	Jeffrey A. Robl					
Customer Number:	23377					
Filer:	SAMUEL VALLA/Joanne Gallagher					
Filer Authorized By:	SAMUEL VALLA					
Attorney Docket Number:	BMS-2856					
Receipt Date:	18-JAN-2013					
Filing Date:	01-DEC-2011					
Time Stamp:	11:44:20					
Application Type:	Utility under 35 USC 111(a)					

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /₊zip	Pages (if appl.)
1	Transmittal Letter	BMS-2856 transmittal.PDF	262602	no	2
·	Hansiintal Ectter	SMS 2030_transfilteral.i Di	8e5106d1ec81a16c38e02e973075a62abfc dd811		2

Warnings:

Information: Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 317 of 373

2		BMS-2856_supplemental_resp onse_to_OA_dtd_05-08-2012. PDF	136534 1c40d87f232354c96586a5ba11ee6350365 d5654	yes	6
	Multip	art Description/PDF files in .	zip description		
	Document Des	scription	Start	E	nd
	Supplemental Response or Sup	1		1	
	Claims	Claims			5
	Applicant Arguments/Remarks	6		6	
Warnings:					
Information:					
		Total Files Size (in bytes):	39	9136	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09) Approved for use through 07/31/2012. OMB 0651-0031

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	Application Number	13/308,658	3				
TRANSMITTAL	Filing Date	December	1, 2011				
FORM	First Named Inventor	Jeffrey A. F	Robol				
	Art Unit	1629					
(to be used for all correspondence after init	Examiner Name	Gregg Pola	ansky				
	8 Attorney Docket Number	BMS-2856					
Total Number of Pages in This Submission							
	ENCLOSURES (Check all t	that apply)				
Fee Transmittal Form Fee Attached Amendment/Reply After Final	Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application		Appea of Appea (Appea	I Communication to TC I Communication to Board eals and Interferences I Communication to TC Il Notice, Brief, Reply Brief) etary Information			
Affidavits/declaration(s) Extension of Time Request	Power of Attorney, Revocation Change of Correspondence Act Terminal Disclaimer		Status	Letter Enclosure(s) (please Identify			
Express Abandonment Request Information Disclosure Statement	Landscape Table on CD						
Certified Copy of Priority Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53							
SIGN Firm Name	IATURE OF APPLICANT, ATTOR	RNEY, O	R AGENT				
Woodcock Washburn L	LP						
Signature /S. Maurice Valla/							
Printed name S. Maurice Valla							
Date January 18, 2013	R	Reg. No.	43,966				
I hereby certify that this correspondence is	CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:						
Signature							
Typed or printed name			Date				

This collection of information is required by 37 CFR 1.5. 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 and1.14. This collection is estimated to 2 hours 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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The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891 EXAMINER
POLANSKY, GREGG

ART UNIT PAPER NUMBER
1629

DATE MAILED: 02/13/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/308,658	12/01/2011	Jeffrey A. Robl	BMS-2856	7781

TITLE OF INVENTION: Cyclopropyl-Fused Pyrrolidine-Based Inhibitors Of Dipeptidyl Peptidase IV And Method

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1770	\$0	\$0	\$1770	05/13/2013

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 SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Sun-Amneal-IPR2016-01104- Ex31006. Part 2, p. 321 of 373

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents

P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (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 m

23377 WOODCOCK CIRA CENTRE 2929 ARCH ST	23377 7590 02/13/2013 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891				rs. Each additiona its own certificate Cer	l paper of mai	such as an assignmenting or transmission. of Mailing or Transmission.	nt or	nestic mailings of the y other accompanying formal drawing, must on sited with the United s mail in an envelope e, or being facsimile licated below.
	,								(Depositor's name)
				_					(Signature) (Date)
APPLICATION NO. 13/308,658	FILING DATE 12/01/2011		FIRST NAMED INVEN Jeffrey A. Robl	TOR		ATTO	RNEY DOCKET NO. BMS-2856	CO	NFIRMATION NO. 7781
TITLE OF INVENTION	N: Cyclopropyl-Fused Pyr	rrolidine-Based Inhibitors	s Of Dipeptidyl Peptida	ise IV	And Method				
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSUI	E FEE	TOTAL FEE(S) DUE		DATE DUE
nonprovisional	NO	\$1770	\$0		\$0		\$1770		05/13/2013
EXAM	MINER	ART UNIT	CLASS-SUBCLASS	5					
POLANSI	XY, GREGG	1629	514-252190						
"Fee Address" in PTO/SB/47; Rev 03-Number is required 3. ASSIGNEE NAME A PLEASE NOTE: Ur recordation as set for	AND RESIDENCE DATA nless an assignee is ident th in 37 CFR 3.11. Com	" Indication form ed. Use of a Customer A TO BE PRINTED ON ified below, no assignee	data will appear on the	nativesingles or a store attored be per typene pagan a	ely, e firm (having as a gent) and the namneys or agents. If orinted. e) tent. If an assign assignment.	membes of uno nam	er a 2er a 2	ocume	ent has been filed for
4a. The following fee(s) Issue Fee Publication Fee (riate assignee category or	4 permitted)	b. Payment of Fee(s): (A check is enclos Payment by credi	Pleased.	Individual	ny previsation is attage the	on or other private griously paid issue feeched.	show	n above)
a. Applicant claim	atus (from status indicate ns SMALL ENTITY statu nd Publication Fee (if req records of the United Sta	us. See 37 CFR 1.27.	b. Applicant is no	long	er claiming SMAI	LL EN	TITY status. See 37 C	FR 1.2	27(g)(2).
morest as shown by the	records of the Office Sta	ness ruem and trademan	a Office.						
Authorized Signature	e				Date				
	ne				-				
This collection of informan application. Confider submitting the complete this form and/or sugges Box 1450, Alexandria, Alexandria, Virginia 22	mation is required by 37 C ntiality is governed by 35 ed application form to the tions for reducing this bu Virginia 22313-1450. DO 313-1450.	FR 1.311. The informati U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain 1.14. This collection i y depending upon the i the Chief Information O COMPLETED FORM	or restindiving	etain a benefit by the mated to take 12 indual case. Any configuration, U.S. Patent and THIS ADDRESS	he publ minutes mment Traden . SENI	ic which is to file (an to complete, including s on the amount of tital tark Office, U.S. Dep O TO: Commissioner	d by th ng gath me yo artmen for Pa	ne USPTO to process) nering, preparing, and u require to complete nt of Commerce, P.O. tents, P.O. Box 1450,

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DATE MAILED: 02/13/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
13/308,658	12/01/2011	Jeffrey A. Robl	BMS-2856	7781				
23377 75	23377 7590 02/13/2013 EXAMINER							
	WOODCOCK WASHBURN LLP POLANSKY, GREGG							
CIRA CENTRE, 1 2929 ARCH STRE			ART UNIT	PAPER NUMBER				
PHILADELPHIA,	PA 19104-2891		1629					

Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for Patent Term Extension or Adjustment under 35 U.S.C. 154(b).

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.

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- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

	Application No.	Applicant(s)	
Notice of Allowability	13/308,658 Examiner	ROBL ET AL. Art Unit	
	Gregg Polansky	1629	
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT I of the Office or upon petition by the applicant. See 37 CFR 1.31	S (OR REMAINS) CLOSED 5) or other appropriate comm RIGHTS. This application is	in this application. If not included nunication will be mailed in due co	ourse. THIS
1. X This communication is responsive to papers filed 8/08/201	1 <u>2 & 1/18/2013</u> .		
 An election was made by the applicant in response to a re requirement and election have been incorporated into this 		h during the interview on; t	he restriction
 The allowed claim(s) is/are 1-22,25-35 and 38-45. As a reserved prosecution Highway program at a participating intellectual please see http://www.uspto.gov/patents/init_events/pph/ir 	ual property office for the cor	responding application. For more	
 Acknowledgment is made of a claim for foreign priority und a) ☐ All b) ☐ Some* c) ☐ None of the: 	der 35 U.S.C. § 119(a)-(d) o	(f).	
 Certified copies of the priority documents have 	ve been received.		
2. Certified copies of the priority documents have			
Copies of the certified copies of the priority d	ocuments have been receive	ed in this national stage application	n from the
International Bureau (PCT Rule 17.2(a)).			
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE noted below. Failure to timely comply will result in ABANDON THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		e a reply complying with the requ	irements
5. CORRECTED DRAWINGS (as "replacement sheets") mu	st be submitted.		
including changes required by the attached Examine Paper No./Mail Date	r's Amendment / Comment o	or in the Office action of	
Identifying indicia such as the application number (see 37 CFR each sheet. Replacement sheet(s) should be labeled as such in			ack) of
 DEPOSIT OF and/or INFORMATION about the deposit of attached Examiner's comment regarding REQUIREMENT F 			
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's	s Amendment/Comment	
2. Information Disclosure Statements (PTO/SB/08),	6. 🗌 Examiner'	s Statement of Reasons for Allow	ance
Paper No./Mail Date 3.	7. 🗌 Other	•	
4. Interview Summary (PTO-413), Paper No./Mail Date			
/SAVITHA RAO/	/Gregg Polans	sky/	
Primary Examiner, Art Unit 1629	Examiner, Art	Unit 1629	

U.S. Patent and Trademark Office PTOL-37 (Rev. 09-12)

Notice of Allowability

Part of Paper No./Mail Date 20130124

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	2	("6395767").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	OFF	2013/01/24 17:16
L3	10	onglyza	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AN D	ON	2013/01/24 17:16
L4	1478	saxagliptin	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:16
L5	1480	L3 or L4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:16
L6	375	BMS-477118	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:16
L7	476	BMS adj "477118"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:16
L8	476	BMS adj2 "477118"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:16
L9	476	L6 or L7	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:16
L10	0	"361442-05-9"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:16
L11	808	548/452.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:20
L12	1048	514/412.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	AND	ON	2013/01/24 17:20

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L13	464	514/412.ccls.	USPAT; UPAD	AND	ON	2013/01/24 17:20
L14	506	548/452.ccls.	USPAT; UPAD	AND	ON	2013/01/24 17:21

1/24/2013 5:21:49 PM

C:\ Users\ gpolansky\ Documents\ EAST\ Workspaces\ 13308658 Reissue of US 6395767.wsp

Application Number	Application No. 13308658	Applicant(s) Robl et al.			
	Notice of Reissue Published in OG on 02/14/2012				
The Maintenance fee status is: Original Patent Number of Patent To Be Reissued is 6395767					
This reissue patent is subject to A Terminal Disclaimer that: was filed during the prosecution of the reissue application. was of record prior to the filing of the reissue application.					
Physical surrender of the letters patent ☐ was made. ☐ was not made, but a statement of loss/inaccessibility was provided. ☐ is not required					
	Final SPRE Review				

BC (INITIALS)

2/7/2013

(DATE)

U.S. Patent and Trademark Office

Search Notes



Application/Control No.	Applicant(s)/Patent Under Reexamination
13308658	ROBL ET AL.
Examiner	Art Unit

1629

CPC- SEARCHED		
Symbol	Date	Examiner

GREGG POLANSKY

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

	US CLASSIFICATION SEARCHED		
Class	Subclass	Date	Examiner
514	412	1/24/2013	GP
548	452	1/24/2013	GP

SEARCH NOTE	ES .	
Search Notes	Date	Examiner
EAST Search: see EAST Search Histroy	5/2/2012	GP
STN Search: see STN Search History	5/2/2012	GP
Litigation Search: see Litigation Search History	5/2/2012	GP
PALM Inventor Search	5/2/2012	GP
EAST Search: see EAST Search Histroy	1/24/2013	GP
Reviewed previous STN Search History	1/24/2013	GP
PALM Inventor Search	1/24/2013	GP

	INTERFERENCE SEARC	CH	
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
514	412	1/24/2013	GP
548	452	1/24/2013	GP

/GREGG POLANSKY/	/SAVITHA RAO/
Examiner.Art Unit 1629	Primary Examiner, Art Unit 1629

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
13308658	ROBL ET AL.
Examiner	Art Unit
GREGG POLANSKY	1629

PC				
nbol		Туре	Version	
	1			
	1			

CPC Combination Sets					
Symbol		Туре	Set	Ranking	Version

US ORIGINAL CLASSIFICATION							INTERNATIONAL CLASSIFICATION								
CLASS SUBCLASS					CLAIMED						NON-CLAIMED				
514			412			С	0	7	D	209 / 02 (2006.01.01)					
CROSS REFERENCE(S)					А	6	1	К	31 / 403 (2006.01.01)						
CLASS	CLASS SUBCLASS (ONE SUBCLASS PER BLOCK)				H										
548	452														

/GREGG POLANSKY/ Examiner.Art Unit 1629	1/24/2013		ims Allowed:		
(Assistant Examiner)	(Date)				
		O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	NONE		

U.S. Patent and Trademark Office

Part of Paper No. 20130124

Issue Classification

	Application/Control No.	Applicant(s)/Patent Under Reexamination						
7	13308658	ROBL ET AL.						
	Examiner	Art Unit						
	GREGG POLANSKY	1629						

/GREGG POLANSKY/ Examiner.Art Unit 1629	1/24/2013	Total Claims Allowed:			
(Assistant Examiner)	(Date)				
		O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	NONE		

U.S. Patent and Trademark Office

Part of Paper No. 20130124

Issue Classification



Application/Control No.	Applicant(s)/Patent Under Reexamination
13308658	ROBL ET AL.
Examiner	Art Unit
CRECC BOLANSKY	1620

☐ Claims renumbered in the same order as presented by applicant									☐ CPA ☐ T.D. ☐ R.1.47						
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17	33	33										
2	2	18	18	34	34										
3	3	19	19	35	35										
4	4	20	20		36										
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10	10	26	26	40	42										
11	11	27	27	41	43										
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13	13	29	29	43	45										
14	14	30	30												
15	15	31	31												
16	16	32	32												

/GREGG POLANSKY/ Examiner.Art Unit 1629 (Assistant Examiner)	1/24/2013 (Date)	Total Claim	
(Accordant Examinor)	(Bate)		
		O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	NONE

U.S. Patent and Trademark Office

Part of Paper No. 20130124



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

BIB DATA SHEET

CONFIRMATION NO. 7781

SERIAL NUME	3ER	FILING or DATI	371(c)		CLASS	GR	OUP ART	UNIT	ATTC	RNEY DOCKET	
13/308,658	3	12/01/2			514		1629			BMS-2856	
		RULI	■								
Richard B David J. A David R. M Lawrence David A. E	Jeffrey A. Robl, Newtown, PA; Richard B. Sulsky, West Trenton, NJ; David J. Augeri, Princeton, NJ; David R. Magnin, Hamilton, NJ; Lawrence G. Hamann, Cherry Hill, NJ; David A. Betebenner, Lawrenceville, NJ;										
** CONTINUING DATA ***********************************											
** FOREIGN APPLICATIONS ************************************											
	itions met	OLANSKY/	Met af Allowa	ter Ince	STATE OR COUNTRY PA		HEETS AWINGS	TOTA CLAII 40	MS	INDEPENDENT CLAIMS 3	
ADDRESS											
CIRA CEN 2929 ARC	NTRE, CH STR LPHIA,	PA 19104-28	?								
TITLE											
Cycloprop	yl-Fuse	ed Pyrrolidine	-Based In	hibitor	s Of Dipeptidyl F	eptid	ase IV An	d Metho	d		
							☐ All Fe	es			
 	EEES.	Authority has	heen give	an in P	aner		☐ 1.16 F	ees (Fil	ing)		
					EPOSIT ACCOU	NT	□ 1.17 F	ees (Pr	ocess	ing Ext. of time)	
3130	No	for	following	:			☐ 1.18 F	ees (lss	sue)		
Other											
							☐ Credit	•			

Index of Claims 13308658 Examiner GREGG POLANSKY Applicant(s)/Patent Under Reexamination ROBL ET AL. Art Unit 1629

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=	Allowed		÷	Restricted	ı	Interfer

N	Non-Elected	Α	Appeal
ı	Interference	0	Objected

☐ Claims	renumbered	in the same	order as pre	esented by a	applicant		☐ CPA	□ т.с	D. 🗆	R.1.47
CLA	MIA		DATE							
Final	Original	05/01/2012	02/06/2013							
1	1	√	=							
2	2	√	=							
3	3	✓	=							
4	4	✓	=							
5	5	✓	=							
6	6	✓	=							
7	7	✓	=							
8	8	✓	=							
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10	10	√	=							
11	11	✓	=							
12	12	✓	=							
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27	27	✓	=							
28	28	✓	=							
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34	34	✓	=							
35	35	✓	=							
	36	✓	-							

U.S. Patent and Trademark Office

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Index of Claims	13308658	ROBL ET AL.
	Examiner	Art Unit
	GREGG POLANSKY	1629

✓ F	Rejected	_ -	Can	celled	N Non-Elected		Α	App	oeal	
=	Allowed	÷	Res	tricted	I	I Interference		0	Obje	cted
☐ Claims	☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47									
CL	AIM					DATE				
Final	Original	05/01/2012	02/06/2013							
	37	✓	-							
36	38	✓	=							
37	39	✓	=		·			·		
38	40	✓	=							

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U.S. Patent and Trademark Office Part of Paper No. : 20130124

PART B - FEE(S) TRANSMITTAL

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	,,						(Depositor's name)
			L				(Signature)
			L				(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	R	ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
13/308,658	12/01/2011	•	Jeffrey A. Robl			BMS-2856	7781
			s Of Dipeptidyl Peptidase				
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUI		UE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1770	\$0	\$0 		\$1770	05/13/2013
EXAM	INER	ART UNIT	CLASS-SUBCLASS				
POLANSK	Y, GREGG	1629	514-252190				
FR 1.363). Change of corresp Address form PTO/SE "Fee Address" indi PTO/SB/47; Rev 03-0 Number is required.	ence address or indication ondence address (or Cha 3/122) attached. ication (or "Fee Address' 12 or more recent) attached	nge of Correspondence ' Indication form ed. Use of a Customer	2. For printing on the (1) the names of up or agents OR, alterna (2) the name of a sin registered attorney o 2 registered patent at listed, no name will be	to 3 registered pat tively, gle firm (having as agent) and the na torneys or agents.	ent attorr a memb mes of u	er a 2 Woodcoo	k Washburn LLP
PLEASE NOTE: Unl recordation as set forth (A) NAME OF ASSIG	ess an assignee is identi h in 37 CFR 3.11. Comp GNEE	ified below, no assignee oletion of this form is NC	THE PATENT (print or to data will appear on the DT a substitute for filing a (B) RESIDENCE: (CIT Princeton, N	patent. If an assign assignment. 'Y and STATE OR			cument has been filed for
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lease check the appropri	iate assignee category or	categories (will not be p	rinted on the patent):	☐ IndividualX☐	Corporati	ion or other private gro	up entity 🖵 Government
a. The following fee(s) a XXX ssue Fee Publication Fee (N Advance Order - #	Io small entity discount р	permitted)	b. Payment of Fee(s): (PI A check is enclosed Payment by credit c XXX The Director is here overpayment, to De	ard. Form PTO-20 by authorized to ch	38 is atta	ched.	,
a. Applicant claims	tus (from status indicated s SMALL ENTITY statu	s. See 37 CFR 1.27.	☐ b. Applicant is no lo				
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n application. Confident abmitting the completed is form and/or suggesti	tiality is governed by 35 I application form to the ons for reducing this but	U.S.C. 122 and 37 CFR USPTO. Time will vary den. should be sent to the	1.14. This collection is a depending upon the industrial Chief Information Office Chief Informat	stimated to take 12 ividual case. Any cer. U.S. Patent an	2 minutes comment d Traden	s to complete, including ts on the amount of tin nark Office, U.S. Depa	by the USPTO to process) g gathering, preparing, and he you require to complete rtment of Commerce, P.O. or Patents, P.O. Box 1450.

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Electronic Patent Application Fee Transmittal							
Application Number:	133	308658					
Filing Date:	01-	01-Dec-2011					
Title of Invention:	Cyclopropyl-Fused Pyrrolidine-Based Inhibitors Of Dipeptidyl Peptidase IV And Method						
First Named Inventor/Applicant Name:	Jeffrey A. Robl						
Filer:	SAMUEL VALLA/Ann Trevisani						
Attorney Docket Number:	BMS-2856						
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	1770	1770		
Extension-of-Time: Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2. p. 336 of 373							

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

Electronic Acknowledgement Receipt					
EFS ID:	14971738				
Application Number:	13308658				
International Application Number:					
Confirmation Number:	7781				
Title of Invention:	Cyclopropyl-Fused Pyrrolidine-Based Inhibitors Of Dipeptidyl Peptidase IV And Method				
First Named Inventor/Applicant Name:	Jeffrey A. Robl				
Customer Number:	23377				
Filer:	SAMUEL VALLA/Ann Trevisani				
Filer Authorized By:	SAMUEL VALLA				
Attorney Docket Number:	BMS-2856				
Receipt Date:	15-FEB-2013				
Filing Date:	01-DEC-2011				
Time Stamp:	14:29:16				
Application Type:	Utility under 35 USC 111(a)				

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$1770
RAM confirmation Number	897
Deposit Account	233050
Authorized User	

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	issue ree rayment (ree ess)	issue_i ee_inansiintaiii si	48570b69ef33e9f3be16d22f5b113851e671 90a1	0	,
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30083	no	2
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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

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04/10/2013

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/308.658	04/30/2013	RE44186	BMS-2856	7781

13/308,658 7590

WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891

23377

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for Patent Term Extension or Adjustment under 35 U.S.C. 154(b).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

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

Jeffrey A. Robl, Newtown, PA; Richard B. Sulsky, West Trenton, NJ; David J. Augeri, Princeton, NJ; David R. Magnin, Hamilton, NJ; Lawrence G. Hamann, Cherry Hill, NJ; David A. Betebenner, Lawrenceville, NJ;

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Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 340 of 373

DOCKET NO.: BMS-2856 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Jeffrey A. Robl; Richard B. Sulsky; David

J. Augeri; David R. Magnin; Lawrence G.

Hamann; David A. Betebenner Confirmation No.: 7781

Application No.: 13/308,658 Filing Date: December 1, 2011

For: CYCLOPROPYL-FUSED PYRROLIDINE-BASED INHIBITORS OF

DIPEPTIDYL PEPTIDASE IV AND METHOD

Commissioner for Patents Attn: Certificate of Correction Branch P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR PTO MISTAKE PURSUANT TO 37 CFR § 1.322(a)

It is respectfully requested that a Certificate of Correction be issued for the above-identified patent. In accordance with 37 CFR § 1.322(a), the patent has errors in it that occurred through the fault of the Patent and Trademark Office as clearly disclosed by the records and files of the office.

Enclosed herewith please find a completed Certificate of Correction form.

Since the errors are not due to applicants' mistake, no correction fee is due. Please charge any fees for copies and any additional fees to our Deposit Account No. 23-3050.

DOCKET NO.: BMS-2856 PATENT

Date: July 3, 2013 /Stephanie A. Lodise/

Stephanie A. Lodise Registration No. 51,430

Woodcock Washburn LLP Cira Centre 2929 Arch Street, 12th Floor Philadelphia, PA 19104-2891 Telephone: (215) 568-3100 Facsimile: (215) 568-3439

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,

Line 56, delete "alkylcyclo alkyl," and insert -- alkylcycloalkyl, --. Line 56, delete "hydroxytricyclo alkyl," and insert -- hydroxytricycloalkyl, --.

Column 17,

Line 48, delete "a-phosphono-sulfonates" and insert -- α -phosphono-sulfonates --.

Column 19,

Line 51, delete "lipoxygevase" and insert -- lipoxygenase --.

Column 28,

Lines 16-17, delete "butoxycarbonylisoleucine" and insert -- butoxycarbonyl-isoleucine --.

Column 33,

Lines 38-39, delete "1-[(3-dimethypamino)propyl]" and insert -- 1-[(3-dimethyl)amino)propyl] --.

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

Column 51,

Lines 1-30, delete "

Scheme 7 General Method E, Examples 45 47

$$\bigcup_{\text{BocHN}} \bigvee_{\text{O}} \bigvee_{\text{CN}} \xrightarrow{\text{a}}$$

a. OsO4, THF:H2O, 1:1; NaIO4; workup, then NaBH4, MeOH, RT. 56% b. TFA:CH2Cl2, 1:2, 0 degrees C. to RT.

"

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

and insert --

Scheme 7

General Method E, Examples 45 47

a.OsO₄, THF:H₂O, 1:1; NaIO₄; workup,then NaBH₄, MeOH, RT. 56% b. TFA:CH₂Cl₂, 1:2, 0 degrees C to RT.

Column 51,

Line 54, delete "OsO4" and insert -- OsO4 --.

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

Column 55,

Lines 19-31, EXAMPLE 57, delete "

and insert --

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

Column 63,

Lines 25-46, EXAMPLE 62, delete "

Step 1

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

and insert --

Column 64,

Line 31, delete "NaHSO₃" and insert -- NaHSO₃ --.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

Column 69,

Lines 20-32, delete "

EXAMPLE 67

Step 1

and insert --

EXAMPLE 67

Step 1--.

Column 70,

Line 59, delete "19,8 mmol" and insert -- 19.8 mmol --.

Column 82,

Line 27, after "30 min" insert -- . --.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO : RE44,186 E APPLICATION NO. : 13/308,658 ISSUE DATE : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl; Richard B. Sulsky; David J. Augeri; David R. Magnin;

Lawrence G. Hamann; David A. Betebenner

Column 87,

Line 7, Claim 1, delete "R4" and insert -- R⁴ --.

Column 92,

Line 21, Claim 36, delete "any one of claim" and insert -- any one

of claims --.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Woodcock Washburn LLP Cira Centre 2929 Arch Street, 12th Floor

Philadelphia, PA 19104-2891

Electronic Acl	knowledgement Receipt			
EFS ID:	16226296			
Application Number:	13308658			
International Application Number:				
Confirmation Number:	7781			
Title of Invention:	Cyclopropyl-Fused Pyrrolidine-Based Inhibitors Of Dipeptidyl Peptidase IV And Method			
First Named Inventor/Applicant Name:	Jeffrey A. Robl			
Customer Number:	23377			
Filer:	Stephanie A. Barbosa/Laura Taylor			
Filer Authorized By:	Stephanie A. Barbosa			
Attorney Docket Number:	BMS-2856			
Receipt Date:	03-JUL-2013			
Filing Date:	01-DEC-2011			
Time Stamp:	10:47:07			
Application Type:	Utility under 35 USC 111(a)			

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	BMS-2856Transmittal.PDF	262282	no	2
'	Miscellaneous incoming eciter	BNS 2030 Hallstilletail Bl	737646480d28b903831e03b6cac6fb353f3 ca960		2

Warnings:

Information: Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 351 of 373

		Total Files Size (in bytes)	4:	79503	
Information	:				
Warnings:					
_			97e3cffefa5eb7df3ce58ae7eaee4e54e2adb 3ae		
3	Request for Certificate of Correction	BMS-2856CertCorr.PDF	137994	no	8
Information	:				•
Warnings:					
2	Request for Certificate of Correction	BMS-2830NeqCertCorr.r DI	213fd4d2d20f04bd0a7d68fb5ba2c2aa8db 7a560		2
2	Request for Certificate of Correction	BMS-2856ReqCertCorr.PDF	79227	no	2

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

				Application Number	13/308,6	58		
TR	ANSI	MITTAL		Filing Date	Decembe	er 1, 2011		
	FO	RM		First Named Inventor	Jeffrey A	. Robl		
				Art Unit	1629			
(to be used for	all correspo	ondence after initial	filina)	Examiner Name	Gregg Po	olansky		
Total Number of Pages in This Submission 12			Attorney Docket Number	r BMS-285	BMS-2856			
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Fee Trans	smittal Fo	rm		Drawing(s)				Allowance Communication to TC
☐ F∈	ee Attache	ed	L L	Licensing-related Papers		$ \sqcup $	of App	Il Communication to Board eals and Interferences
Amendme	ent/Reply		_	Petition			Appea (Appe a	ll Communication to TC Il Notice, Brief, Reply Brief)
Af	fter Final		L	Petition to Convert to a Provisional Application		$ \sqcup $	Propri	etary Information
Af	ffidavits/de	eclaration(s)		Power of Attorney, Revoca Change of Correspondence				Letter
Extension	of Time F	Request	│□ ▫	Terminal Disclaimer		V	below	
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Incomplet		tion ssing Parts						
		FR 1.52 or 1.53						
		SIGNA	TURE O	OF APPLICANT, ATT	ORNEY,	OR AG	ENT	
Firm Name	Woodco	ck Washburn LLP	ı					
Signature	/Stephar	nie A. Lodise/						
Printed name	Stephan	ie A. Lodise						
Date	July 3, 2	013			Reg. No.	51430	·	
7		CI	ERTIFIC	CATE OF TRANSMIS	SION/MA	AILING		·
	as first cl							ited States Postal Service with Alexandria, VA 22313-1450 on
Signature	CIOW.							
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Typed or printed r	name						Date	

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.

This collection of information is required by 37 CFR 1.5. 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 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

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

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

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
- 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

DATE	:July 18. 2013	
TO SPE OF	: ART UNIT1629	
SUBJECT	: Request for Certificate of Correc	tion for Appl. No.: 13308658 Patent No.: RE44186
		COCIN mailroom date: _July 3, 2013
Please resp	 ond to this request for a cer 	tificate of correction within 7 days.
FOR IFW F	ILES:	
the IFW app		orrections as shown in the COCIN document(s) in tter should be introduced nor should the scope or
	plete the response (see belinent code COCX .	ow) and forward the completed response to scanning
FOR PAPE	R FILES:	
		orrections as shown in the attached certificate of see below) and forward it with the file to:
Rang	ificates of Correction Bran dolph Square – 9D10-A n Location 7580	nch (CofC)
Rang Palm	dolph Square – 9D10-A n Location 7580	Valerie Jackson
Rang	dolph Square – 9D10-A n Location 7580	
Rand Palm In Particulai	dolph Square – 9D10-A n Location 7580	Valerie Jackson Certificates of Correction Branch
Rang Palm In Particular Thank You Fo	dolph Square – 9D10-A n Location 7580 r note: or Your Assistance	Valerie Jackson Certificates of Correction Branch
Rand Palm In Particular Thank You Fo The reques	dolph Square – 9D10-A n Location 7580 r note: or Your Assistance st for issuing the above-ide	Valerie Jackson Certificates of Correction Branch 703-756-1814
Range Palm In Particular Thank You Form The requese Note your decision	dolph Square – 9D10-A n Location 7580 r note: or Your Assistance st for issuing the above-ide on on the appropriate box.	Valerie Jackson Certificates of Correction Branch 703-756-1814 entified correction(s) is hereby:
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Rang Palm In Particular Thank You Fo The reques Note your decisio	dolph Square – 9D10-A n Location 7580 r note: or Your Assistance st for issuing the above-ide on on the appropriate box. Approved Approved in Part	Valerie Jackson Certificates of Correction Branch 703-756-1814 entified correction(s) is hereby: All changes apply. Specify below which changes do not apply. State the reasons for denial below.
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Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 355 of 373

U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

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PTOL-306 (REV. 7/03)

U.S. DEPARTMENT OF COMMERCE Patent and Trademark 0613

DATE	:July 18, 2013		
	<u> </u>		
TO SPE OF	: ART UNIT1629		
SUBJECT	: Request for Certificate of Correct	ion for Appl. No.:	13308658 Patent No.: RE44186
	· .		COCIN mailroom date: _July 3, 2013
Please resp	- oond to this request for a cert	tificate of correction	on within 7 days.
FOR IFW F	ILES:		
the IFW app	ew the requested changes/co plication image. No new mat the claims be changed.	orrections as sho tter should be intr	wn in the COCIN document(s) in oduced nor should the scope or
	plete the response (see beloment code COCX .	ow) and forward t	ne completed response to scannin
FOR PAPE	R FILES:		
	ew the requested changes/co Please complete this form (s		wn in the attached certificate of rward it with the file to:
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Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 357 of 373
/Jeffrey S. Lundgren/ 1629
U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

SPE

Art Unit

Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 358 of 373

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE44,186 E Page 1 of 4

APPLICATION NO. : 13/308658

DATED : April 30, 2013

INVENTOR(S) : Jeffrey A. Robl et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specifications:

Column 4,

Line 56, delete "alkylcyclo alkyl," and insert -- alkylcycloalkyl, --.

Line 56, delete "hydroxytricyclo alkyl," and insert

-- hydroxytricycloalkyl, --.

Column 17,

Line 48, delete "a-phosphono-sulfonates" and insert -- α -phosphono-sulfonates --.

Column 19,

Line 51, delete "lipoxygevase" and insert -- lipoxygenase --.

Column 28,

Lines 16-17, delete "butoxycarbonylisoleucine" and insert

-- butoxycarbonyl-isoleucine --.

Column 33,

Lines 38-39, delete "1-[(3-dimethypamino)propyl]" and insert

-- 1-[(3-dimethyl)amino)propyl] --.

Signed and Sealed this Eighth Day of October, 2013

Teresa Stanek Rea

Deputy Director of the United States Patent and Trademark Office

In the Specifications:

Column 51,

Scheme 7 General Method E, Examples 45 47

a. OsO4, THF:H2O, 1:1; NaIO4; workup, then NaBH4, MeOH, RT. 56% b. TFA:CH2Cl2, 1:2, 0 degrees C. to RT.

Lines 1-30, delete "

and insert

--Scheme 7

General Method E, Examples 45 47

a.OsO4, THF:H2O, 1:1; NaIO4; workup,then NaBH4, MeOH, RT. 56% b. TFA:CH2Cl2, 1:2, 0 degrees C to RT.

Column 51,

Line 54, delete "OsO4" and insert -- OsO4 --.

In the Specifications:

Column 55,

Lines 19-31, EXAMPLE 57, delete "

insert --

insert --

Column 63,

Lines 25-46, EXAMPLE 62, delete "

Sun-Amneal-IPR2016-01104- Ex. 1006. Part 2, p. 361 of 373

In the Specifications:

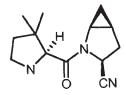
Column 64,

Line 31, delete "NaHSO3" and insert -- NaHSO3 ---.

Column 69,

EXAMPLE 67

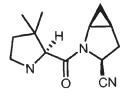
Step 1



Lines 20-32, delete "

" and

EXAMPLE 67



Step 1

insert --

Column 70,

Line 59, delete "19,8 mmol" and insert -- 19.8 mmol --.

Column 82,

Line 27, after "30 min" insert -- . --.

In the Claims:

Column 87,

Line 7, Claim 1, delete "R4" and insert -- R⁴ --.

Column 92,

Line 21, Claim 36, delete "any one of claim" and insert -- any one of claims --.

AO 120 (Rev. 08/10) REPORT ON THE Mail Stop 8 TO: FILING OR DETERMINATION OF AN Director of the U.S. Patent and Trademark Office ACTION REGARDING A PATENT OR P.O. Box 1450 Alexandria, VA 22313-1450 **TRADEMARK** In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been on the following A Patents. (☐ the patent action involves 35 U.S.C. § 292.): ☐ Trademarks or U.S. DISTRICT COURT
United States District Court for the District of Delaware DOCKET NO. DATE FILED DEFENDANT PLAINTIFF ASTRAZENECA AB WOCKHARDT BIO AG and WOCKHARDT USA LLC DATE OF PATENT PATENT OR HOLDER OF PATENT OR TRADEMARK OR TRADEMARK TRADEMARK NO. April 30, 2013 AstraZeneca AB 1 RE44,186 AstraZeneca AB 2 7,951,400 May 31, 2011 3 4 5 In the above—entitled case, the following patent(s)/ trademark(s) have been included: DATE INCLUDED INCLUDED BY \square Amendment ☐ Cross Bill ☐ Other Pleading ☐ Answer DATE OF PATENT PATENT OR HOLDER OF PATENT OR TRADEMARK OR TRADEMARK TRADEMARK NO. 2 3 In the above—entitled case, the following decision has been rendered or judgement issued: DECISION/JUDGEMENT

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

(BY) DEPUTY CLERK

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DATE

AO 120 G	Rev. 08/10)					
TO:	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450			REPORT ON TH FILING OR DETERMINAT ACTION REGARDING A P TRADEMARK	ION OF AN	
In	fil	ed in the U.S. District Co	urt for the	§ 1116 you are hereby advised that a cour District of New Jersey on the following he patent action involves 35 U.S.C. § 292	•	
DOCKET		DATE FILED		U.S. DISTRICT COURT		
PLAINTI	-03552-MLC-I IFF ENECA AB	JEA 6/3/2014		TRENTON, NJ DEFENDANT SUN PHARMA GLOBAL FZE		
1	ΓENT OR EMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRA	DEMARK	
1 US RE4	14,186 E	April 30, 2013		Bristol-Myers Squibb Com	pany	
2 US 7,95	51,400 B2	May 31, 2011		Bristol-Myers Squibb Company		
3 US 8,62	28,799 B2	January 14, 2014		Bristol-Myers Squibb Company		
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CLERK			(BA) DED	UTY CLERK	DATE	
	iam T. Walsh			rlene Kalbach	6/3/2014	

TO:

Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

	P.O. Box 1450 ndria, VA 22313-1450		ACTION REGARDING A PATENT OR TRADEMARK
filed in the U.S. Dist		Dis	\$ 1116 you are hereby advised that a court action has been strict of Delaware on the following es 35 U.S.C. § 292.):
DOCKET NO.	DATE FILED		STRICT COURT
	6/2/2014	0.3. DI	District of Delaware
PLAINTIFF			DEFENDANT
ASTRAZENECA AB			SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES LTD. and CARACO PHARMACEUTICAL LABORATORIES LTD.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRADEMARK
1 RE44,186	4/30/2013	Astr	aZeneca AB
2 7,951,400	5/31/2011	Astr	aZeneca AB
3 8,628,799	1/14/2014	Astr	aZeneca AB
4			
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	In the above—entitled case, the	following	patent(s)/ trademark(s) have been included:
DATE INCLUDED	INCLUDED BY	Tollowing	puton(s) tudeman(s) nave een metaeca.
	☐ Ame	ndment	☐ Answer ☐ Cross Bill ☐ Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRADEMARK
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In the abov	ve—entitled case, the following	decision h	as been rendered or judgement issued:
DECISION/JUDGEMENT			
CLEDY	(DV)) DEPUTY	CLERK DATE
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TO:

Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

	P.O. Box 1450 ndria, VA 22313-1450	TRADEMARK	
filed in the U.S. Dist	rict Court	Dist	1116 you are hereby advised that a court action has been trict of Delaware on the following
☐ Trademarks or	Patents. (the patent action		
DOCKET NO.	DATE FILED 6/2/2014	U.S. DIS	STRICT COURT District of Delaware
PLAINTIFF			DEFENDANT
ASTRAZENECA AB			AMNEAL PHARMACEUTICALS LLC
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRADEMARK
1 RE44,186	4/30/2013	Astra	aZeneca AB
2 7,951,400	5/31/2011	Astra	aZeneca AB
3 8,628,799	1/14/2014	Astra	aZeneca AB
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	In the above—entitled case, the	following	patent(s)/ trademark(s) have been included:
DATE INCLUDED	INCLUDED BY		
PATENT OR	DATE OF PATENT	ndment	☐ Answer ☐ Cross Bill ☐ Other Pleading
TRADEMARK NO.	OR TRADEMARK		HOLDER OF PATENT OR TRADEMARK
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DECISION/JUDGEMENT			
CLERK	(BY)	DEPUTY	CLERK DATE

TO:

Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

Alexa	andria, VA 22313-1450		TRADEMARK		
filed in the U.S. Dis	nce with 35 U.S.C. § 290 and/ strict Court Patents. (the patent	Dis	trict of Delaware	9	tion has been on the following
DOCKET NO.	DATE FILED 6/2/2014	U.S. DI	STRICT COURT	District of Delaware	
PLAINTIFF			DEFENDANT		
ASTRAZENECA AB			MYLAN PHAF	RMACEUTICALS, IN	C.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDE	ER OF PATENT OR TRA	ADEMARK
1 RE44,186	4/30/2013	Astr	aZeneca AB		
2 7,951,400	5/31/2011	Astr	aZeneca AB		
3 8,628,799	1/14/2014	Astr	aZeneca AB		
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	In the above—entitled case	, the following	g patent(s)/ trademar	k(s) have been included:	
DATE INCLUDED	INCLUDED BY				
		Amendment	☐ Answer	Cross Bill [Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDE	ER OF PATENT OR TRA	ADEMARK
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In the abo	ove—entitled case, the follow	ring decision h	as been rendered or	judgement issued:	
DECISION/JUDGEMENT					
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	Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450		REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK	
In Complia			§ 1116 you are hereby advised that a court action has been District of West Virginia on the following	
☐ Trademarks or	Patents. (the patent act	ion involv	ves 35 U.S.C. § 292.):	
OOCKET NO.	DATE FILED 6/3/2014	U.S. D	DEFENDANT DEFENDANT	
LAINTIFF ASTRAZENECA AB	0/0/2014		DEFENDANT MYLAN PHARMACEUTICALS, INC. U.S. DISTRICT CO	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRADEMARK	
ı RE44,186	4/30/2013	Astr	raZeneca AB	
2 7,951,400	5/31/2011	AstraZeneca AB		
3 8,628,799	1/14/2014	AstraZeneca AB		
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DATE INCLUDED	INCLUDED BY	e following	g patent(s)/ trademark(s) have been included: Answer Cross Bill Other Pleading	
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DECISION/JUDGEMENT				
CLERK	(BY) DEPUT	Y CLERK DATE	

TO:

Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

Alexan	Iulia, VA 22313 1430	
filed in the U.S. Dist	rict Court for the	or 15 U.S.C. § 1116 you are hereby advised that a court action has been District of Delaware on the following action involves 35 U.S.C. § 292.):
DOCKET NO.	DATE FILED 8/15/2014	U.S. DISTRICT COURT for the District of Delaware
PLAINTIFF		DEFENDANT
ASTRAZENECA AB		WATSON LABORATORIES, INC., ACTAVIS, INC. and ACTAVIS LLC
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 RE44,186	4/30/2013	AstraZeneca AB
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In Co	mpliance wi fil	th 35 U.S.C. § 290 and/or ed in the U.S. District Cor Trademarks or X Patents	urt for the	District of New Jerse	${\bf v}$ on the following	r•
	DOCKET NO. DATE FILED			U.S. DISTRICT COURT TRENTON, NJ		
3:14-cv-03552-MLC-DEA 6/3/2014 PLAINTIFF ASTRAZENECA AB			DEFENDANT SUN PHARMA GLOBAL FZE			
PATEI TRADEM		DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRADE		DEMARK
1 US RE44,	186 E	April 30, 2013		Bristol-M	Iyers Squibb Com	pany
2 US 7,951,4	400 B2	May 31, 2011		Bristol-M	lyers Squibb Com	pany
3 US 8,628,	799 B2	January 14, 2014		Bristol-Myers Squibb Company		pany
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DECISION/J	In the at UDGEMEN	pove—entitled case, the fo	llowing de	cision has been rendere	ed or judgement is:	sued:
CLERK William	T. Walsh			JTY CLERK lene Kalbach		DATE 6/3/2014

AO 120 (Rev. 08/10) Mail Stop 8 TO:

REPORT ON THE

Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450		FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK			
filed in the U.S. Distr	rict Court	Dist	1116 you are hereby advised that a court rict of New Jersey	action has been on the following	
☐ Trademarks or ✓	Patents. (the patent ac	tion involve	es 35 U.S.C. § 292.):		
DOCKET NO. 14-cv-5513 (KSH)	DATE FILED 9/3/2014	U.S. DI	STRICT COURT District of New Jere	sey	
PLAINTIFF LifePort Sciences LLC			DEFENDANT C.R. Bard Inc. Bard Peripheral Vascular Inc.		
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TE	RADEMARK	
1 6,673,103	1/6/2004	LifeF	Port Sciences LLC		
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3					
4					
5					
Iı	n the above—entitled case, the	e following	patent(s)/ trademark(s) have been included	:	
DATE INCLUDED	INCLUDED BY	endment	☐ Answer ☐ Cross Bill	☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRADEMARK		
1					
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4					
5					
In the above-	entitled case, the following o	decision has	been rendered or judgement issued:		
DECISION/JUDGEMENT					
		- <u></u>			
CLERK	I(BY)	DEPUTY (CLERK	DATE	
		ROY DUNBAR		9/3/2014	

TO:

Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

P.O. Box 1450 Alexandria, VA 22313-1450		ACTION REGARDING A PATENT OR TRADEMARK		
filed in the U.S. Distr		strict of De		on has been on the following
DOCKET NO.	DATE FILED 10/31/2014	U.S. DISTRICT COURT for the District of Delaware		
PLAINTIFF	10/31/2014		DEFENDANT	
ASTRAZENECA AB			ACTAVIS LABORATORIES FL, INC. f/k/a WA' INC., WATSON LABORATORIES, INC., ACTA	TSON LABORATORIES FL, VIS, INC., and ACTAVIS LLC,
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRA	DEMARK
1 RE44,186	4/30/2013		AstraZeneca AB	
2 8,628,799	1/14/2014		AstraZeneca AB	
3				
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DATE INCLUDED	INCLUDED BY	e following	g patent(s)/ trademark(s) have been included: Answer Cross Bill	Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK		HOLDER OF PATENT OR TRA	DEMARK
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In the abo	ve—entitled case, the following	g decision	has been rendered or judgement issued:	
DECISION/JUDGEMENT				
CLERK	(B)	Y) DEPUT	Y CLERK	DATE

Mail Stop 8 TO: Director of the U.S. Patent and Trademark Office

FILING OR DETERMINATION OF AN

REPORT ON THE

P.O. Box 1450 Alexandria, VA 22313-1450		ACTION REGARDING A TRADEMAR		
In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court for the District of Delaware on the following ☐ Trademarks or ☐ Patents. (☐ the patent action involves 35 U.S.C. § 292.):				
DOCKET NO. DATE FILED 12/9/2014 U.S. DISTRICT COURT for the District of Delaware				
PLAINTIFF ASTRAZENECA AB		DEFENDANT AUROBINDO PHARMA LTD., and AUROBINDO PHARMA U.S.A., INC.		
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRA	DEMARK	
1 RE 44,186	4/30/2013	AstraZeneca AB		
2				
3	·			
4				
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DATE INCLUDED	In the above—entitled case, the follow INCLUDED BY	ing patent(s)/ trademark(s) have been included:]	
PATENT OR	DATE OF PATENT	t Answer Cross Bill	Other Pleading	
TRADEMARK NO.	OR TRADEMARK	HOLDER OF PATENT OR TRA	DEMARK	
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In the abov	e—entitled case, the following decision	n has been rendered or judgement issued:		
DECISION/JUDGEMENT				
CLERK	(RV) DEDI	TY CLERK	DATE	
CLLAK	(B1) DEI C	11 CELIA	Ditto	