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MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).

(21) International Application Number:

PCT/IB2019/055806

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) Title: C-MANNOSIDE COMPOUNDS USEFUL FOR THE TREATMENT OF URINARY TRACT INFECTIONS

(57) Abstract: Disclosed herein are new C-mannoside compounds and compositions and their application as pharmaceuticals for the treatment of human disease. Methods of inhibition of FimH activity in a human subject are also provided for the treatment diseases such as urinary tract infection.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

AHERN, Jenna Marie
GLAXOSMITHKLINE
Corporate Intellectual Property CN925.1
980 Great West Road
Brentford, Middlesex TW8 9GS
ROYAUME UNI

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing
(day/month/year)

05.06.2020

Applicant's or agent's file reference
PU66563

IMPORTANT NOTIFICATION

International application No.
PCT/IB2019/055806

International filing date (day/month/year)
08.07.2019

Priority date (day/month/year)
10.07.2018

Applicant
GlaxoSmithKline Intellectual Property Development

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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D-80298 Munich
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PU66563	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/IB2019/055806	International filing date (<i>day/month/year</i>) 08.07.2019	Priority date (<i>day/month/year</i>) 10.07.2018	
International Patent Classification (IPC) or national classification and IPC INV. C07D309/10			
Applicant GlaxoSmithKline Intellectual Property Development			
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ (<i>sent to the applicant and to the International Bureau</i>) a total of <u>8</u> sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions). ☐ sheets containing rectifications, where the decision was made by this Authority not to take them into account because they were not authorized by or notified to this Authority at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2). ☐ superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)). b. ☐ (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing, in the form of an Annex C/ST.25 text file, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3ter of Annex C of the Administrative Instructions).			
4. This report contains indications relating to the following items: ☒ Box No. I Basis of the report ☐ Box No. II Priority ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☒ Box No. VII Certain defects in the international application ☐ Box No. VIII Certain observations on the international application			
Date of submission of the demand 06.05.2020		Date of completion of this report 05.06.2020	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465		Authorized officer Kleidernigg, Oliver Telephone No. +49 89 2399-2143 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2019/055806

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a) and (b))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-54 as originally filed

Claims, Numbers

1-36 filed with the letter of

22-05-2020

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
5. ☐ This report has been established:
- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
 - ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.4bis and 70.2(e)).

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2019/055806

6. ☒ With regard to top-up searches (Rules 66.1 *ter* and 70.2(f)):
- ☒ A top-up search was carried out by this Authority on 14.05.2020 (all discovered documents are listed in the Supplemental Box Relating to Top-up Search).
 - ☐ Additional relevant documents have been discovered during the top-up search.
 - ☐ No top-up search was carried out by this Authority because it would serve no useful purpose.
7. ☐ Supplementary international search report(s) from Authority(ies) has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded".

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-36</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-36</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-36</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

ad Section V

Reference is made to the following documents:

- D1 WO 2017/156508 A1 (FIMBRION THERAPEUTICS INC [US]) 14 September 2017 (2017-09-14)
- D2 WO 2014/194270 A1 (UNIV WASHINGTON [US]; JANETKA JAMES W [US] ET AL.) 4 December 2014 (2014-12-04)
- D3 LAUREL MYDOCK-MCGRANE ET AL: "Antivirulence C -Mannosides as Antibiotic-Sparing, Oral Therapeutics for Urinary Tract Infections", JOURNAL OF MEDICINAL CHEMISTRY, vol. 59, no. 20, 14 October 2016 (2016-10-14), pages 9390-9408, XP055550436, US
ISSN: 0022-2623, DOI: 10.1021/acs.jmedchem.6b00948

The present application is directed to C-mannoside compounds of formula (I) and their application in the field of inhibition of FimH activity.

Novelty

D1-D3 (cf. passages indicated in the SR) are also directed to C-mannoside compounds, which differ from the subject matter of claim 1 in R3.

Thus, the subject matter of claim 1 is novel. Claims 2-36 directly or indirectly refer to the compounds of claim 1 and are thus novel by analogy.

Inventive step

D1 represents the closest prior art.

The effect accompanied with the distinguishing features is seen in a decrease of the bioavailability.

In view of the distinguishing features with respect to the closest prior art of D1, the objective technical problem may be considered as the provision of improved inhibitors of FimH.

The solution is given in claim 1 and concerns the compounds of formula (I).

Starting from D1 the skilled person in the art gets no hint that the compounds of claim 1 may show an improved bioavailability compared the compound of the closest prior art of D1 (cf. compound 51). The value for %F is an indicator for the bioavailability. The compounds of the present application show a %F value above 10 (%F = ++ or +++; cf. table 2 on pages 52-53 of the application) whereas compound 51 of D1 only shows a %F value of less than 10 (%F = +). This has been shown by the applicant with the supplementary technical data filed with the letter dated 06-05-2020 (Annex 1). The same applies to D2 (cf. passages indicated in the SR) and D3 (cf. passages indicated in the SR). Additionally the skilled person in the art is not motivated to modify the teaching of D1, D2 or D3 taken alone or in combination in order to arrive at the presently claimed subject matter.

Consequently, the subject matter of claim 1 is inventive.

Claims 2-36 directly or indirectly refer to the compounds of claim 1 and are therefore inventive by analogy.

Medical use

Claims 22-32 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT.

The patentability can be dependent upon the formulation of the claims. The EPO, for example, does not recognise as patentable claims to the use of a compound in medical treatment, but may allow claims to a product, in particular substances or compositions for use in a first or further medical treatment.

Patentability, in particular novelty and inventive step, of claims 22-32 has been assessed on the basis of a purpose-limited product claim taking into account the alleged effects of the compound/composition.

ad Section VII

In claim 1 optional features are put into brackets which renders the scope of the claim unclear.



Letter accompanying subsequently filed items under the Patent
Cooperation Treaty (PCT) - Online filing

The document(s) listed below is (are) subsequently filed documents pertaining to the following application:

1. General information	
Filing Office and capacity IPEA/EP	Application number PCT/IB2019/055806
International filing date 08-07-2019	(Earliest) Priority date 10-07-2018
Title of the invention C-MANNOSIDE COMPOUNDS USEFUL FOR THE TREATMENT OF URINARY TRACT INFECTIONS	

2. Reference number JMA/PU66563/WO
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3. Attached documents			
Document type/content	Language	No. of sheets	Original file name
Amendments (Article 34 and Rule 60.1(g))			
1) Amended claims	English	5	PU66563 WO - claims amended under Article 34 PCT corrected.pdf
2) Letter accompanying the replacement sheet(s)	English	1	PU66563 WO letter 22 May 2020.pdf

4. Fees (EUR)
Total amount 0.00

5. Method of payment Not applicable

6. Reimbursement instructions
☐ Reimbursement, if any, to be made to deposit account with the EPO: Account holder:

7. Note(s) for EPO

8. Signature(s)
Digitally signed by: Subject: Jenna Ahern 45060; Issuer: European Patent Office, European Patent Office CA G2 Date: 22 May 2020 Capacity: Representative



Intellectual Property

By electronic submission (EPOLINE)

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22 May 2020

Our Ref. JMA/PU66563/WO

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Dear Sirs,

**Re: International (PCT) Patent Application No. PCT/IB2019/055806
GlaxoSmithKline Intellectual Property Development Limited &
Fimbrion Therapeutics, Inc**

In response to the communication issued by the IPEA dated 20 May 2020, we are filing an amended claim set as amended under Article 34 PCT.

The claim numbering has been corrected so that claim 14 is now correctly numbered.

Yours faithfully,

Jenna Marie AHERN
Authorised Representative

Acknowledgement of receipt

We hereby acknowledge receipt of the following subsequently filed document(s):

Submission number	8650144	
Application number	PCT/IB2019/055806	
Date of receipt	22 May 2020	
Filing Office / capacity	European Patent Office, The Hague	IPEA
Your reference	JMA/PU66563/WO	
Applicant	All applicants as on file	
Documents submitted	package-data.xml pct-sfd-fee-sheet.xml CLMSAMD.pdf (5 p.)	pct-sfd-request.xml pct-sfd.pdf (1 p.) IPEAAMLET.pdf (1 p.)
Submitted by	CN=Jenna Ahern 45060	
Method of submission	Online	
Date and time receipt generated	22 May 2020, 12:35 (CEST)	
Message Digest	ED:4E:09:5D:30:D7:5C:53:E0:D7:38:D1:16:9C:64:5B:E8:E4:A3:1A	

Correction by the EPO of errors in debit instructions filed by eOLF

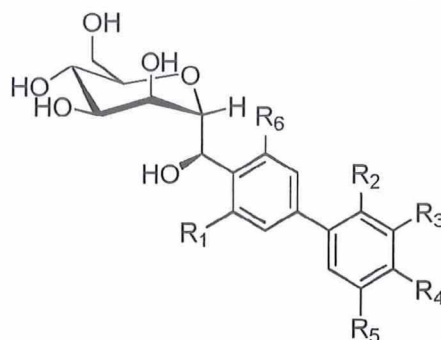
Errors in debit instructions filed by eOLF that are caused by the editing of Form 1038E entries or the continued use of outdated software (all forms) may be corrected automatically by the EPO, leaving the payment date unchanged according to point 6.3 ff ADA, Supplement to OJ EPO 3/2014 (see decision T 152/82, OJ EPO 1984, 301).

/European Patent Office/

PU66563 WO Claims amended under Article 34 PCT

What is claimed is:

1. A compound of Formula I, or a pharmaceutically acceptable salt thereof,



(I)

in which

R_1 is CH_3 , CF_3 , or Cl ;

R_2 is F , Cl , OR' , or H ;

R_3 , R_4 , and R_5 are independently H , F , Cl , Br , $\text{C}_{3-6}\text{cycloalkyl}$, OR' , $-\text{N}(\text{C}_{1-6}\text{alkyl})_2$, $\text{C}_{2-6}\text{alkenyl}$, $\text{C}_{2-6}\text{alkynyl}$, $\text{C}_{1-6}\text{alkyl}$ (optionally substituted with up to seven fluorine atoms, up to one hydroxy, up to one $-\text{N}(\text{C}_{1-6}\text{alkyl})_2$, and up to one $-\text{OC}_{1-6}\text{alkyl}$); provided not all R_3 , R_4 , and R_5 are hydrogen simultaneously.

R_6 is H or F ;

R' is independently H or $\text{C}_{1-6}\text{alkyl}$ optionally substituted with up to seven fluorine atoms.

2. A compound or pharmaceutically acceptable salt thereof according to claim 1, wherein R_1 is CH_3 or CF_3 .

3. A compound or pharmaceutically acceptable salt thereof according to claim 1 or 2, wherein R_1 is CH_3 .

4. A compound or a pharmaceutically acceptable salt thereof of claim 1 in which

R_1 is CH_3 or CF_3 ;

PU66563 WO Claims amended under Article 34 PCT

R₂ is H;

R₃ is F;

R₄ is CH₃, Cl, Br, vinyl, CF₃, F, or H;

R₅ is F or H; and

R₆ is H.

5. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(3',5'-Difluoro-3,4'-dimethyl-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
6. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(4'-Chloro-3',5'-difluoro-3-methyl-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
7. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(4'-Bromo-3',5'-difluoro-3-methyl-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
8. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(3',5'-Difluoro-3-methyl-4'-vinyl-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
9. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(3'-Fluoro-3-methyl-4'-(trifluoromethyl)-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
10. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(3'-Fluoro-3-methyl-5'-(trifluoromethyl)-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
11. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-Hydroxy(3',4',5'-trifluoro-3-methyl-[1,1'-biphenyl]-4-yl)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.

PU66563 WO Claims amended under Article 34 PCT

12. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(3',5'-Difluoro-3-(trifluoromethyl)-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
13. The compound of claim 4 that is (2R,3S,4S,5S,6R)-2-((R)-(3',5'-Difluoro-3-methyl-[1,1'-biphenyl]-4-yl)(hydroxy)methyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol.
14. A compound or a pharmaceutically acceptable salt thereof recited in any one of claims 1-13 for use as a medicament.
15. A compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 for use in the prevention or treatment of a disease or condition ameliorated by the inhibition of FimH function or activity.
16. A compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 for use in the prevention or treatment of a bacterial infection, Crohn's disease (CD), and Inflammatory Bowel Disease (IBD).
17. A compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 for use in the prevention or treatment of urinary tract infection (UTI).
18. A compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 for use in the manufacture of a medicament for the prevention or treatment of a disease or condition ameliorated by the inhibition of FimH function or activity.
19. A compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 for use in the manufacture of a medicament for the prevention or treatment of a bacterial infection, Crohn's disease (CD), and Inflammatory Bowel Disease (IBD).
20. A compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 for use in the manufacture of a medicament for the prevention or treatment of urinary tract infection.

PU66563 WO Claims amended under Article 34 PCT

21. A pharmaceutical composition comprising a compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 together with a pharmaceutically acceptable carrier.
22. A method of inhibition of FimH function comprising contacting FimH with a compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13.
23. A method of treatment of a FimH-mediated disease comprising the administration of a therapeutically effective amount of a compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 to a human patient in need thereof.
24. The method as recited in claim 23 wherein said disease is chosen from a bacterial infection, Crohn's disease (CD), and Inflammatory Bowel Disease (IBD).
25. The method as recited in claim 24 wherein said bacterial infection is a urinary tract infection.
26. The method as recited in claim 25 wherein said urinary tract infection is recurrent.
27. The method as recited in claim 25 wherein said urinary tract infection is chronic.
28. The method as recited in claim 24 wherein said bacterial infection is an antibiotic-resistant bacterial infection.
29. The method as recited in claim 24 wherein said disease is Crohn's disease.
30. A method of treatment of a FimH-mediated disease comprising the administration of:
 - a. a therapeutically effective amount of a compound or a pharmaceutically acceptable salt thereof as recited any one of claims 1-13; and
 - b. another therapeutic agent.
31. The method as recited in claim 30 wherein said disease is Urinary Tract Infection.
32. The method as recited in claim 30 wherein said disease is Crohn's Disease.

PU66563 WO Claims amended under Article 34 PCT

33. The method as recited in claim 30 wherein said disease is Inflammatory Bowel Disease.

34. A pharmaceutical composition comprising a compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 formulated for oral (PO) administration.

35. The pharmaceutical composition as recited in claim 34, wherein said composition is chosen from a tablet and a capsule.

36. A pharmaceutical composition comprising a compound or a pharmaceutically acceptable salt thereof as recited in any one of claims 1-13 formulated for topical administration.

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