TPOs filed between December 2018 and April 2020

Below is an Annex containing summaries of TPOs filed between December 2018 and April 2020 with respect to PCT applications relevant to HIV, HCV and TB. The Annex will feature in our upcoming report documenting a one-year experience of using the TPO system.

Note:
TPO No. refers to publisher's internal reference number.
Appl. No. provides information on the International Application No. and the Publication Number.
National phase as of 07.10.2022 reflects information provided on WIPO's PATENTSCOPE database as at that date. However, this data is dynamic and may not provide accurate information on the actual status of the patent application.

Annex 1: Case Summaries

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Part A: Case Summaries – HIV Applications

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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018127800</td></tr>
<tr><td>Applicants</td><td>ViiV Healthcare UK (No. 5) Limited</td></tr>
<tr><td>Priority Date</td><td>03.01.2017</td></tr>
<tr><td>Details</td><td>This application claims pyridin-3-yl acetic acid derivatives for the treatment of HIV.</td></tr>
<tr><td>Claims</td><td>The application has 16 claims, of which 3 are independent claims and 13 are dependent. One Markush structure is claimed. Overall, there are 2 specific compounds included in the claims. Of the 16 claims, 7 are secondary claims, 4 are formulation claims and 3 use claims and 2 are for methods of treatment. Two of the claims include combinations.

Of the 4 formulation claims, 1 claim is for a composition claim per se, 1 claim is for a composition of a combination per se and 2 claims are method of treatment claims. Of the 2 combination claims, 1 claim overlaps with formulation claims (as it is for composition of combination) and 1 claim overlaps with method of treatment claims. The 2 method of treatment claims both overlap with formulation claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 5 documents as prior art. Of these, 1 was X and 4 were PX documents.</td></tr>
<tr><td>TPO</td><td>The TPO cited 4 prior art documents; all 4 challenged both novelty and inventive step. Three of the prior art documents were patent documents and 1 was a periodical.</td></tr>
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<tr><td>Japan</td><td>02.07.2019</td><td>2019536131</td><td></td></tr>
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[1] TPO No. refers to publisher's internal reference number
[2] Appl. No. provides information on the International Application No. and the Publication Number
[3] National phase as of 07.10.2022 reflects information provided on WIPO's patentscope database as at that date. However, this data is dynamic and may not provide accurate information on the actual status of the patent application.

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<tr><td>Applicants</td><td>ViiV Healthcare UK (No. 5) Limited</td></tr>
<tr><td>Priority Date</td><td>03.01.2017</td></tr>
<tr><td>Details</td><td>The application also claims pyridin-3-yl acetic acid derivatives for the treatment of HIV. The only difference in the Markush scaffolds of WO’800 and WO’801 is that both monocyclic and bicyclic rings can be substituted at position 4 of the pyridine ring in WO’800 and is specifically claimed to be isoquinoline (bicyclic) ring in WO’801.</td></tr>
<tr><td>Claims</td><td>The application has 12 claims, of which 1 is an independent claim and 11 are dependent. One Markush structure is claimed but no specific compounds are claimed. Of the 12 claims, 7 are secondary claims, 4 are formulation claims and 3 use claims and 2 are for methods of treatment. Two of the claims include combinations.

Of the 4 formulation claims, 1 claim is for a composition claim per se, 1 claim is for a composition of a combination per se and 2 claims are method of treatment claims. Of the 2 combination claims, 1 claim overlaps with formulation claims (as it is for composition of combination) and 1 claim overlaps with method of treatment claims. The 2 method of treatment claims both overlap with formulation claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 5 documents as prior art. Of these, 1 was A and 4 were PX documents.</td></tr>
<tr><td>TPO</td><td>The TPO cited 4 prior art documents; all 4 challenged both novelty and inventive step. Three of the prior art documents were patent documents and 1 was a periodical.</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018128993</td></tr>
<tr><td>Applicants</td><td>OyaGen, Inc.</td></tr>
<tr><td>Priority Date</td><td>04.01.2017</td></tr>
<tr><td>Details</td><td>The application covers pharmaceutical composition of compounds that inhibit the self-association of Viral Infectivity Factor (Vif) in HIV-infected cells. The application claims pharmaceutical composition of compounds that inhibit Vif self-association, enhance APOBEC3G activity or cause RNA mutations that produce defective virions. The 3 compounds specifically listed and claimed as having this activity are all known compounds and have been sourced from other entities. The 3 compounds for which compositions are claimed belong to the class of camptothecins (one of which is a modified analogue of irinotecan) which are known to have anti-cancer activity. The application claims compositions of these compounds for anti-HIV activity.</td></tr>
<tr><td>Claims</td><td>The application has 23 claims, of which 5 are independent claims and 18 are dependent. All 23 claims are secondary claims, of which 22 are formulation claims. There are no Markush structures claimed. There are 3 method of treatment claims, 7 claims are for combinations.

The applicant claims pharmaceutical compositions of specific isomeric forms of 3 compounds, their salts and prodrug of 1 of them. The applicant does not claim the compounds or the prodrug per se. Of the 22 formulation claims, 20 are for the composition per se and 2 overlap with method of treatment claims. Of the 3 method of treatment claims, 1 is a method of treatment claimed per se and 2 overlap with formulation and combination claims. Of the 7 combination claims, 5 overlap with formulation claims and 2 overlap with method of treatment claims. All of the 5 independent claims in this application are characterised by the mechanism of action. Several dependent claims too are characterised by mechanism of action. However, for this application, none of these are counted as “Other claims”.</td></tr>
<tr><td>ISR</td><td>The ISR cited 8 documents as prior art. Of these, 1 was AX, 2 were Y, 5 were A. In the ISR, the document listed for novelty (X) was also listed for inventive step (Y).</td></tr>
<tr><td>TPO</td><td>The TPO cited 5 prior art documents; 1 prior art document challenged only inventive step while 4 prior art documents challenged both novelty and inventive step. One of the prior art documents was a patent document and 4 were periodicals.</td></tr>
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Granted 14.09.2021</td></tr>
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<tr><td>Applicants</td><td>Merck Sharpe & Dohme Corp</td></tr>
<tr><td>Priority Date</td><td>26.01.2017</td></tr>
<tr><td>Details</td><td>The application covers a substituted quinolizine derivative for the treatment of HIV. The application claims prodrugs of an already known molecule. This known molecule is very similar to established carbamoyl pyridones such as dolutegravir. Dolutegravir has 2 nitrogen atoms in the saturated ring attached to the pyridine ring whereas the molecule in the application has only 1 nitrogen atom in the saturated ring attached to the pyridine ring.</td></tr>
<tr><td>Claims</td><td>The application has 17 claims, of which 1 is an independent claim and 16 are dependent. All 17 claims are secondary claims, of which 2 are formulation claims. There are 17 claims covering different forms like salts etc. There are no Markush structures claimed. There are 2 claims for use, 3 method of treatment claims and 2 claims are for combinations.

The application claims prodrugs of a known compound. The prodrug is represented by a Markush structure (Formula I). Because the claims all relate to prodrugs (and not a basic molecule), the claim for the Markush structure of prodrugs is not counted as Markush structure. As all 17 claims relate to prodrugs, these are all counted as secondary claims and also as “other forms” claims. Of the 2 formulation claims, 1 claim is for a composition per se and 1 claim overlaps with a combination claim. Of the 3 method of treatment claims, 1 claim overlaps with a combination claim. Of the 2 combination claims, 1 claim overlaps with a formulation claim and 1 claim overlaps with a method of treatment claim.</td></tr>
<tr><td>ISR</td><td>The ISR cited 4 documents as prior art, all of which are A documents.</td></tr>
<tr><td>TPO</td><td>The TPO cited 7 prior art documents, of which 5 challenged only novelty and 2 challenged both novelty and inventive step. Two of the prior art documents were patent documents and 5 were periodicals.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 25.05.2019</td></tr>
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Granted 29.09.2020</td></tr>
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<tr><td>Applicants</td><td>Institute for Cancer Research d.b.a The Research Institute of Fox Chase Cancer Center</td></tr>
<tr><td>Priority Date</td><td>26.01.2017</td></tr>
<tr><td>Details</td><td>The application covers a method for inhibiting HIV-1 integrase multimerisation. The applicant followed a procedure of screening a commercial library which has been described in a prior art patent document by the applicant itself to discover compounds with a specific activity for treatment of HIV. On doing so, the applicant discovered compounds from the commercial library that exhibited such activity, categorised them into two scaffolds and claimed them for the treatment of HIV.</td></tr>
<tr><td>Claims</td><td>The application has 42 claims, of which 2 are independent claims and 40 are dependent. All 42 claims are secondary claims, of which 2 are formulation claims. All 42 claims are method of treatment claims.

All claims are drafted as method of treatment claims. The applicant claims method of treatment of HIV with 2 Markush structures and 18 specific compounds. These are not included in columns P and Q as the application itself is a secondary application claiming method of inhibiting HIV-1 multimerisation with claimed compounds. The 2 formulation claims overlap with method of treatment claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 3 documents as prior art. Of these, 2 were Y, 1 was A.</td></tr>
<tr><td>TPO</td><td>The TPO cited 4 prior art documents, of which 1 was a document also cited by the ISR. Two of the prior art documents challenged only inventive step and two challenged both novelty and inventive step. Two of the prior art documents were patent documents and 2 were periodicals.</td></tr>
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Granted 12.01.2021</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018144390</td></tr>
<tr><td>Applicants</td><td>Gilead Sciences Inc.</td></tr>
<tr><td>Priority Date</td><td>31.01.2017</td></tr>
<tr><td>Details</td><td>The application covers crystalline forms of a known drug tenofovir alafenamide for treatment of HIV. The basic molecule is a nucleoside reverse transcriptase inhibitor (NRTI).

The application claims crystalline forms of salts of tenofovir alafenamide such as hemipamoate-I, II, sebacate-I, napsylate-I, orotate-I, II, III, vanillate, bisxenofoate salt forms.</td></tr>
<tr><td>Claims</td><td>The application has 76 claims, of which 2 are independent claims and 74 are dependent. All 76 claims are secondary claims, of which 12 are formulation claims. All 76 claims cover various forms of tenofovir alafenamide such as salts and crystalline forms thereof. There are 4 claims for use, 6 claims for method of treatment and 4 claims for combinations.

Of the 12 formulation claims, 8 claims are for composition per se and 4 claims are for combinations. As all 76 claims relate to salts and their crystalline forms, these are all counted as secondary claims and also as “other forms” claims. Of the 6 method of treatment claims, 4 are for method of treatment per se and 2 overlap with use claims. All 4 combination claims are drafted as formulation claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 4 documents as prior art. Of these, 2 were X, 1 was Y, 1 was A. In the ISR, 2 of the documents listed for novelty (X) were also listed for inventive step (Y), and of the documents listed for inventive step (Y) 1 document was also a A document.</td></tr>
<tr><td>TPO</td><td>The TPO cited 7 prior art documents. Four of the prior art documents challenged only inventive step and three challenged both novelty and inventive step. Four of the prior art documents were patent documents, 2 were periodicals and 1 was a book. In the TPO, for citation 4, a (machine) translated version in English of the Korean patent (i.e., 1 additional document) was uploaded.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 31.05.2019</td></tr>
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<tr><td>Canada</td><td>28.06.2019</td><td>3049028</td><td>Divisional 15.08.2022</td></tr>
<tr><td>Japan</td><td>29.07.2019</td><td>2019541123</td><td></td></tr>
<tr><td>China</td><td>30.07.2019</td><td>201880009292.1</td><td>Published: 13.09.2019</td></tr>
<tr><td>India</td><td>08.08.2019</td><td>201917032116</td><td></td></tr>
<tr><td>Republic of Korea</td><td>28.08.2018</td><td>1020217034440</td><td>Divisional 23.04.2021
Published 05.11.2021
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<tr><td>EPO</td><td>02.09.2019</td><td>2018705239</td><td></td></tr>
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TPO No.	16
Appl. No.	PCT/US2018/016893 : WO2018145021
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018145021
Applicants	Gilead Sciences Inc.
Priority Date	06.02.2017
Details	The application covers atazanavir analogues (i.e., protease inhibitors) for treating HIV infection.
Claims	The application has 101 claims, of which 2 are independent claims and 99 are dependent. The claims cover 6 Markush structures and 246 specific compounds. There are 43 secondary claims, of which 12 are formulation claims. There is 1 claim for dosage, 20 for use, 12 method of treatment claims and 40 claims for combinations. Of the 6 Markush structures, 1 is the main Markush structure and the other 5 are derivative Markush structures. The dosage claim is a unitary dosage claim that is drafted as a use claim. Of the 40 combination claims, 11 claims overlap with the pharmaceutical composition claims, 11 overlap with the method of treatment claims and 18 overlap with the use claims.
ISR	The ISR cited 2 documents as prior art. Of these, 1 was X, 1 was A.
TPO	The TPO cited 6 prior art documents, including 2 that were also cited in the ISR. Three of the prior art documents challenged only inventive step and 3 challenged both novelty and inventive step. Four of the prior art documents were patent documents and 2 were periodicals. (Two additional periodical documents were filed along with the first periodical citation uploaded in the TPO.)
Date of Filing of TPO	The TPO was filed on 06.06.2019

National Phase as of 07.10.2022

Office	**Entry Date**	**National Number**	**National Status**
Canada	25.07.2019	3051588	Granted 23.08.2022
Israel	25.07.2019	268282	
Australia	31.07.2019	2018215546	Published 22.08.2019
New Zealand	31.07.2019	755929	Divisional 30.08.2018 Published 13.05.2021 Granted 30.11.2021
Singapore	31.07.2019	11201907058T	
Mexico	02.08.2019	MX/a/2019/009212	Published 07.10.2019
Costa Rica	05.08.2019	CR2019-000354	Published 19.09.2019
Dominican Republic	05.08.2019	DOP2019000201	Published 30.08.2019
Japan	05.08.2019	2019542392	
Peru	05.08.2019	001536-2019	Published 18.09.2019
Philippines	05.08.2019	12019501786	
Eurasian Patent Organization	09.08.2019	201991684	Published 29.01.2020 Granted 30.04.2022
India	09.08.2019	201917032272	

South Africa	22.08.2019	2019/05573	
Republic of Korea	03.09.2019	1020227027022	Divisional 04.08.2022 Published 22.08.2022
Ukraine	03.09.2019	A201909440	Published 10.02.2020 Granted 10.03.2021
EPO	06.09.2019	2018706072	Granted 21.04.2021
China	29.09.2019	201880023198.1	Published 03.12.2019
Saudi Arabia	01.03.2022	519402405	

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<tr><td>Applicants</td><td>Sandoz AG</td></tr>
<tr><td>Priority Date</td><td>16.02.2017</td></tr>
<tr><td>Details</td><td>The application covers crystalline forms of cabotegravir sodium. The basic molecule cabotegravir is an integrase inhibitor.</td></tr>
<tr><td>Claims</td><td>The application has 14 claims, of which 1 is an independent claim and 13 are dependent. All 14 claims are secondary claims. There are 3 claims for new forms like salts etc. There are 2 claims for use. The claims relate to over 10 diseases including HIV, viral infections caused by DNA virus, RA virus, herpes virus, hepadnavirus, papilloma virus, adenoviruses.

Of the 3 claims for forms, 2 claims relate to one crystalline form and 1 claim relates to a pharmaceutical composition which includes the amorphous form. There are also 4 process claims. Of the 6 formulation claims, 1 overlaps with a use claim and 1 overlaps with a dosage claim.</td></tr>
<tr><td>ISR</td><td>The ISR cited 5 documents as prior art, all of which are A.</td></tr>
<tr><td>TPO</td><td>The TPO cited 5 prior art documents. Three of the prior art documents challenged only inventive step and 2 challenged both novelty and inventive step. One of the prior art documents was a patent document and 4 were periodicals. (One translated copy from Chinese to English of a patent application was uploaded along with original document.)</td></tr>
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<tr><td>United States of America</td><td>13.08.2019</td><td>16485541</td><td>Published 10.12.2020
Granted 22.06.2021</td></tr>
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Granted 13.12.2021</td></tr>
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<tr><td>Russian Federation</td><td>16.09.2019</td><td>2019125378</td><td>Published 16.03.2021</td></tr>
<tr><td>China</td><td>16.10.2019</td><td>201880025341.0</td><td>Published 17.12.2019</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018156595</td></tr>
<tr><td>Applicants</td><td>Emory University</td></tr>
<tr><td>Priority Date</td><td>21.02.2017</td></tr>
<tr><td>Details</td><td>The application covers compounds which act as chemokine CXCR4 receptor modulators and is a basic molecule application.</td></tr>
<tr><td>Claims</td><td>The application has 25 claims, of which 4 are independent claims and 21 are dependent. There are 4 Markush structures claimed that cover 322 specific compounds. Ten claims are secondary claims and 3 are formulation claims. There are 2 claims for use, 4 claims for method of treatment and 4 claims for combinations. The claims relate to over 10 diseases including HIV, viral infection, abnormal cellular proliferation, retinal degeneration, inflammatory diseases, immunostimulant, immunosuppressant, cancer.

Apart from salts, prodrugs of the compounds are also claimed. Of the 3 formulation claims, 1 claim overlaps with a combination claim. Of the 4 combination claims, 1 claim is drafted as a formulation claim and 2 claims are drafted as method of treatment claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 4 documents as prior art. Of these, 2 were Y and 2 were A.</td></tr>
<tr><td>TPO</td><td>The TPO cited 5 prior art documents. Four of the prior art documents challenged only inventive step and 1 challenged both novelty and inventive step. Two of the prior art documents were patent documents and 3 were periodicals.</td></tr>
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<tr><td>Australia</td><td>10.09.2019</td><td>2018225556</td><td>Published 03.10.2019</td></tr>
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<tr><td>China</td><td>21.10.2019</td><td>201880026481.X</td><td>Published 06.12.2019</td></tr>
<tr><td>Israel</td><td></td><td>292923</td><td>Divisional 10.05.2022</td></tr>
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TPO No.	29
Appl. No.	PCT/US2018/027418: WO2018191579
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018191579
Applicants	Contravir Pharmaceuticals, Inc.
Priority Date	14.04.2017
Details	The application covers a method of treating and/or preventing HIV or HBV by administering a combination of a modified cyclophilin inhibitor (known compounds) and reverse transcriptase inhibitors for the treatment of HIV, HBV.
Claims	The application has 68 claims, of which 23 are independent claims and 45 are dependent. All 68 claims are secondary claims and 6 are formulation claims. There are 23 claims for dosage, 16 claims for use, 49 claims for method of treatment and 68 claims for combinations. Sixty-five of the 68 claims are drafted as method of treatment or use claims. The applicant claims method of treatment with/use of a combination of cyclosporine analogue (1 Markush structure) with reverse transcriptase inhibitors (1 primary + 1 derivative Markush structure). Amongst the reverse transcriptase inhibitors, they specifically claim tenofovir, a specific prodrug of tenofovir and certain specific salts of the prodrug. Of the 6 formulation claims, 1 claims the composition per se, 1 claims the composition for method of treatment and 4 claim the composition for use. One of these use claims also specifically claims a synergistic composition. All the dose/dosage-related claims are drafted as method of treatment claims. There is also a process claim and a claim for a kit.
ISR	The ISR cited 6 documents as prior art. Of these, 4 were X, 2 were PX. Of the 4 X documents in the ISR, 3 were also listed as Y documents.
TPO	The TPO cited 6 prior art documents. One of the prior art documents challenged only inventive step and 5 challenged both novelty and inventive step. Two of the prior art documents were patent documents, 3 were periodicals and 1 of them was an “other” prior art document (specifically, poster of a conference proceeding). Four additional documents were filed along with the main prior art documents; of these, 2 periodical documents were uploaded in support of a periodical article and the other 2 were additional press release documents uploaded in support of the “other” prior art document.
Date of Filing of TPO	The TPO was filed on 12.08.2019
National Phase as of 07.10.2022	No national phase entries

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<tr><td>Appl. No.</td><td>PCT/IB2018/053014 : WO2018203235</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018203235</td></tr>
<tr><td>Applicants</td><td>ViiV Healthcare UK (No.5) Limited</td></tr>
<tr><td>Priority Date</td><td>02.05.2017</td></tr>
<tr><td>Details</td><td>The application claims compounds for the treatment of HIV. The mechanism of action is not disclosed.</td></tr>
<tr><td>Claims</td><td>The application has 15 claims, of which 1 is an independent claim and 14 are dependent. There are 2 Markush structures claimed and 270 specific compounds. Ten claims are secondary claims and 2 are formulation claims. There are 3 claims for use, 5 claims for method of treatment and 2 claims for combinations.

Of the 2 Markush structures claimed, 1 is a derivative of the general Markush structure. Another formula is also specifically claimed, but it is a stereoisomer of the second derivative Markush structure and therefore has not been counted as a separate third Markush structure. All 3 use claims are drafted in the form of compounds for use claims. Of the 5 method of treatment claims, 2 are for combinations. Both the combination claims are drafted as method of treatment claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 2 documents as prior art, both of which are A.</td></tr>
<tr><td>TPO</td><td>The TPO cited 2 prior art documents, both of which challenged both novelty and inventive step. Both prior art documents were patent documents.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 02.09.2019</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>United States of America</td><td>18.10.2019</td><td>16606345</td><td>Granted 23.03.2022</td></tr>
<tr><td>Japan</td><td>31.10.2019</td><td>2019559837</td><td></td></tr>
<tr><td>EPO</td><td>02.12.2019</td><td>2018727428</td><td>Published 11.03.2020
Granted 06.04.2022</td></tr>
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<tr><td>TPO No.</td><td>40</td></tr>
<tr><td>Appl. No.</td><td>PCT/IB2018/055257: WO2019016679</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019016679</td></tr>
<tr><td>Applicants</td><td>ViiV Healthcare Company</td></tr>
<tr><td>Priority Date</td><td>18.07.2017</td></tr>
<tr><td>Details</td><td>The application claims a pharmaceutical combination comprising the integrase strand transfer inhibitor, cabotegravir, with the nucleoside reverse transcriptase translocation inhibitor (NRTTI), 4'-ethynyl-2-fluoro-2'-deoxyadenosine, known as EFdA (MK-8591, islatravir). is listed as being in Phase II clinical trials in the TAG Pipeline Report 2018.

The pharmaceutical combination claimed in the application is a combination of cabotegravir (formula I) and EFdA (MK-8591, islatravir), both of which are known drugs for the treatment and prevention of HIV.</td></tr>
<tr><td>Claims</td><td>The application has 13 claims, of which 2 are independent claims and 11 are dependent. All 13 are secondary claims, 1 is a formulation claim and 1 is a new form claim. There are 3 claims for use, 7 claims for method of treatment and 13 claims for combinations.

All the claims pertain to a combination of cabotegravir and islatravir for the prevention or treatment of HIV. The applicant claims sodium salt of cabotegravir (formula I) in two of the claims (1 claim is for combination and 1 claim is for method of treatment).</td></tr>
<tr><td>ISR</td><td>The ISR cited 3 documents as prior art, all of which are Y.</td></tr>
<tr><td>TPO</td><td>The TPO cited 6 prior art documents. Two of these challenged only inventive step and 4 challenged both novelty and inventive step. One prior art document was used after the priority date but before the filing date. In the TPO, the P document was used for both novelty and inventive step. Three of the prior art documents were patent documents and 3 were periodicals. Three additional documents were filed; 1 additional periodical article was filed each with Citations 2 and 3 (both periodical articles) and 1 additional document (US Department of Health and Human Services guideline) was filed with Citation 4 (a periodical article).</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 18.11.2019</td></tr>
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<tr><td>Japan</td><td>16.01.2020</td><td>2020502228</td><td></td></tr>
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<tr><td>Appl. No.</td><td>PCT/US2018/042937 : WO2019018676</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019018676</td></tr>
<tr><td>Applicants</td><td>Janssen Sciences and Gilead Sciences</td></tr>
<tr><td>Priority Date</td><td>20.07.2017</td></tr>
<tr><td>Details</td><td>The application claims method of treatment with single unit dosage form of darunavir (or its hydrate or solvate), cobicistat, emtricitabine and tenofovir alfenamide, or a salt thereof, for treatment of HIV, and single unit dosage forms.

The applicant claims a once daily single unit dosage form of a combination of 4 known drugs and method of treatment using the same. For the method of treatment claims, it also sets out the patient’s conditions prior to the administration of the combination (e.g., the viral load of HIV prior to administration, presence or absence of certain mutations, previous discontinued first regimen etc.), treatment outcome and the previous treatment that the subject was on. Further, the applicant claims the known doses of the known anti-HIV drugs that are combined into a single unit and the process of making the single unit dosage form, more specifically in tablet form.</td></tr>
<tr><td>Claims</td><td>The application has 42 claims, of which 2 are independent claims and 40 are dependent. All 42 are secondary claims. There are 16 formulation claims and 3 are claims for new forms. There are 9 claims for dosage and 34 claims for method of treatment and 42 claims for combinations.
All the claims are directed to a single unit dosage form, either as method of treatment or single unit dosage forms per se. However, because of the manner in which they are drafted, not all of them are counted as formulation claims. Of the 16 formulation claims, 6 are formulation claims per se (single unit dosage form), 9 are drafted as method of treatment claims and 1 is product by process claim (product by process). Of these 16 formulation claims, 9 also include dose/dosage limitations (4 formulation claims per se and 5 method of treatment claims).</td></tr>
<tr><td>ISR</td><td>The ISR cited 5 documents as prior art, all of which are X.</td></tr>
<tr><td>TPO</td><td>The TPO cited 5 prior art documents, including 2 that were also cited in the ISR. One of these challenged only inventive step and 4 challenged both novelty and inventive step. Two of the prior art documents were patent documents, 2 were periodicals and 1 “other” prior art document was a poster of a conference proceeding. Three additional documents were uploaded.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 20.11.2019</td></tr>
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<tr><td>Mexico</td><td>17.01.2020</td><td>MX/a/2020/000694</td><td>Published 13.08.2020</td></tr>
<tr><td>Canada</td><td>20.01.2020</td><td>3070713</td><td></td></tr>
<tr><td>Brazil</td><td>28.01.2020</td><td>112020000842</td><td></td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019016732</td></tr>
<tr><td>Applicants</td><td>ViiV Healthcare Company and Janssen Sciences</td></tr>
<tr><td>Priority Date</td><td>21.07.2017</td></tr>
<tr><td>Details</td><td>The application claims method of treating HIV comprising administering long-acting intramuscular administration (4 weeks or less, or 8 weeks) of a combination of cabotegravir and rilpivirine (or their pharmaceutical salts). [Integrase inhibitor (cabotegravir); non-nucleoside reverse transcriptase inhibitor (rilpivirine)]</td></tr>
<tr><td>Claims</td><td>The application has 16 claims, of which 3 are independent claims and 13 are dependent. All 16 are secondary claims. All 16 claim methods of treatment. And all 16 claim combinations. There are 9 dosage claims. All claims relate to HIV.

All the claims are for method of treating HIV comprising administering long-acting intramuscular administration of a combination of cabotegravir and rilpivirine (or their pharmaceutically acceptable salts). Therefore, they are all method of treatment claims as well as combination claims. The 9 dosage claims are claims which mention either the doses of the components or the frequency of administration. Some of the method of treatment claims are with respect to discontinuing a previous treatment regimen (n = 4), patient's condition prior to administration of the claimed long-acting combination (n = 1) and treatment outcomes after 96 weeks (n = 3).</td></tr>
<tr><td>ISR</td><td>The ISR cited 3 documents as prior art, of which 2 are X documents and 1 is an A document.</td></tr>
<tr><td>TPO</td><td>The TPO cited 2 prior art documents, both of which challenged both novelty and inventive step. One was a patent document and 1 was another document. One additional document was also filed. The 1 “other” prior art document used was a poster from a conference proceeding. For this document, the additional document (being the relevant extracts of the abstract book) was uploaded.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 21.11.2019</td></tr>
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<tr><td>United States of America</td><td>17.01.2020</td><td>16631868</td><td>Published : 14.05.2020</td></tr>
<tr><td>Japan</td><td>20.10.2020</td><td>2020502979</td><td></td></tr>
<tr><td>Mexico</td><td>20.01.2020</td><td>MX/a/2020/000790</td><td>Published 08.12.2020</td></tr>
<tr><td>Republic of Korea</td><td>17.02.2020</td><td>1020207004521</td><td>Published 24.03.2020</td></tr>
<tr><td>Australia</td><td>20.02.2020</td><td>2018304591</td><td>Published 05.03.2020</td></tr>
<tr><td>EPO</td><td>21.02.2020</td><td>2018749568</td><td></td></tr>
<tr><td>Russian Federation</td><td>21.02.2020</td><td>2020102304</td><td>Published 23.08.2021</td></tr>
<tr><td>China</td><td>20.03.2020</td><td>201880061354.3</td><td>Published 05.05.2020</td></tr>
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<tr><td>TPO No.</td><td>43</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/044415 : WO2019027920</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019027920</td></tr>
<tr><td>Applicants</td><td>Gilead Sciences Inc.</td></tr>
<tr><td>Priority Date</td><td>01.08.2017</td></tr>
<tr><td>Details</td><td>The application claims crystalline and amorphous forms of GS-9131 (a prodrug of GS-9148), and its vanillate, phosphate and xinafoate salts and phosphate acetonitrile solvate for treating viral infections like HIV. The application relates to various forms of GS-9131, i.e., rovafovir etalafenamide, an oral nucleoside reverse transcriptase inhibitor. It is presently in Phase II clinical trials for the treatment of HIV. GS-9131 is listed in the TAG Pipeline Report 2018.</td></tr>
<tr><td>Claims</td><td>The application has 70 claims, of which 9 are independent claims and 61 are dependent. All 70 are secondary claims. There are 14 claims for formulations, 53 claims for various forms such as salts and 1 claim for dosage. There are 2 claims for use, 2 claims for methods of treatment and 10 claims for combinations. All claims relate to HIV.

Of the 14 claims for formulations, 6 are for pharmaceutical compositions and 8 are for solid dosage forms. Some of the claims are directed to single layer, multilayer and bilayer tablets. There are 53 claims directed to various forms of GS-9131 itself or its salts, i.e., two crystalline forms of GS-9131; two crystalline forms of vanillate salt of GS-9131; one crystalline form each of phosphate, xinafoate salt and phosphate acetonitrile solvate Form I of GS-9131; and amorphous form of GS-9131 or a pharmaceutically acceptable salt, co-crystal or solvate thereof. The various forms are characterised by one or more known techniques such as XRPD, DSC, TGA thermogram and dynamic vapour sorption isotherm. There is 1 claim where the solid dosage form is formulated for once-a-day dosing. This has been counted as a dosage claim. Of the 2 use claims, 1 is a use claim per se and 1 claim is drafted as a claim for a solid dosage form for use. Of the 10 combination claims, 2 are for compositions further comprising 1 to 3 additional therapeutic agents active against HIV. Eight claims are further dependent claims relating to pharmaceutical composition and solid dosage form, which may include such combinations.</td></tr>
<tr><td>ISR</td><td>The ISR cited 1 document as prior art, which was an X document.</td></tr>
<tr><td>TPO</td><td>The TPO cited 10 prior art documents, including the 1 document cited in the ISR. Eight of the documents challenged only inventive step and 2 challenged both novelty and inventive step. Of these prior art documents, 3 were periodicals, 6 were patent documents and 1 was another document, being a poster presented in a conference proceeding.

Three additional documents were filed along with the 10 prior art documents. Of these, 2 documents (being a description of the poster and a periodical article showing the disclosure of the combination) were uploaded for the 1 “other” document (i.e., conference proceeding). One additional periodical document was uploaded in support of a patent document.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 02.12.2019</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>EPO</td><td>02.03.2020</td><td>2018755368</td><td>Granted 28.07.2021</td></tr>
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<tr><td>Appl. No.</td><td>PCT/IB2018/055828 : WO2019030625</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019030625</td></tr>
<tr><td>Applicants</td><td>ViiV Healthcare Company</td></tr>
<tr><td>Priority Date</td><td>09.08.2017</td></tr>
<tr><td>Details</td><td>The application claims methods of treating or preventing HIV in a patient using a combination of bictegravir and lamivudine and optionally other agents as well as compositions containing such compounds. [Integrase inhibitor (bictegravir); nucleoside transcriptase inhibitor (lamivudine)]</td></tr>
<tr><td>Claims</td><td>The application has 11 claims, of which 5 are independent claims and 6 are dependent. All 11 are secondary claims. There are 10 claims for formulations and 3 claims for dosage. There are 2 claims for use, 3 claims for methods of treatment and 11 claims for combinations. There are also 4 other claims. All claims relate to HIV.

The claims are directed to a combination of bictegravir and lamivudine or their pharmaceutically acceptable salts. Of the 10 claims for formulations, 3 claims are for compositions per se (including dose), 3 are method of treatment claims (including with the pharmaceutical compositions of the individual drugs), 2 are for kits comprising composition and 2 are for use of the composition (kit or combination). Of the 3 dosage claims, 1 claim specifically mentions the dose. 2 further dependent "use" claims impliedly include the dose limitation. The 2 use claims are for use of the composition, kit or combination. The 3 method of treatment claims include preventing or treating HIV with a combination of bictegravir and lamivudine (or their salts) or formulations thereof. All the 11 claims relate to the combination of bictegravir and lamivudine. Of the 11 claims, 4 claims specifically claim the combination of the 2 active ingredients or their salts, their formulations and dose. 3 claims are method of treatment claims, 2 claims are for kits and 2 claims are claims for the use of the claimed composition, kit or combination. Of the 4 "other" claims, 2 claims are claims for kits per se and 2 relate to use of the claimed kits (apart from the claimed combination or composition).</td></tr>
<tr><td>ISR</td><td>The ISR cited 3 documents as prior art, of which 2 were Y documents and 1 was a PX document.</td></tr>
<tr><td>TPO</td><td>The TPO cited 4 prior art documents, including one of the documents cited in the ISR. Three of the documents challenged only inventive step and 1 challenged both novelty and inventive step. Three were periodicals and 1 was a patent document. One additional document was also uploaded in support of a periodical article, being the supplementary information of the said periodical article.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 09.12.2019</td></tr>
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<tr><td>Japan</td><td>07.02.2020</td><td>2020507085</td><td></td></tr>
<tr><td>EPO</td><td>09.03.2020</td><td>2018844317</td><td>Published : 17.06.2020</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019030626</td></tr>
<tr><td>Applicants</td><td>ViiV Healthcare Company</td></tr>
<tr><td>Priority Date</td><td>09.08.2017</td></tr>
<tr><td>Details</td><td>The application claims compositions of a combination of bictegravir (an HIV integrase inhibitor) and emtricitabine (nucleoside reverse transcriptase inhibitor) and method of treating and preventing HIV using this combination.</td></tr>
<tr><td>Claims</td><td>The application has 11 claims, of which 5 are independent claims and 6 are dependent. All 11 are secondary claims. There are 5 claims for formulations and 3 claims for dosage. There are 2 claims for use, 3 claims for methods of treatment and 11 claims for combinations. There are also 4 other claims. All claims relate to HIV.

All the claims pertain to a combination of bictegravir and emtricitabine for the prevention or treatment of HIV. One claim that specifically claims only the combination (not composition, kit, method of treatment, etc.) also generally claims the salt forms of the compounds. Of the 5 formulation claims, 1 claims the composition (and kits and combination) for use in medical therapy and 1 claims the composition (and kits and combination) for use in method of treatment. Thus 2 of the 5 formulation claims also include claims to a kit and a combination for use in therapy and use in method of treatment. Of the 5 formulation claims, 1 claim also claims the doses of each of the 2 drugs and 2 claims pertain to a separate dosage form or single dosage form. The 2 claims for use claim a composition, kit and combination for (i) use in medical therapy and (ii) method of treatment respectively. The claim for use for method of treatment is not counted as a method of treatment claim. Of the 4 "other" claims, 2 are specifically only for kits. As noted above, 2 claims for use in medical therapy and use in method of treatment also refer to kits (and pharmaceutical compositions and combination). These, too, have been counted as "other" claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 4 documents as prior art, of which 1 is an X document, 2 are Y documents and 1 is a PX document. The X document referred to in the ISR is also marked as a Y document.</td></tr>
<tr><td>TPO</td><td>The TPO cited 5 prior art documents, including 1 document cited in the ISR. All 5 documents challenged both novelty and inventive step. Three were periodicals and 2 were patent documents. The supplementary material of one of the periodical articles was uploaded as an additional document.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 09.12.2019</td></tr>
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<tr><td>Japan</td><td>07.02.2020</td><td>2020506979</td><td></td></tr>
<tr><td>EPO</td><td>09.03.2020</td><td>2018843567</td><td>Published : 17.06.2020</td></tr>
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TPO No.	49
Appl. No.	PCT/IB2018/056982 : WO2019053617
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019053617
Applicants	GlaxoSmithKline Intellectual Property Development Limited
Priority Date	12.09.2017
Details	This application claims macrocyclic salicyclamide derivatives which act as ecto-5′-nucleotidase (ecto-5'-NT, CD73) inhibitors which could be used for treating cancer and HIV, among others. The application covers a basic molecule, i.e., ecto-5′-nucleotidase (ecto-5'-NT), that are CD73 inhibitors.
Claims	The application has 25 claims, of which 1 is an independent claim and 24 are dependent. There are 4 Markush structures claimed which cover 63 specific compounds. Nineteen of the claims are secondary claims. There are 2 claims for formulations and 1 claim for dosage. There are 3 claims for use, 13 claims for methods of treatment and 2 claims for combinations. There is also 1 other claim. The claims cover over 10 diseases, including cancer (various forms), AIDS, HIV, infections, atherosclerosis and ischemia-reperfusion injury. Of the 4 Markush structures, 1 is a primary Markush structure and the other 3 are derived from it. Of the 2 formulation claims, 1 also mentions a dose range of the active ingredient and excipient. Of the 3 claims for use, 1 is drafted as a claim for compound for use. Of the 13 method of treatment claims, 2 are for combinations. Both the combination claims are drafted as method of treatment claims.
ISR	The ISR cited 2 documents as prior art, of which 1 is an A document and there is 1 other document. The “other” document referred to in the ISR is a PA document.
TPO	The TPO cited 5 prior art documents, including 1 document cited in the ISR. Two of these challenged only inventive step while 3 challenged both novelty and inventive step. One document was published after the priority date but before the filing date and challenged both novelty and inventive step. Of the prior art documents cited in the TPO, 2 were periodicals and 3 were patent documents. The ISR document used in the TPO was the P (i.e., PA) document (published after the priority date but before the filing date of the application).
Date of Filing of TPO	The TPO was filed on 13.01.2020
National Phase as of 07.10.2022	No national phase entries

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<tr><td>Appl. No.</td><td>PCT/US2018/052503 : WO2019060860</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019060860</td></tr>
<tr><td>Applicants</td><td>Suzhou Yunxuan Yiyao Keji Youxian Gongsi and Zhang Xiaohu</td></tr>
<tr><td>Priority Date</td><td>25.09.2017</td></tr>
<tr><td>Details</td><td>The application claims heteroaryl compounds that are useful in the therapies targeting C-X-C chemokine receptor type 4 (CXCR4) inhibitors, and use of these CXCR4 inhibitors for therapeutic intervention in infectious diseases, inflammatory diseases, tumours and cancers. The application covers a basic molecule which is a chemokine receptor type 4 inhibitor.</td></tr>
<tr><td>Claims</td><td>The application has 21 claims, of which 1 is an independent claim and 20 are dependent. There are 10 Markush structures claimed which cover 198 specific compounds. Three of the claims are secondary claims. There is 1 claim for formulations. There is 1 claim for use and 1 claim for combinations. The claims cover over 10 diseases, i.e., HIV infection, myocardial infarction, rheumatoid arthritis, myasthenia gravis, juvenile diabetes, glomerulonephritis, autoimmune thyroiditis, graft rejection, etc.

The claims cover hydrate, solvate, stereoisomer and tautomer forms. Of the 10 Markush structures, 1 is the primary Markush structure and the remaining 9 Markush structures are derived from it. The 1 use claim is drafted as a claim for a compound for treating various diseases.</td></tr>
<tr><td>ISR</td><td>The ISR cited 5 documents as prior art, of which all are A documents.</td></tr>
<tr><td>TPO</td><td>The TPO cited 5 prior art documents, including 1 document cited in the ISR. Two of the documents challenged only inventive step while 3 challenged both novelty and inventive step. Two were periodicals and 3 were patent documents. One of the A documents of the ISR was used as prior art in the TPO; however, instead of the US version cited in the ISR, the WO equivalent of the document was used.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 27.01.2020</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
<table>
<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>United States of America</td><td>24.03.2020</td><td>16649983</td><td>Published 30.07.2020
Granted 26.07.2022</td></tr>
<tr><td>Japan</td><td>25.03.2020</td><td>2020538760</td><td></td></tr>
<tr><td>Republic of Korea</td><td>08.04.2020</td><td>1020207010206</td><td>Published 27.05.2020</td></tr>
<tr><td>EPO</td><td>28.04.2020</td><td>2018859565</td><td>Published 05.08.2020</td></tr>
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TPO No.	56
Appl. No.	PCT/IB2018/057724 : WO2019069269
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019069269
Applicants	GlaxoSmithKline Intellectual Property Development Limited
Priority Date	05.10.2017
Details	The application claims combination of diamidobenzimidazoles (or their tautomers or salts) with one or more additional pharmaceutical agents active against HIV to treat, prevent and cure HIV. It also claims method of curing HIV with diamidobenzimidazoles (which work as STING modulators) and the use of diamidobenzimidazoles for curing HIV.
Claims	The application has 43 claims, of which 2 are independent claims and 41 are dependent. All 43 are secondary claims. There are 9 claims for use and 26 claims for combinations. There are 18 claims for method of treatment. The claims relate to HIV. The first 26 claims relate to combination of diamidobenzimidazoles (or their tautomers or salts) with one or more additional pharmaceutical agents active against HIV to treat, prevent and cure HIV. The remaining claims relate to method of curing HIV with diamidobenzimidazoles (which work as STING modulators) and the use of diamidobenzimidazoles for curing HIV. Though the applicant does not claim the diamidobenzimidazole compounds per se, it claims their combination with other agents or their subsequent use (curing HIV infection). For these secondary claims, the applicant claims diamidobenzimidazole compounds with 4 Markush structures and 15 specific compounds. Of the 4 Markush structures, 1 is the primary Markush structure (I-N) and 3 are derivative Markush structures (I, I-N-B' and I-N-b'). Among the 3 derivative Markush structures, 1 derivative (I-N-b') is a further derivative of another (I-N-B'). Amongst the diamidobenzimidazoles, it claims 10 specific compounds and geometric isomers of 4 of them. Of the 9 claims for use, 7 are directed to the combination and 2 to the compounds per se. Of the 7 use claims for combination, 4 are drafted as claims for the "combination for use". Of the 2 use claims for the compounds per se, 1 claim is for the use of diamidobenzimidazole compounds for curing HIV and 1 claim is drafted as a claim to use of the claimed diamidobenzimidazole compounds for manufacture of medicament to cure HIV. Of the 18 method of treatment claims, 3 claims are for method of preventing, treating or curing HIV using a combination; 15 are for method of curing HIV with the diamidobenzimidazole compounds. Of the 26 combination claims, 17 claims are for the combination per se, 3 claims are for method of treating, preventing or curing HIV with the claimed combination and 6 claims are for use of the claimed combination (of which 3 are drafted as claims for combinations for use).
ISR	The ISR cited 3 documents as prior art, of which 2 are A documents and 1 is another document. The “other” document in the ISR is an L document, "which may throw doubts on priority claim(s) ... or other special reason (as specified)". This document has been used in the TPO to assail novelty as it discloses the same diamidobenzimidazole compounds and their combination which form the subject matter of the present application. In the alternative, this document is cited as a PX document.
TPO	The TPO cited 3 prior art documents, including 1 document cited in the ISR. One of the documents challenged only novelty, 1 challenged only inventive step while 1 challenged both novelty and inventive step. Two of the documents were published after the priority date but before the filing date. Of the 2 documents used after the priority date, 1 is the document marked as "L" in the ISR. As per the WOSA, the application cannot claim the protection of the priority date as it is not the first filed application and the L document, being the first filed application, anticipates the claims of the present application. This document has been used in the TPO to assail novelty as it discloses the same diamidobenzimidazole compounds and their combination which form the subject matter of the present application. In the alternative, this has also been used as a PX document in the TPO. The WOSA states that as the priority document of the present application is not the first application filed for the invention, the priority claimed for the subject matter is invalid.

<table>
<tr><td></td><td>Therefore, the filing date of the present application, i.e., 4.10.2018, is the relevant priority date.

All 3 of the prior art documents cited in the TPO were patent documents, and an additional document filed with the TPO was also a patent document.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 05.02.2020</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><td>United States of America</td><td>01.04.2020</td><td>16652780</td><td>Published 05.08.2021</td></tr>
<tr><td>Japan</td><td>03.04.2020</td><td>2020519389</td><td></td></tr>
<tr><td>Australia</td><td>06.04.2020</td><td>2018344902</td><td>Published 23.04.2020</td></tr>
<tr><td>EPO</td><td>06.05.2020</td><td>2018795802</td><td></td></tr>
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<tr><td>TPO No.</td><td>58</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/054825 : WO2019074826</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019074826</td></tr>
<tr><td>Applicants</td><td>ViiV Healthcare Company</td></tr>
<tr><td>Priority Date</td><td>13.10.2017</td></tr>
<tr><td>Details</td><td>The application claims a "bi-layer tablet formulation comprising HIV integrase strand transfer inhibitor dolutegravir with the nucleoside reverse transcriptase inhibitor lamivudine".</td></tr>
<tr><td>Claims</td><td>The application has 13 claims, of which 1 is an independent claim and 12 are dependent. All 13 are secondary claims. There are 8 claims for dosage use and 13 claims for combinations.

All the 13 claims are for formulations, i.e., a bilayer tablet formulation comprising dolutegravir and lamivudine. With respect to specific forms, the 1 independent claim specifically mentions dolutegravir sodium, while all the other dependent claims only mention dolutegravir. Of the 8 dosage claims, 6 claims specifically mention the dose of the ingredients while 2 are dependent claims which impliedly include the dose limitations. Four claims for the tablets are characterised by the AUC parameters (n = 4), of which 2 are for AUC in fasted patients and 2 claims are characterised by dissolution parameters. All these are counted as formulation claims.</td></tr>
<tr><td>ISR</td><td>The ISR cited 4 documents as prior art, of which 1 is an X document and 3 are A documents. The international application was published without the ISR. The ISR (mailed 27 December 2018), search strategy and WOSA (mailed 27 December 2018) were all published after the TPO was filed.</td></tr>
<tr><td>TPO</td><td>The TPO cited 7 prior art documents. Two of the documents challenged only inventive step while 5 challenged both novelty and inventive step. Three of the prior art documents were periodicals, 2 were patent documents, 1 was a book and there was 1 other document. Three additional documents were also filed.

In the TPO, the 1 "other" prior art document used was a conference proceeding (for which both the eposter and oral abstract were uploaded). Of the 3 additional documents filed, 2 were US FDA labels for the active ingredients. The other was, as mentioned above, the oral abstract of the conference proceeding.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 13.02.2020</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
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<tr><td>Autralia</td><td>31.03.2020</td><td>2018347990</td><td>Published 23.04.2020</td></tr>
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<tr><td>Canada</td><td>06.04.2020</td><td>3078624</td><td></td></tr>
<tr><td>China</td><td>10.04.2020</td><td>201880066314.8</td><td>Published 05.06.2020</td></tr>
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<tr><td>EPO</td><td>13.05.2020</td><td>2018866268</td><td></td></tr>
<tr><td>Russian Federation</td><td>13.05.2020</td><td>2020118376</td><td>Published 16.10.2020</td></tr>
<tr><td>Mexico</td><td>13.07.2020</td><td>MX/a/2020/003377</td><td>Published 16.10.2020</td></tr>
<tr><td>Brazil</td><td>15.09.2020</td><td>112020006783</td><td></td></tr>
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<tr><td>TPO No.</td><td>59</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/055554 : WO2019075291</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019075291</td></tr>
<tr><td>Applicants</td><td>Gilead Sciences, Inc.</td></tr>
<tr><td>Priority Date</td><td>13.10.2017</td></tr>
<tr><td>Details</td><td>The application claims oxoimidazolidine derivatives and their salts as HIV protease inhibitors. It also claims pharmaceutical compositions thereof and methods for treating HIV and also combinations with other anti-HIV agents. The application covers a basic molecule.</td></tr>
<tr><td>Claims</td><td>The application has 53 claims, of which 7 are independent claims and 46 are dependent claims. There are 5 Markush structures covering 372 specific compounds. There are 8 secondary claims. There are 6 formulation claims, 2 method of treatment claims and 6 claims for combinations. All claims relate to HIV.

Of the 5 Markush structures, 1 is the primary Markush structure (Formula I) and 4 are derivative Markush structures (Formula Ia to Id). The primary Markush structure is claimed in both Claims 1 and 2 but has been counted only once. Of the 6 formulation claims, 1 claim is for a pharmaceutical composition per se and 5 claims are for pharmaceutical compositions comprising 1 to 4 additional therapeutic agents. One claim specifically claims only tenofovir and its various forms as the additional agent. Of the 2 method of treatment claims, 1 claim is for a method of treatment with the claimed compound and 1 claim is for method of treatment in combination with 1 to 4 additional therapeutic agents.</td></tr>
<tr><td>ISR</td><td>The ISR cited 2 documents as prior art, of which 1 is an A document and 1 is another document. The 1 "other" document cited in the ISR is an AP document.</td></tr>
<tr><td>TPO</td><td>The TPO cited 3 prior art documents. Two of the documents challenged only inventive step while 1 challenged both novelty and inventive step. Of the prior art documents cited in the TPO, 1 was a periodical and 2 were patent documents. One additional document was filed.

The additional document is a PX document in futher support of a prior art patent document. Thus, a PX document was not added as a standalone prior art document, but was referred to in another note.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 13.02.2020</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><td>Eurasian Patent Organization</td><td>17.03.2020</td><td>202090530</td><td>Published 30.10.2020
Withdrawn 12.10.2021</td></tr>
<tr><td>Canada</td><td>23.03.2020</td><td>3076761</td><td></td></tr>
<tr><td>Australia</td><td>26.03.2020</td><td>2018347541</td><td>Published 16.04.2020</td></tr>
<tr><td>New Zealand</td><td>26.03.2020</td><td>762995</td><td>Published 27.03.2020</td></tr>
<tr><td>Costa Rica</td><td>01.04.2020</td><td>CR2020-000149</td><td>Published 22.05.2020</td></tr>
<tr><td>Israel</td><td>06.04.2020</td><td>273842</td><td></td></tr>
<tr><td>Thailand</td><td>08.04.2020</td><td>2001002000</td><td></td></tr>
<tr><td>China</td><td>10.04.2020</td><td>201880066480.8</td><td>Published 29.05.2020</td></tr>
<tr><td>Japan</td><td>10.04.2020</td><td>2020520483</td><td></td></tr>
<tr><td>Philippines</td><td>13.04.2020</td><td>12020550256</td><td></td></tr>
<tr><td>Dominican Republic</td><td>06.05.2020</td><td>DOP2020000078</td><td>Published 15.10.2020</td></tr>
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	Republic of Korea	12.05.2020	1020207013543	Published 18.06.2020
	EPO	13.05.2020	2018796285	
	Ukraine	13.05.2020	A202001859	Published 25.06.2020 Withdrawn 24.09.2021
	Peru	15.05.2020	000525-2020	Published 29.12.2020
	Mexico	13.07.2020	MX/a/2020/003430	Published 13.08.2020

TPO No.	65
Appl. No.	PCT/US2018/066744 : WO2019126464
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019126464
Applicants	Lentigen Technology, Inc.
Priority Date	20.12.2017
Details	The application claims nucleic acid and amino acid sequences for chimeric antigen receptors (CARs) containing HIV envelope antigen binding domains (mD1.22, m36.4 and/or C46). It also claims recombinant expression vectors, host cells, antigen binding fragments and pharmaceutical compositions relating to the CARs and methods of treating or preventing HIV infection in a subject, and methods of making CAR-T cells. This application covers a biologic.
Claims	The application has 42 claims, of which 4 are independent claims and 38 are dependent. Twelve are secondary claims, 6 are formulation claims and 5 are claims for method of treatment. All 42 claims are for combinations. There are also 4 other claims. The claims cover more than 10 diseases including HIV, cancer and HIV-associated diseases. Of the 6 formulation claims, 3 are for pharmaceutical compositions per se (i.e., 1 independent claim for composition comprising an anti-HIV effective amount of a population of human T cells, wherein the T cells comprise a nucleic acid sequence that encodes a CAR, and 2 dependent claims including 1 for the transmembrane domain of the claimed CAR) and 3 claims are method of treatment claims for treating HIV, cancer disorder or condition associated with an elevated expression of an HIV-1 envelope antigen by administration of the claimed pharmaceutical composition (i.e., 2 independent claims and 1 dependent claim for the transmembrane domain of the claimed CAR). Of the 5 method of treatment claims, 1 claim is a method for providing an anti-HIV immunity in a mammal by administration of the claimed T cell, 1 claim is a method of treating or preventing HIV-1 by administration of the claimed CAR to the mammal, and the other 3 claims are for method of treatment claims for treating HIV/AIDS, cancer disorder or condition associated with an elevated expression of an HIV-1 envelope antigen by administration of the claimed pharmaceutical composition. Of the 4 "other" claims, 2 claims are for a process to produce CAR-expressing cell, 1 claim is for making a cell by transduction of a T cell with a vector comprising a promoter, and 1 claim is a method for generating a population of RNA engineered cells. The application claims CAR molecules (bispecific and trispecific mono and duo CAR) comprising at least one extracellular antigen binding domain comprising an anti-HIV envelope antigen binding domain (mD1.22, m36.4 and/or C46) encoded by nucleotide sequences and amino acid sequences, at least one transmembrane domain and at least one intracellular signalling domain. The applicant claims that the claimed pharmaceutical composition is for treating cancer or diseases, disorders or conditions with an elevated expression of HIV-1 envelope antigen. Also, in the description these AIDS defining diseases have been listed. Therefore, the number of diseases is considered as >10.
ISR	The ISR cited 7 documents as prior art, of which 6 are A documents and 1 is a PX document. The application was initially published without the ISR (A2). The later published A3 version on 08.08.2019 was published along with the ISR.
TPO	The TPO cited 8 prior art documents. Six of these challenged only inventive step and 2 challenged both novelty and inventive step. One of the documents challenging inventive step was after the priority date but before the filing date. Of the prior art documents cited in the TPO, 4 were periodicals and 4 were patent documents. Four additional documents were filed with the TPO. Of the 4 additional documents, a periodical and a patent document were uploaded in support of a periodical article (i.e., n = 2) and 1 periodical article was uploaded to support a periodical article (n = 1). The other additional document, a comparative table, was uploaded to show the similarity in disclosures between the prior art patent document and the claims of the application.
Date of Filing of TPO	The TPO was filed on 20.04.2020

National Phase as of 07.10.2022

Office	Entry Date	National Number	National Status
Canada	19.06.2020	3086612	
Japan	19.06.2020	2020534253	
EPO	20.07.2020	2018890907	
China	18.08.2020	201880089736.7	Published 17.11.2020

Part B: Case Summaries – HCV Applications

TPO No.	1
Appl. No.	PCT/CN2017/096814 : WO2018028634
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018028634
Applicants	Sunshine Lake Pharma Co. Ltd
Priority Date	11.08.2016
Details	The application is for salt forms of known compound previously described in a patent document. The said compound exhibits inhibitory activity against HCV NS3/4A protein. Thus, this is an application for HCV.
Claims	The application has 13 claims, all of which are secondary claims. There are 2 independent claims, 1 for the base addition salt and 1 for the acid addition salt of the compound. There are 4 claims that specifically claim the salt forms. As the patent application is for salt forms, apart from the 4 specific claims for the salts, all other claims (including formulations, use, method of treatment, etc.) too claim the compound in the salt form. There are 9 formulation claims, 8 combination claims, 4 claims for use and 2 claims for method of treatment. Of the 9 formulation claims, 3 claims are for pharmaceutical compositions per se, 4 claims claim use of the composition (apart from use of the salts) and 2 claim method of treatment with the composition (apart from method of treating with the salts). Of the 8 combination claims, 2 claims are specifically for compositions (i.e., formulations) of such combinations, 4 claims claim use of combinations (apart from use of the salts of the claimed compound) and 2 claims claim method of treatment using the combination (apart from method of treating with the salts of the claimed compound).
ISR	The ISR, WOSA and International Preliminary Report on Patentability (IPRP) have been published; the State Intellectual Property Office of the P.R. China is the ISA. The ISR has 3 documents, of which 2 attacked the novelty of all the claims and an additional document (published after the priority date, but before the filing date) too attacked the novelty of all the claims. Though the search strategy has not been separately published, the ISR lists the electronic databases searched as well as the search terms used.
TPO	The TPO cited 7 documents, none of which were cited in the ISR. The TPO has 2 documents that assail the lack of inventive step and 5 documents that assail the lack of novelty and/or inventive step of the claims made in the application. The TPO used 5 articles published in periodicals and 2 patent documents. The TPO introduced general journal articles relating to salt selection that show the state of the art in the field.
Date of Filing of TPO	The TPO was filed on 11.12.2018.
National Phase as of 07.10.2022	No national phase entries.

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<tr><td>TPO No.</td><td>11</td></tr>
<tr><td>Appl. No.</td><td>PCT/EP2018/051110: WO2018134254</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018134254</td></tr>
<tr><td>Applicants</td><td>Heparegenix GMBH</td></tr>
<tr><td>Priority Date</td><td>17.01.2017</td></tr>
<tr><td>Details</td><td>The application is for basic molecules that are MKK4 (mitogen activated protein kinase 4) inhibitors for promoting liver regeneration or reducing or preventing hepatocyte death. The claimed MKK4 inhibitors are alleged to selectively inhibit protein kinase MKK4 over protein kinases JNK and MKK7.

This is an application for HCV and more than 10 other diseases, such as Hep B, E, autoimmune hepatitis, alcoholic hepatitis, primary biliary cirrhosis and other liver diseases.</td></tr>
<tr><td>Claims</td><td>Of the 29 claims, 2 are independent claims and 27 are dependent claims. The independent claims also claim the pharmaceutically acceptable salts, solvates and optical isomers thereof. Subsequent dependent claims and secondary claims too claim the compounds, pharmaceutically acceptable salts, solvates and optical isomers thereof.

The application claims 2 Markush structures and 84 specific compounds. Of the 2 Markush structures claimed, 1 is a derivative of the other.

There are 11 secondary claims, of which 7 claims are for use and 1 each for method of treatment, formulation and dosage. The 1 “other” claim is a claim which characterises the claimed compounds by the mechanism of action. It has not been counted as a method of treatment claim.</td></tr>
<tr><td>ISR</td><td>The ISR, WOSA and IPRP have been published; the European Patent Office, Rijswijk, Netherlands, is the ISA.

The ISR has 2 X documents.

The search strategy has been published. It indicates a search using the IPC codes.</td></tr>
<tr><td>TPO</td><td>The TPO does not refer to any of the documents cited in the ISR.

The TPO refers to 5 documents, of which 2 are used only for novelty and 3 are used for both novelty and inventive step. Of the 5 documents, 2 are periodicals and 3 are patent documents.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 15.05.2019.</td></tr>
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<tr><td>Mexico</td><td>15.07.2019</td><td>MX/a/2019/008458</td><td>Published 14.01.2020
Granted 07.07.2022</td></tr>
<tr><td>United States of America</td><td>15.07.2019</td><td>16478006</td><td>Published 05.12.2019
Granted 22.06.2021</td></tr>
<tr><td>Japan</td><td>16.07.2019</td><td>2019559391</td><td></td></tr>
<tr><td>China</td><td>17.07.2019</td><td>201880007339.0</td><td>Published 27.09.2019
Granted 27.05.2022</td></tr>
<tr><td>Brazil</td><td>23.07.2019</td><td>112019014593</td><td></td></tr>
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	Australia	29.07.2019	2018209164	Published 15.08.2019
	India	29.07.2019	201947030479	Published 09.08.2019
	New Zealand	29.07.2019	755835	Published 30.08.2019
	EPO	19.08.2019	2018702425	Granted 22.06.2022

<table>
<tr><td>TPO No.</td><td>15</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/016301: WO2018144640</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018144640</td></tr>
<tr><td>Applicants</td><td>Atea Pharmaceuticals, Inc</td></tr>
<tr><td>Priority Date</td><td>01.02.2017</td></tr>
<tr><td>Details</td><td>The application is an application for a salt form.

It claims the hemisulphate salt of a known modified guanosine nucleotide prodrug for the treatment of hepatitis C virus and for HCV-related diseases such as HCV-related chronic liver inflammation, liver cancer, cirrhosis and fatigue.

The basic molecule is an NS5B polymerase inhibitor. The NS5B polymerase inhibitor is AT511 (prodrug) and the hemisulphate form is now identified as AT527. It is now also being explored for COVID-19.</td></tr>
<tr><td>Claims</td><td>All the 77 claims are secondary claims, of which 7 are independent and 70 are dependent claims.

Of the 77 claims, 36 are for formulations, 4 are for various forms (i.e., hemisulphate salt and crystalline form thereof), 27 are for dosage, 9 are use claims, 28 are method of treatment claims, 5 are combination claims and 18 are other claims.

Of the 3 claims that characterise the crystalline form, 2 claims characterise the crystalline form claimed in terms of storage conditions.

Of the 27 dosage claims, 9 overlap as formulation claims. Fourteen of the dosage claims overlap as method of treatment claims. Four of the dosage claims overlap as use claims.

Twelve claims characterise the salt form or metabolite with steady state trough plasma values and 6 claims characterise the AUC of the metabolite.</td></tr>
<tr><td>ISR</td><td>The ISR, WOSA and IPRP have been published; the USPTO is the ISA.

The ISR has 7 documents, of which 4 are Y documents and 3 are A documents.

The search strategy has been published. The search strategy indicates a focus on sulphuric acid of nucleoside or nucleotide and phosphoramide and guanosine.</td></tr>
<tr><td>TPO</td><td>The TPO cites 5 documents, including 1 patent document cited in the ISR.

The ISR document used in the TPO is an earlier patent document of the applicant. The TPO refers to the WO equivalent of the US patent document referred to in the ISR.

In the TPO, 4 of the documents are cited only for inventive step and 1 is cited for both novelty and inventive step. Of the 5 documents, 3 are periodicals and 2 are patent documents. The 3 periodical articles are articles that set out the general state of the art regarding salts and solid states.

The applicant has filed a response to the TPO. The response is primarily with regard to the compound not ever having been used in the hemisulphate form which is being claimed. The applicant denies that using the hemisulphate form is obvious to a person skilled in the art.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 03.06.2019.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><td>New Zealand</td><td>28.06.2019</td><td>754996</td><td>Published 26.07.2019
Divisional15.09.2021
Granted 28.06.2022</td></tr>
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Singapore	02.07.2019	11201906163T	
Israel	15.07.2019	295609	Divisional 14.08.2022
Ukraine	19.07.2019	A201907086	Published 10.01.2020
India	23.07.2019	201917029812	
Brazil	30.07.2019	112019014738	
Japan	30.07.2019	2019541346	
Mexico	31.07.2019	MX/a/2019/009114	Published 11.11.2019 Granted 01.08.2022
China	01.08.2019	201880009871.6	Published 17.09.2019
Eurasian Petent Organisation	29.08.2019	201991810	Published 31.01.2020
EPO	02.09.2019	2018747587	
Russian Federation	02.09.2019	2019127284	Published 02.03.2021
Republic of Korea		1020217039328	Published 13.12.2021

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<tr><td>Applicants</td><td>Metacrine, Inc.</td></tr>
<tr><td>Priority Date</td><td>15.03.2017</td></tr>
<tr><td>Details</td><td>The application is for a basic molecule, i.e., farnesoid X receptor agonists for the treatment of HCV and more than 10 other diseases such as HIV-associated steatohepatitis and cirrhosis, gastrointestinal diseases, ulcerative colitis, non-alcoholic steatohepatitis (NASH), biliary cirrhosis, Crohn’s disease, etc.

The applicant filed 5 applications pertaining to farsenoid X receptors on the same date. The scaffolds claimed in the present application are very similar to the scaffolds described in Metacrine’s other applications WO’166, WO’167, WO’173 and WO’182, with only minor changes in the substituents substituted.</td></tr>
<tr><td>Claims</td><td>Of the 55 claims, 2 are independent claims and 53 are dependent claims.

The application claims 10 Markush structures and 94 specific compounds. Of the 10 Markush structures, 1 is the primary Markush structure and the remaining 9 Markush structures are derived from it. The application discloses 1 more Markush structure (Formula X). However, this is not claimed.

The application also claims pharmaceutically acceptable salts and solvates of the claimed compounds.

There are 25 secondary claims, of which 3 are formulation claims, 22 are method of treatment claims and 1 is a combination claim (drafted as a method of treatment claim; there is no claim for a combination per se).</td></tr>
<tr><td>ISR</td><td>The ISR, WOSA and IPRP have been published; the Korean Intellectual Property Office is the ISA.

The ISR cites 5 documents, of which 2 are X documents, 2 are A documents and 1 is a PX document.

Though the search strategy has not been separately published, the ISR lists the electronic databases searched as well as the search terms used.</td></tr>
<tr><td>TPO</td><td>The TPO cites 5 documents, of which 2 were also cited in the ISR. Of these 5 documents, 1 document is used to assail novelty (a PX document) and the other 4 are used to assail inventive step. Of the documents cited, 1 is a periodical and the other 4 are patent documents.

In the TPO, the novelty ground is based on a PX document.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 15.07.2019.</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018170166</td></tr>
<tr><td>Applicants</td><td>Metacrine, Inc.</td></tr>
<tr><td>Priority Date</td><td>15.03.2017</td></tr>
<tr><td>Details</td><td>The application is for a basic molecule, i.e., farnesoid X receptor agonists for the treatment of HCV and more than 10 other diseases such as HIV-associated steatohepatitis and cirrhosis, gastrointestinal diseases, ulcerative colitis, non-alcoholic steatohepatitis (NASH), biliary cirrhosis, Crohn’s disease, etc.

The applicant filed 5 applications pertaining to farsenoid X receptors on the same date. The scaffolds claimed in the present application are very similar to the scaffolds described in Metacrine’s other applications WO’165, WO’167, WO’173 and WO’182, with only minor changes in the substituents substituted.</td></tr>
<tr><td>Claims</td><td>Of the 57 claims, 2 are independent claims and 55 are dependent claims.

The application claims 10 Markush structures and 65 specific compounds. Of the 10 Markush structures, 1 is the primary Markush structure and the remaining 9 Markush structures are derived from it. The application discloses 1 more Markush structure (Formula X). However, this is not claimed.

The application also claims pharmaceutically acceptable salts and solvates of the claimed compounds.

There are 25 secondary claims, of which 3 are formulation claims, 22 are method of treatment claims and 1 is a combination claim (drafted as a method of treatment claim; there is no claim for a combination per se).</td></tr>
<tr><td>ISR</td><td>The ISR, WOSA and IPRP have been published; the Korean Intellectual Property Office is the ISA.

The ISR cites 5 documents, of which 2 are X documents, 2 are A documents and 1 is a PX document.

Though the search strategy has not been separately published, the ISR lists the electronic databases searched as well as the search terms used.</td></tr>
<tr><td>TPO</td><td>The TPO cites 5 documents, of which 2 were also cited in the ISR. Of these 5 documents, 1 document is used to assail novelty (a PX document) and the other 4 are used to assail inventive step. Of the documents cited, 1 is a periodical and the other 4 are patent documents.

In the TPO, the novelty ground is based on a PX document.</td></tr>
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Granted 30.03.2021</td></tr>
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<tr><td>Applicants</td><td>Metacrine, Inc.</td></tr>
<tr><td>Priority Date</td><td>15.03.2017</td></tr>
<tr><td>Details</td><td>The application is for a basic molecule, i.e., farnesoid X receptor agonists for the treatment of HCV and more than 10 other diseases such as HIV-associated steatohepatitis and cirrhosis, gastrointestinal diseases, ulcerative colitis, non-alcoholic steatohepatitis (NASH), biliary cirrhosis, Crohn’s disease, etc.

The applicant filed 5 applications pertaining to farsenoid X receptors on the same date. The scaffolds claimed in the present application are very similar to the scaffolds described in Metacrine’s other applications WO’165, WO’166, WO’173 and WO’182, with only minor changes in the substituents substituted.</td></tr>
<tr><td>Claims</td><td>Of the 70 claims, 2 are independent claims and 68 are dependent claims.

The application claims 5 Markush structures and 104 specific compounds. Of the 5 Markush structures, 1 is the primary Markush structure and the remaining 4 Markush structures are derived from it.

The application also claims pharmaceutically acceptable salts and solvates of the claimed compounds.

There are 24 secondary claims, of which 3 are formulation claims, 21 are method of treatment claims and 1 is a combination claim (drafted as a method of treatment claim; there is no claim for a combination per se).</td></tr>
<tr><td>ISR</td><td>The ISR, WOSA and IPRP have been published; the Korean Intellectual Property Office is the ISA.

The ISR cites 5 documents, of which 2 are X documents, 2 are A documents and 1 is a PX document.

Though the search strategy has not been separately published, the ISR lists the electronic databases searched as well as the search terms used.</td></tr>
<tr><td>TPO</td><td>The TPO cites 5 documents, of which 2 were also cited in the ISR. Of these 5 documents, 1 document is used to assail novelty (a PX document) and the other 4 are used to assail inventive step. Of the documents cited, 1 is a periodical and the other 4 are patent documents.</td></tr>
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<tr><td>Applicants</td><td>Metacrine, Inc.</td></tr>
<tr><td>Priority Date</td><td>15.03.2017</td></tr>
<tr><td>Details</td><td>The application is for a basic molecule, i.e., farnesoid X receptor agonists for the treatment of HCV and more than 10 other diseases such as HIV-associated steatohepatitis and cirrhosis, gastrointestinal diseases, ulcerative colitis, non-alcoholic steatohepatitis (NASH), biliary cirrhosis, Crohn’s disease, etc.

The applicant filed 5 applications pertaining to farsenoid X receptors on the same date. The scaffolds claimed in the present application are very similar to the scaffolds described in Metacrine’s other applications WO’165, WO’166, WO’167 and WO’182, with only minor changes in the substituents substituted.</td></tr>
<tr><td>Claims</td><td>Of the 62 claims, 2 are independent claims and 60 are dependent claims.

The application claims 9 Markush structures and 85 specific compounds. Of the 9 Markush structures, 1 is the primary Markush structure and the remaining 8 Markush structures are derived from it. The application discloses 2 more Markush structures (Formula XI and XII). However, these are not claimed.

The application also claims pharmaceutically acceptable salts and solvates of the claimed compounds.

There are 25 secondary claims, of which 3 are formulation claims, 22 are method of treatment claims and 1 is a combination claim (drafted as a method of treatment claim; there is no claim for a combination per se).</td></tr>
<tr><td>ISR</td><td>The ISR, WOSA and IPRP have been published; the Korean Intellectual Property Office is the ISA.

The ISR cites 5 documents, of which 2 are X documents, 2 are A documents and 1 is a PX document.

Though the search strategy has not been separately published, the ISR lists the electronic databases searched as well as the search terms used.</td></tr>
<tr><td>TPO</td><td>The TPO cites 5 documents, of which 2 were also cited in the ISR. Of these 5 documents, 1 document is used to assail novelty (a PX document) and the other 4 are used to assail inventive step. Of the documents cited, 1 is a periodical and the other 4 are patent documents.</td></tr>
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<tr><td>Applicants</td><td>Metacrine, Inc.</td></tr>
<tr><td>Priority Date</td><td>15.03.2017</td></tr>
<tr><td>Details</td><td>The application is for a basic molecule, i.e., farnesoid X receptor agonists for the treatment of HCV and more than 10 other diseases such as HIV-associated steatohepatitis and cirrhosis, gastrointestinal diseases, ulcerative colitis, non-alcoholic steatohepatitis (NASH), biliary cirrhosis, Crohn’s disease, etc.

The applicant filed 5 applications pertaining to farsenoid X receptors on the same date. The scaffolds claimed in the present application are very similar to the scaffolds described in Metacrine’s other applications WO’165, WO’166, WO’167 and WO’173, with only minor changes in the substituents substituted.</td></tr>
<tr><td>Claims</td><td>Of the 70 claims, 2 are independent claims and 68 are dependent claims.

The application claims 9 Markush structures and 540 specific compounds. Of the 9 Markush structures, 1 is the primary Markush structure and the remaining 8 Markush structures are derived from it.

The application also claims pharmaceutically acceptable salts and solvates of the claimed compounds.

There are 25 secondary claims, of which 3 are formulation claims, 22 are method of treatment claims and 1 is a combination claim (drafted as a method of treatment claim; there is no claim for a combination per se).</td></tr>
<tr><td>ISR</td><td>The ISR, WOSA and IPRP have been published; the Korean Intellectual Property Office is the ISA.

The ISR cites 5 documents, of which 2 are X documents, 2 are A documents and 1 is a PX document.

Though the search strategy has not been separately published, the ISR lists the electronic databases searched as well as the search terms used.</td></tr>
<tr><td>TPO</td><td>The TPO cites 5 documents, of which 2 were also cited in the ISR. Of these 5 documents, 1 document is used to assail novelty (a PX document) and the other 4 are used to assail inventive step. Of the documents cited, 1 is a periodical and the other 4 are patent documents.

In the TPO, the novelty ground is based on a PX document.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 15.07.2019.</td></tr>
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<tr><td>Brazil</td><td>24.09.2019</td><td>112019019154</td><td></td></tr>
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	India		20191741302	Published 22.11.2019

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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018196823</td></tr>
<tr><td>Applicants</td><td>Birdie Biopharmaceuticals, Inc. and Zeng Zhaohui</td></tr>
<tr><td>Priority Date</td><td>27.04.2017</td></tr>
<tr><td>Details</td><td>The application claims 2-amino-quinoline derivatives that are agonists of toll-like receptors 7 and 8 (TLR7/8), its pharmaceutical compositions, and methods of use of the compounds and compositions to treat various diseases, such as viral diseases, cancer and allergic diseases, including HCV infection.</td></tr>
<tr><td>Claims</td><td>The application has 43 claims, of which 4 are independent claims and 39 dependent claims. There are 4 Markush structures – 1 is the main Markush structure and 3 are derived from the main structure. About 47 specific compounds have been claimed, and additionally optionally substituted compounds have also been claimed. There are 4 secondary claims, of which 1 is for a formulation (that includes the dosage too), 1 is for the use of the compounds and 2 are for method of treatment. The compounds claimed are for treatment of three broad categories of diseases – viral diseases, cancer and allergies, and specifically HCV too.</td></tr>
<tr><td>ISR</td><td>The ISR/WOSA/IPRP were published, with the State Intellectual Property Office of the P.R. of China being the office of ISA. The ISR contains 3 general documents.</td></tr>
<tr><td>TPO</td><td>The TPO contained 3 documents, 1 of which would affect inventive step and 2 would affect both novelty and inventive step of the claims in the application. Two of the prior art documents referred to in the TPO were periodical articles and 1 was a patent document. An additional document was attached in support of the prior art annexed.</td></tr>
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<tr><td>New Zealand</td><td>04.10.2019</td><td>757892</td><td>Published 25.10.2019</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsfdocId=WO2018209354</td></tr>
<tr><td>Applicants</td><td>Enanta Pharmaceuticals, Inc.</td></tr>
<tr><td>Priority Date</td><td>12.05.2017</td></tr>
<tr><td>Details</td><td>The application claims compounds with a parent Markush structure which inhibit the apoptosis signal-regulating kinase 1 (ASK-1), which is associated with autoimmune disorders, neurodegenerative disorders, inflammatory diseases, chronic kidney disease and cardiovascular disease. More specifically, ASK-1 has been associated with hepatic steatosis, including non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). The parent Markush structure comprises a pyridine or phenyl ring which at position 2 is substituted with an amide group which is further attached to a 5 or 6 membered heteroaryl ring (A) which itself is further attached to a 5 membered ring comprising 2, 3 or 4 nitrogen atoms (R). The central pyridine or phenyl ring is also substituted at position 4 with an imidazole ring, which itself is further substituted (R3); and is also substituted at position 5 (R2) (claim 1 of WO’354). Also, to note that all claimed Markush scaffolds and compounds are derived from a known Gilead molecule selonsertib (primary indication: non-alcoholic steatohepatitis); wherein the only difference between this known compound and compounds of the present application are minor modifications to the substituents attached on the peripheral ring.</td></tr>
<tr><td>Claims</td><td>The application has 26 claims (1 independent and 25 dependent claims), of which 13 are secondary claims wherein 1 claim is for formulation, 1 is for use and 11 for method of treatment. Of the 37 Markush structures, 1 is an independent structure and the remaining 36 are dependent. The 36 derivative Markush structures are classified into 9 groups/families, each containing 4 variations (i.e., Formulae Ia to Id, IIa-1 to IIa-4, IIb-1 to IIb-4, IVa-1 to IVa-4, IVb-1 to IVb-4, Va-1 to Va-4, Vb-1 to Vb-4, VIa-1 to VIa-4, VIb-1 to VIb-4).The applicant claims 600 specific compounds in one claim. The applicant also claims pharmaceutically acceptable salt and esters of these claimed compounds. There is one other claim which claims 71 specific compounds. But, as per the trend of subsequent applications, these 71 should be a subset of the 600 specific compounds previously claimed. This has not been verified by cross-checking each of the compounds.</td></tr>
<tr><td>ISR</td><td>The ISR comprises 5 documents, of which 2 have been listed for inventive step (Y) and 3 documents are as listed to describe only the general state of the art and not considered to be of particular relevance (A). For all 4 of the Enanta applications (see below), the ISR has been authored by the same ISA.</td></tr>
<tr><td>TPO</td><td>The TPO was filed on 12.09.2019 and comprised 3 prior art documents. Of the 3 documents, 1 document was not uploaded to the WIPO website. Two of the 3 documents were patent applications and 1 was a periodical article. Also, 2 documents (i.e., patent documents) were used for both novelty and inventive step and 1 periodical article was used only for inventive step.</td></tr>
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	Republic of Korea	09.12.2019	1020197036358	Published 21.01.2020
	India	10.12.2019	201947051124	Published 13.12.2019
	EPO	12.12.2019	2018798479	
	Russian Federation	12.12.2019	2019140447	Published 15.06,2021
	China	07.01.2020	201880045573.2	Published 06.03.2020

TPO No.	36
Appl. No.	PCT/US2018/034429: WO2018218044
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsfdocId=WO2018218044
Applicants	Enanta Pharmaceuticals, Inc.
Priority Date	25.05.2017
Details	The application claims compounds with a parent Markush structure which inhibit the apoptosis signal-regulating kinase 1 (ASK-1), which is associated with autoimmune disorders, neurodegenerative disorders, inflammatory diseases, chronic kidney disease and cardiovascular disease. More specifically, ASK-1 has been associated with hepatic steatosis, including non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). The parent Markush structure comprises a 5+6 bicyclic fused ring wherein the 5 membered ring may contain up to 2 heteroatoms and the 6 membered ring may either be a phenyl or pyridine ring. The 6 membered ring of the bicyclic ring is attached to an amide group which is further attached to a heteroaryl ring containing up to 3 nitrogen atoms, which itself is further substituted (R1, R2). The 5 membered ring of the bicyclic ring is also further substituted (R3) (claim 1 of WO'044). Compounds derived from the above parent Markush structure act on an identical target ASK-1 and are claimed for the purpose of treating disorders/diseases relating to liver dysfunction as in the previous application WO'354. Also, the parent Markush structure and compounds claimed in the present application WO'044 are similar to the Markush structures claimed in Enanta's 3 other applications. However, the closest structural similarity can be found with the Markush structure of WO'354 wherein the parent Markush structure is comprised of a central phenyl/pyridine ring (6 membered ring) substituted with an imidazole ring, which has been replaced in the present application with a bicyclic ring structure containing phenyl/pyridine ring fused to an imidazole ring (or oxazole, thiazole rings) at an analogous position.
Claims	The application has 30 claims (1 independent and 29 dependent claims), of which 14 are secondary claims wherein 2 claims are for formulation, 1 is for use and 11 for method of treatment. Of the 25 Markush structures, 1 is the primary Markush structure (Formula I) and 24 are derivative Markush structures. Of the 24 derivative Markush structures, 8 are Markush structures (IIa-h) belonging to Formula II and another 4 are Markush structures (IIIa-d) belonging to Formula III. The applicant claims 738 specific compounds and pharmaceutically acceptable salts thereof. There is one further claim which claims 75 specific compounds. These 75 should be a subset of the 738 specific compounds previously claimed. This has been verified by cross-checking each of the compounds.
ISR	The ISR comprises 3 documents; all of them listed to describe only the general state of the art and not considered to be of particular relevance (A). The application was initially published as an A2 document without the ISR; it was based on this that the TPO was filed. After the TPO was filed, the ISR was made available in the documents section of the application on 06.03.2020. Also, even though there is 1 common document referred to by both the TPO and the ISR, this has not been included in "No. of ISR documents used in TPO". For all 4 of the Enanta applications, the ISR has been authored by the same ISA. Of the four, 3 of these applications (i.e., WO'042, WO'044 and WO'051) comprise a central fused ring in the scaffold; for these 3 applications, the prior art documents listed in the ISRs are identical.
TPO	The TPO was filed on 24.09.2019 and comprises 4 prior art documents. Of the 4 documents, 1 document was not uploaded to the WIPO website. Three of the 4 documents were patent applications and 1 was a periodical article. Also, 2 documents (i.e., patent documents) were used for both novelty and inventive step and 2 documents (patent and periodical article each) were used only for inventive step. A single patent document, i.e., WO2016049069, was used as a prior art document in both the present application and the previous application WO'354. Also, all 4 prior art documents used in the TPO of the present application were also been used in 2 other Enanta applications, WO'042 and WO'051.
Date of Filing of TPO	The TPO was filed on 24.09.2019.

National Phase as of 07.10.2022	No national phase entries

TPO No.	37
Appl. No.	PCT/US2018/034423: WO2018218042
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsfdocId=WO2018218042
Applicants	Enanta Pharmaceuticals, Inc.
Priority Date	25.05.2017
Details	The application claims compounds with a parent Markush structure which inhibit the apoptosis signal-regulating kinase 1 (ASK-1), which is associated with autoimmune disorders, neurodegenerative disorders, inflammatory diseases, chronic kidney disease and cardiovascular disease. More specifically, ASK-1 has been associated with hepatic steatosis, including non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). The parent Markush structure comprises a 6 + 6 bicyclic fused ring wherein a 6 membered aromatic ring containing up to 2 nitrogen atoms is fused to another 6 membered ring (either a phenyl or pyridine ring). The phenyl/pyridine ring of the bicyclic ring is attached to an amide group which is further attached to a heteroaryl ring containing up to 3 nitrogen atoms which itself is further substituted (R1, R2). The other 6 membered ring of the bicyclic ring is also further substituted (R3 and R4) (claim 1 of WO'042). Compounds derived from the above parent Markush structure act on an identical target ASK-1 and are claimed for the purpose of treating disorders/diseases relating to liver dysfunction as in the previous applications WO'354 and WO'044. Also, the parent Markush structure and compounds claimed in the present application WO'042 are similar to the Markush structures claimed in the other three Enanta applications. However, the closest structural similarity can be found with the Markush structure of WO'044 wherein the scaffold also comprises a central phenyl/pyridine ring (6 membered ring). However, in WO'044 this central ring is fused to an imidazole ring (or oxazole, thiazole rings) a 5 membered ring containing 2 nitrogen atoms which has been replaced in the present application, with a 6 membered pyrimidine ring also containing 2 nitrogen atoms.
Claims	The application has 36 claims (1 independent and 35 dependent claims), of which 14 are secondary claims wherein 2 claims are for formulation, 1 is for use and 11 for method of treatment. Of the 35 Markush structures, 1 is the primary Markush structure (Formula I) and 34 are derivative Markush structures. Of the 34 derivative Markush structures, 8 are Markush structures (IIa-h) belonging to Formula II and another 8 are Markush structures (IIIa-h) belonging to Formula III. The applicant claims 1440 specific compounds and pharmaceutically acceptable salts and esters thereof. There is one further claim which claims 41 specific compounds. These 41 should be a subset of the 1440 specific compounds previously claimed. This has been verified by cross-checking each of the compounds.
ISR	The ISR comprises 3 documents, all of them listed to describe only the general state of the art and not considered to be of particular relevance (A). For all 4 of the Enanta applications, the ISR has been authored by the same ISA; and for 3 of these applications (i.e., WO'042, WO'044 and WO'051) which comprise a central fused ring in the scaffold, the prior art documents listed in the ISR are identical. However, at the time of filing the TPO for WO'042, the ISR was available, unlike with the previous described application WO'044. One of the documents (US 8378108 by Gilead Sciences Inc.) listed in the ISR has been used as a prior art document for the TPO (WO version of the patent, i.e., WO2011008709) and has been included in "No. of ISR documents used in TPO".
TPO	The TPO was filed on 25.09.2019 and comprises 4 prior art documents. Of the 4, 3 were patent applications and 1 was a periodical article. Also, 2 documents (i.e., patent documents) were used for both novelty and inventive step and 2 documents (patent and periodical article each) were used only for inventive step. A single patent document, i.e., WO2016049069, was used as a prior art document in both the present application

	and WO'354. Also, all 4 prior art documents used in the TPO of the present application were also used in 2 other Enanta applications WO'044 and WO'051.
Date of Filing of TPO	The TPO was filed on 25.09.2019.
National Phase as of 07.10.2022	No national phase entries

TPO No.	38
Appl. No.	PCT/US2018/034441: WO2018218051
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsfdocId=WO2018218051
Applicants	Enanta Pharmaceuticals, Inc.
Priority Date	25.05.2017
Details	The application claims compounds with a parent Markush structure which inhibit the apoptosis signal-regulating kinase 1 (ASK-1), which is associated with autoimmune disorders, neurodegenerative disorders, inflammatory diseases, chronic kidney disease and cardiovascular disease. More specifically, ASK-1 has been associated with hepatic steatosis, including non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). The parent Markush structure comprises a 6 + 6 bicyclic fused ring wherein one of the 6 membered rings is a piperidine ring (saturated ring containing a single nitrogen atom) and the other 6 membered ring fused to it may be either a phenyl or pyridine ring. The phenyl/pyridine ring of the bicyclic ring is attached to an amide group which is further attached to a heteroaryl ring containing up to 3 nitrogen atoms which itself is further substituted (R1, R2). The piperidine ring of this bicyclic ring system is also further substituted on the nitrogen atom (R3) (claim 1 of WO'051). Compounds derived from the above parent Markush structure act on an identical target ASK-1 and are claimed for the purpose of treating disorders/diseases relating to liver dysfunction as in the previous applications WO'354, WO'044 and WO'042. Also, the parent Markush structure and compounds claimed in the present application WO'051 are similar to the Markush structures claimed in the other three applications. However, the closest structural similarity can be found with the Markush structure of WO'042 which comprises a central phenyl/pyridine ring fused to an unsaturated six membered ring containing up to 2 nitrogen atoms; whereas in WO'051 the central phenyl/pyridine ring is fused to a saturated analogue of an identical six membered ring (i.e., piperidine; containing a single nitrogen atom).
Claims	The application has 28 claims (1 independent and 27 dependent claims), of which 14 are secondary claims wherein 2 claims are for formulation, 1 is for use and 11 for method of treatment. Of the 19 Markush structures, 1 is the primary Markush structure (Formula I) and 18 are derivative Markush structures. Of the 18 derivative Markush structures, 2 are Markush structures (XIIa-XIIb) belonging to Formula XII, 2 are Markush structures (XIIIa-XIIIb) belonging to Formula XIII, 2 are Markush structures (XIVa-XIVb) belonging to Formula XIV and another 2 are Markush structures (XVa-XVb) belonging to Formula XV. The applicant claims 600 specific compounds and pharmaceutically acceptable salt forms thereof. There is one further claim which claims 364 specific compounds. But, as per the trend of subsequent applications, these 364 should be a subset of the 600 specific compounds previously claimed. This has not been verified by cross-checking each of the compounds.
ISR	The ISR comprises 3 documents, all of them listed to describe only the general state of the art and not considered to be of particular relevance (A). For all 4 of the Enanta applications, the ISR has been authored by the same ISA; and for three of these applications (i.e., WO'042, WO'044 and WO'051) which comprise a central fused ring in the scaffold, the prior art documents listed in the ISR are identical. However, at the time of filing the TPO for WO'051, the ISR was available, unlike with the previous described application WO'044, and one of the documents (US 8378108 by Glead Sciences Inc.) listed in the ISR has been used as a prior art document for the TPO (WO version of the patent, i.e., WO2011008709).
TPO	The TPO was filed on 25.09.2019 and comprises 4 prior art documents. Of the 4, 3 were patent applications and 1 was a periodical article. Also, 2 documents (i.e., patent documents) were used for both novelty and inventive step and 2 documents (patent and periodical article each) were used only for inventive step. A single patent document, i.e., WO2016/049069, has been used as a prior art document in both the present

	application and WO'354. Also, all 4 prior art documents used in the TPO of the present application were also used in 2 other Enanta applications WO'044 and WO'042.
Date of Filing of TPO	The TPO was filed on 25.09.2019.
National Phase as of 07.10.2022	No national phase entries

<table>
<tr><td>TPO No.</td><td>44</td></tr>
<tr><td>Appl. No.</td><td>PCT/EP2018/071156: WO2019025600</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019025600</td></tr>
<tr><td>Applicants</td><td>Sandoz AG, Switzerland</td></tr>
<tr><td>Priority Date</td><td>03.08.2017</td></tr>
<tr><td>Details</td><td>The application claims sofosbuvir hydrate, more precisely the monohydrate form, for the treatment of HCV and pharmaceutical compositions thereof. It is the NS5B polymerase inhibitor of the hepatitis C virus.</td></tr>
<tr><td>Claims</td><td>The application has 16 claims, 1 independent and 15 dependent claims. This is a secondary application, so all 16 claims are secondary claims, mainly for the crystalline form of the hydrate compound – 6 claims for the hydrate, 9 claims for compositions, 1 claim for the process thereof. The hydrate is characterised using XRPD, fourier transform infrared spectrum, differential scanning calorimeter. There are 2 claims for use of the compound – 1 of which is for preparation of the pharmaceutical composition and 1 is for use of treatment of viral infections, HCV.</td></tr>
<tr><td>ISR</td><td>The ISR/WOSA/IPRP were published, with the European Patent Office, Rijswijk, Netherlands, being the ISA. The ISR listed 5 prior art documents, 4 of which were general documents and 1 document was against the novelty claim of the applicants (but was published after the priority date but prior to the filing date of the application).</td></tr>
<tr><td>TPO</td><td>The TPO used 4 prior art documents, 1 of which was an ISR document. Two documents used in the TPO challenged the inventive step and 2 challenged both inventive step and novelty of the claims in the application. Three of the prior art documents were periodicals and 1 was a patent document.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 3.12.2019.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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TPO No.	51
Appl. No.	PCT/US2018/052239: WO/2019/060740
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsfdocId=WO2019060740
Applicants	Riboscience LLC
Priority Date	21.09.2017
Details	The application claims combinations of nucleoside derivatives as inhibitors of HCV replicon RNA replication. In particular, the application is concerned with the use of combinations of cytidine and uridine pyrimidine nucleoside derivatives as inhibitors of subgenomic hepatitis C virus RNA replication and pharmaceutical compositions containing such compounds. The applicant alleges a synergistic effect for the claimed combination. The applicant claims modified forms of a known anti-HCV drug sofobuvir; wherein Formula II comprises an identical nucleobase uridine; and nucleobase in Formula II is cytidine (replacement of one oxo group of uridine with an amine group). Further minor modifications have also been carried out on the sugar moiety attached to the nucleobase; and also on the phosphoramidate prodrug portion of the scaffold in both of the claimed Markush structures.
Claims	The application has 37 claims (5 independent and 32 dependent claims), wherein all 37 of the claims are for various forms (specifically prodrugs), 36 are secondary claims, 1 claim is for formulation, 35 are for method of treatment and all the secondary claims are also combination claims. The application is primarily directed at methods of treatment with a combination of prodrugs of nucleoside analogues, i.e., cytidine and uridine analogues and pharmaceutically acceptable salt forms thereof. The prodrugs are depicted by 2 Markush structures, i.e., Formulae I and II represent prodrugs of nucleoside analogues of cytidine and uridine respectively. First, the formulae claimed show minor changes in the substituents attached to the sugar moiety of the nucleoside (at 2' and 4' position). Due to the possibility of various substituents being attached at 2' and 4' position of the sugar moiety, the parent molecule itself will differ. Second, 1 of the independent claims is directed to 15 specific compounds, i.e., prodrugs of cytidine nucleoside analogues. This application has, therefore, been marked as a basic molecule application. The secondary method of treatment claims of the application relate to 2 Markush structures of prodrugs of cytidine and uridine nucleoside analogues. The secondary method of treatment claims also relate to 19 specific compounds, i.e., 15 cytidine nucleoside analogues (and their stereoisomers) and 4 uridine nucleoside analogues. Though the application claims stereoisomers for each of the specific 15 cytidine nucleoside analogues, the stereoisomers are not counted as separate compounds. The application also has an independent claim for the same 15 cytidine nucleoside analogues and their stereoisomers. Of the 5 independent claims, 3 are method of treatment claims, 1 is a composition claim (relating to the claimed combination) and 1 is a claim for specific compounds, i.e., prodrugs of cytidine analogues. The 3 independent method of treatment claims are for treating HCV with a combination of prodrugs of cytidine and uridine analogues (n=1), and in further combination with NS3A HCV protease inhibitors (n = 1) and NS5B HCV polymerase inhibitors (n = 1). There is only 1 formulation claim for the combination of prodrugs of cytidine and uridine nucleoside analogues. One dependent claim (claim 32) seems to have been erroneously drafted as a method of treatment claim instead of a composition claim. For the purpose of this analysis, this claim has not been counted as a composition claim. Thirty-six of the 37 claims are secondary claims (method of treatment or composition) re prodrugs of cytidine and uridine nucleoside analogues. One claim is for the prodrugs of cytidine nucleoside analogues. Of the 35 method of treatment claims, 31 are for a combination of prodrugs of cytidine and uridine analogues and 4 are for further combination with NS3A HCV protease inhibitors or NS5B HCV polymerase inhibitors. Thirty-six of the 37 claims are combination claims wherein combinations of prodrugs of cytidine (Formula I) and uridine (Formula II) nucleoside derivatives are claimed. Some of the claims are for combination with further

<table>
<tr><td></td><td>therapeutic agents. Only 1 claim, which is for specific cytidine nucleoside analogues (claim 37), is not a combination claim.</td></tr>
<tr><td>ISR</td><td>The ISR comprises 3 documents, all of them listed to describe only the general state of the art and not considered to be of particular relevance (A). However, the ISA notes that in light of one of the documents listed in the ISR (i.e., US8334270B2; Sofia et al.), the claimed invention lacks unity of invention as it does not provide a contribution over the existing prior art.</td></tr>
<tr><td>TPO</td><td>The TPO was filed on 21.01.2020 and comprises 2 prior art documents. Of the 2 documents, 1 was a patent application and the other a book chapter. Both the prior art documents were used for both novelty and inventive step. A table of comparison of structures disclosed in prior art (WO 2014/186637) and the structures claimed in the application was uploaded as an additional document.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 21.01.2020.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>Australia</td><td>09.03.2020</td><td>2018335411</td><td>Published 26.03.2020</td></tr>
<tr><td>Canada</td><td>11.03.2020</td><td>3075645</td><td></td></tr>
<tr><td>Singapore</td><td>17.03.2020</td><td>11202002431S</td><td></td></tr>
<tr><td>Israel</td><td>18.03.2020</td><td>273398</td><td></td></tr>
<tr><td>Japan</td><td>19.03.2020</td><td>2020538752</td><td></td></tr>
<tr><td>China</td><td>20.03.2020</td><td>201880061322.3</td><td>Published 22.05.2020</td></tr>
<tr><td>New Zealand</td><td>20.03.2020</td><td>762823</td><td>Published 27.03.2020</td></tr>
<tr><td>Republic of Korea</td><td>16.04.2020</td><td>1020207011082</td><td>Published 22.05.2020</td></tr>
<tr><td>EPO</td><td>21.04.2020</td><td>2018859097</td><td></td></tr>
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TPO No.	57
Appl. No.	PCT/US2018/054574: WO/2019/071105
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsfdocId=WO2019071105
Applicants	Spring Bank Pharmaceuticals, Inc.
Priority Date	05.10.2017
Details	The application claims a crystalline form of SB9200 (also known as inagravirsoproxil) that is diastereomerically pure and stable at certain conditions, i.e., the Rp form of SB9200 and its hemi-tartrate salt. It also claims certain specific pharmaceutically acceptable salts thereof (i.e., hemi-tartrate salt, oxalate salt, citrate salt and fumarate salt), and compositions thereof and methods of using them. SB9200 is under clinical trials for treatment of HBV and HCV. It appears that Spring Bank has discontinued development of inarigivir to treat hepatitis B after the death of a patient (https://www.clinicaltrialsarena.com/news/spring-bank-stops-inarigivir-hbv/). It further appears that Spring Bank has suspended development of inarigivir for HIV, but is still exploring or licensing it for HCV and also planning its clinical trials as an adjuvant therapy for COVID-19 infections (https://adisinsight.springer.com/drugs/800038150).
Claims	The application has 87 claims (8 independent and 79 dependent claims), wherein all 87 claims are secondary claims, 20 of the claims are for various forms, 55 are for formulation, 7 are for method of treatment, 35 are for combination and 10 are “other” claims. Of the 20 claims for forms, 5 are product by process claims. The applicant claims the Rp form of SB9200 and the Rp form of the hemi-tartrate salt of SB9200 and characterises them using XRPD and ^{P}NMR. It also claims the hemi-tartrate salt, oxalate salt, citrate salt and fumarate salt of SB9200. Of the 55 claims for formulations, 12 are for compositions of Formula I, 13 are for Formula III, 27 are for combination of SB9200 with tenofovir or its prodrugs, and 3 are for solid oral dosage form. In the claims for compositions comprising the combinations, the applicant makes distinct claims for composition, particulate composition and pharmaceutical composition of the aforementioned combinations. In some of the formulation claims, the applicant characterises the composition as free from chemical impurities and lists the impurities, including the S-isomer. Of the 35 combination claims, 28 are drafted as claims for formulations (compositions or oral solid dosage form) and 7 are for method of treatment using the claimed compositions. Of the 10 "other" claims, 5 are process claims and 5 are product by process claims, the product being the Rp form. The product by process claims, therefore, overlap with the claims for the crystalline forms.
ISR	The ISR comprises 3 documents, all of them listed to describe only the general state of the art and not considered to be of particular relevance (A). However, the ISA (the ISA for the present application, WO’740 and the Enanta applications above is the same entity) notes that in light of one of the documents listed in the ISR (i.e., Coughlin et al.), the claimed invention lacks unity of invention as it does not provide a contribution over the existing prior art.
TPO	The TPO was filed on 05.02.2020 and comprises 5 prior art documents. Of the 5, 2 are patent applications and 3 are book chapters. One additional patent document was filed with 1 of the patent documents. None of the books were uploaded.Two documents were used for both novelty and inventive step, and 3 documents were used only for inventive step.
Date of Filing of TPO	The TPO was filed on 05.02.2020.
National Phase as of 07.10.2022	No national phase entries

PART C: Case Summaries: TB Applications

TPO No.	2
Appl. No.	PCT/SG2017/050553: WO2018084809
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018084809
Applicants	Nanyang Technological University, Schweizerisches Tropen- und Public Health-Institut and Universitat Basel Vizerektorat Forschung
Priority Date	02.11.2016
Details	The application is for the method of treating or preventing various mycobacteria deficient for or expressing cytochrome bd oxidase or a disease resulting from such infection. It claims the use of a compound capable of inhibiting cytochrome bc1 of the respiratory electron transport chain in combination with a therapeutic agent capable of inhibiting cytochrome bd oxidase. It specifically claims four such mycobacteria and three diseases, tuberculosis, leprosy and buruli ulcer.
Claims	The application has 16 claims, all of which are secondary claims, that is, they are all method of treatment claims. There are 2 Markush structures containing an imidazopyridine and an imidazothiazole scaffold and 11 specific compounds, including Q203, with a couple of claims for the combination of the drug with other drugs, and wherein the method kills the mycobacterium. The applicant also includes method of treatment with combinations of the claimed compounds with an additional therapeutic agent capable of inhibiting cytochrome bd oxidase. It specifically claims a combination with "quinolone compounds, Aurachin, nitric oxide (NO) donors such as PA-824, antibiotics LL- Z1272, Gramicidin S, and derivatives thereof". Interestingly, the WOSA points out that because the priority document did not disclose method of treatment with combination, the priority claim is invalid for the combination claims (claims 9 to 16).
ISR	The ISR had about 9 documents, comprising 5 documents and an additional 2 documents (published after the priority date, but before the filing date) that challenged the novelty of the drug, and 2 general documents.
TPO	The TPO had about 10 documents, 2 of which were ISR documents. The TPO had 1 document that dislodged the novelty of the claims in the application, with 3 documents bringing forth the lack of inventive step and 6 documents that disclosed the lack of novelty and/or inventive step of the claims made in the application. The TPO used 7 articles published in periodicals and 3 patent documents.
Date of Filing TPO	04.03.2019
National Phase as of 07.10.2022	No national phase entries.

<table>
<tr><td>TPO No.</td><td>3</td></tr>
<tr><td>Appl. No.</td><td>PCT/IB2017/057225: WO2018092089</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018092089</td></tr>
<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited</td></tr>
<tr><td>Priority Date</td><td>18.11.2016</td></tr>
<tr><td>Details</td><td>This application discloses and claims heterocyclic amides that inhibit RIP1 kinase and methods of making and using the same. It relates to developing a potent, selective, small molecule inhibitor which would block RIP1 -dependent cellular necrosis and thereby provide a therapeutic benefit in diseases or events associated with danger associated molecular patterns (DAMPs), cell death and/or inflammation.</td></tr>
<tr><td>Claims</td><td>The application has 32 claims (6 independent claims and 26 dependent claims), of which 15 claims are secondary claims wherein 4 deal with formulation, 9 with uses, 2 with method of treatment and 2 with combination. Of the 4 formulation (pharmaceutical composition) claims, 2 overlap with the combination claims. Both the combination claims are drafted as formulation claims. There are 2 Markush structures and 3 specific compounds in the claims comprising a core of a 5-membered ring, 4,5-dihydro-1H-pyrazole ring which connects through nitrogen N1 to a piperidine ring through a carbonyl group. The application claims compounds for RIP1 kinase mediated diseases, including bacterial and viral infections. Though TB is mentioned in the description, it is not specifically claimed. The compounds are claimed specifically for treatment of other RIP1 mediated diseases such as ulcerative colitis, rheumatoid arthritis and psoriasis.</td></tr>
<tr><td>ISR</td><td>The ISR has 2 documents, both of which deal with the general state of the art which is not considered to be of particular relevance and therefore does not attack the novelty or inventive step of the molecule.</td></tr>
<tr><td>TPO</td><td>The TPO has 7 documents, none of which are ISR documents. It has 1 document that attacks the novelty of the claims and 3 additional documents attacking both novelty and inventive step. Additionally, 3 documents have disclosed the lack of novelty and/or inventive step of the claims made in the application. The TPO uses 5 articles published in periodicals and 2 patent documents.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 18.03.2019.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>United States of America</td><td>16.05.2019</td><td>16461410</td><td>Published 14.11.2019</td></tr>
<tr><td>EPO</td><td>18.06.2019</td><td>2017811721</td><td>Withdrawn 15.03.2022</td></tr>
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<tr><td>TPO No.</td><td>4</td></tr>
<tr><td>Appl. No.</td><td>PCT/GB2017/053787:WO2018109504</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018109504</td></tr>
<tr><td>Applicants</td><td>Louise Golding et al.,</td></tr>
<tr><td>Priority Date</td><td>16.12.2016</td></tr>
<tr><td>Details</td><td>The application relates to novel ionophores comprising bicyclic or tricyclic nitrogen containing N-oxide functionalised heterocycles, methods for their preparation and their medical use, in particular as anti-neoplastic and anti-infective agents. The application indicates that these compounds will have enhanced membrane penetration.</td></tr>
<tr><td>Claims</td><td>The application has 45 claims (1 dependent and 44 dependent), of which 11 are secondary claims pertaining to formulation (8 claims), uses (6 claims) and 1 for the method of treatment. Of the 8 formulation (composition) claims, 1 is specifically for a composition per se, 6 claims claim use of the composition (apart from the claimed compounds) and 1 claim claims method of treatment using the formulation (apart from the claimed compounds). There are 11 claims for the combinations. Of the 11 combination claims, 3 are specifically for combinations per se. The remaining 8 claims are for formulation, use and method of treatment which claim both the claimed compounds as combinations. The claims contain 10 Markush structures with 490 specific compounds comprising either bicyclic or tricyclic nitrogen containing aromatic core where one or both of the nitrogen atoms are in the form of N-oxide. Of these 10 Markush structures, 5 are unique structures and 5 are corresponding variants of each of these 5 unique structures. Apart from TB, the application claims use for treatment of various types of cancers, bacterial and fungal infections.</td></tr>
<tr><td>ISR</td><td>The ISR had 11 documents, of which 10 documents and 1 additional document (published after the priority date, but before the filing date) directly attack the novelty of the application and 7 of these also cover the general state of the art.</td></tr>
<tr><td>TPO</td><td>The TPO had 8 documents, 1 of which was an ISR document. Of these, 6 documents have been used to dislodge novelty and 2 for attacking both novelty and inventive step. The TPO used 6 articles published in periodicals and 2 patent documents.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 16.04.2019.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>Unites States of America</td><td>14.06.2019</td><td>16469948</td><td>Published 26.03.2020
Granted 29.06.2021</td></tr>
<tr><td>EPO</td><td>16.07.2019</td><td>2017817848</td><td></td></tr>
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TPO No.	5
Appl. No.	PCT/IB2017/058326: WO2018116260
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018116260
Applicants	Yuria-Pharm Limited Liability Company
Priority Date	22.12.2016
Details	The application claims isonicotninylhydrazones as anti-tuberculosis agents. The primary compound claimed is a slightly modified analogue of isoniazid. Clinical trials were conducted for a pharmaceutical formulation containing this molecule as the primary compound for activity against MDR-TB.
Claims	The application has 17 claims (1 independent and 16 dependent claims), all of which are secondary claims for formulation.
ISR	The ISR had 5 documents, all of which target the inventive step and none for dislodging the novelty of the application.
TPO	The TPO had 8 documents, which included 1 ISR document. Of these 8 documents, 1 was exclusively for attacking novelty, 4 for both novelty and inventive step, and 3 only for inventive step. The prior art documents comprised 7 articles published in periodicals and 1 patent document.
Date of Filing TPO	The TPO was filed on 22.04.2019.
National Phase as of 07.10.2022	No national phase entries.

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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018151681</td></tr>
<tr><td>Applicants</td><td>Nanyang Technological University and National University of Singapore</td></tr>
<tr><td>Priority Date</td><td>15.02.2017</td></tr>
<tr><td>Details</td><td>The application relates to pyrimidine compounds and compositions for treating tuberculosis. These compounds have been proposed to target the F1 domain of F-ATP synthase. Inhibition of ATP synthase in the mycobacteria leads to shutting off the supply of cellular energy, thereby causing cell death. The application claims pyrimidine compounds alone and in combination with bedaquiline or 6-chloro-2-ethyl-N-[[4-[4-[4-(trifluoromethoxy)phenyl]piperidin-1-yl]phenyl]methyl]imidazo[1,2-a]pyridine-3-carboxamide (Q203) or a combination thereof.</td></tr>
<tr><td>Claims</td><td>The application has 25 claims (2 independent and 23 dependent), of which 17 claims are secondary claims. There are 3 formulation claims, 7 claims for uses, 2 claims for method of treatment, 6 claims for combinations and 7 “other” claims. Of the 3 formulation claims, 2 claims overlap with use claims and all 3 claims are for combination. Of the 7 claims for use, 2 claims overlap with pharmaceutical formulation claims and 3 claims overlap with combination claims. Of the 2 method of treatment claims, 1 claim overlaps with a combination claim. Of the 6 combination claims, 1 overlaps with the use claims, 1 claim overlaps with method of treatment claims and 1 of the claims is for a kit. Of the 7 “other” claims, 6 are process claims and 1 claim is for a kit.</td></tr>
<tr><td>ISR</td><td>The ISR had 11 documents, of which 10 attacked novelty and 1 document was a general state of the art document.</td></tr>
<tr><td>TPO</td><td>The TPO had 6 documents and 1 of these was an ISR document. Of these 6 documents, 4 dislodged novelty and an additional 2 documents attacked both novelty and inventive step. The TPO prior art consisted of 4 articles published in periodicals and 2 patent documents.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 17.06.2019.</td></tr>
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Granted 03.08.2021</td></tr>
<tr><td>India</td><td>11.09.2019</td><td>201917036557</td><td>Published 15.11.2019</td></tr>
<tr><td>Canada</td><td>13.09.2019</td><td>3056590</td><td></td></tr>
<tr><td>Russian Federation</td><td>16.09.2019</td><td>2019128534</td><td>Published 16.03.2021
Withdrawn 11.10.2021</td></tr>
<tr><td>China</td><td>14.10.2019</td><td>201880025012.6</td><td>Published 29.11.2019</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018158280</td></tr>
<tr><td>Applicants</td><td>Janssen Science Ireland Unlimited Co.</td></tr>
<tr><td>Priority Date</td><td>01.03.2017</td></tr>
<tr><td>Details</td><td>The application claims a combination of known anti-TB drugs, i.e., PZA + bc1 inhibitor (more specifically Q203). It also claims a further combination with other antibacterial agents.</td></tr>
<tr><td>Claims</td><td>The application has 16 claims (1 independent and 15 dependent), all of which are secondary claims. Of these, 2 claims pertain to formulation, 2 claims are for dosage forms, 5 claims for use, 2 claims are for treatments, all 16 for combinations, and there are 2 “other claims”. Of the 16 combination claims, 2 claims overlap with the formulation claims, 2 overlap with dosage claims, 5 overlap with use claims, 2 overlap with method of treatment claims and 2 of the claims are process claims. The 2 “other claims” are process claims. The diseases claimed are specifically TB (including MDR, latent TB) and mycobacterial infections.</td></tr>
<tr><td>ISR</td><td>The ISR had 2 documents, of which 1 attacked the novelty and the other was a general state of the art document.</td></tr>
<tr><td>TPO</td><td>The TPO had 6 documents, out of which 1 was referred in the ISR. Of these 6 documents, 3 documents dislodged novelty of the application and the other 3 challenged both novelty and inventive step. The TPO used 4 articles published in periodicals and 2 patent documents.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 01.07.2019.</td></tr>
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<tr><td>Japan</td><td>30.08.2019</td><td>2019547409</td><td></td></tr>
<tr><td>Philippines</td><td>02.09.2019</td><td>12019502002</td><td></td></tr>
<tr><td>United States of America</td><td>03.09.2019</td><td>16490677</td><td>Published 31.01.2020</td></tr>
<tr><td>Brazil</td><td>10.09.2019</td><td>112019017901</td><td></td></tr>
<tr><td>Eurasian Patent Organization</td><td>24.09.2019</td><td>201991997</td><td>Published 31.01.2020</td></tr>
<tr><td>Ukraine</td><td>30.09.2019</td><td>A201910076</td><td>Published 10.01.2020</td></tr>
<tr><td>EPO</td><td>01.10.2019</td><td>2018707713</td><td></td></tr>
<tr><td>Republic of Korea</td><td></td><td>1020197025379</td><td>Published 25.10.2019</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018175185</td></tr>
<tr><td>Applicants</td><td>Merck Sharp & Dohme Corp.</td></tr>
<tr><td>Priority Date</td><td>20.03.2017</td></tr>
<tr><td>Details</td><td>The application relates to oxazolidinone compounds for inhibiting growth of mycobacterial cells as well as a method of treating mycobacterial infections by Mycobacterium tuberculosis. The application also claims administering a therapeutically effective amount of an oxazolidinone and/or a pharmaceutically acceptable salt thereof, or a composition comprising such compound and/or salt.</td></tr>
<tr><td>Claims</td><td>The application has 20 claims (2 independent and 18 dependent), of which 9 claims are secondary claims. There are 8 claims for formulation, 1 claim for use, 7 claims for method of treatment and 2 claims for combination. Of the 8 formulation claims, 1 claim is for a composition per se and 7 claims overlap with method of treatment claims as they claim method of treatment with the compound as well as composition. All 7 method of treatment claims claim both method of treatment with the compound as well as composition. The method of treatment claims overlap with combination claims. Both combination claims overlap with or are drafted with method of treatment claims. There are no claims for combination per se. The application claims 1 Markush structure with 23 specific compounds. Apart from the specific claim for the treatment of tuberculosis and resistant tuberculosis, the application also claims treatment for various bacterial infections.</td></tr>
<tr><td>ISR</td><td>The ISR had 1 document which attacks the novelty of the application.</td></tr>
<tr><td>TPO</td><td>The TPO had 5 prior art documents which were different from the ISR document. All these documents dislodged both novelty and inventive step. The TPO had 3 articles published in periodicals and 2 patent documents.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 22.07.2019.</td></tr>
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<tr><td>United States of America</td><td>04.09.2019</td><td>16490958</td><td>Published 09.01.2020
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018177302</td></tr>
<tr><td>Applicants</td><td>Institute of Materia Medica, Chinese Academy of Medical Sciences</td></tr>
<tr><td>Priority Date</td><td>28.03.2017</td></tr>
<tr><td>Details</td><td>The application claims nitrogen containing heterocycle substituted benzoxazine oxazolidinone compounds, preparation method of these compounds and the use in the preparation of a drug for treating Mycobacterium tuberculosis. It also claims stereoisomers, pharmaceutically acceptable salts thereof, and a pharmaceutical composition comprising the compound disclosed in the application.</td></tr>
<tr><td>Claims</td><td>The application has 16 claims (1 independent and 15 dependent), of which there are 3 secondary claims, 2 claims for formulation, 1 claim for use and 1 other claim. Of the 2 formulation claims, 1 claim is for composition per se and 1 claim overlaps with the use claim which claims use of the compounds and compositions thereof. The 1 other claim is a process claim. The claims contain 9 Markush structures with 36 specific compounds. Of the 9 Markush structures, 1 is the primary Markush structure and 8 are derivative Markush structures. Of the 8 derivative Markush structures, 2 are isomers of the primary Markush structure, 3 are derivatives of one such isomer and 3 are derivatives of the second such isomer. Claim 12 sets out a relatively limited number of possible substituents for some of the Markush structures.</td></tr>
<tr><td>ISR</td><td>The ISR had 2 documents, both of which deal with the general state of the art which is not considered to be of particular relevance and therefore does not attack the novelty or inventive step of the molecule.</td></tr>
<tr><td>TPO</td><td>The TPO had 5 documents, none from the ISR. Of these documents, 1 document attacked inventive step and the rest attacked both novelty and inventive step. The TPO contained 2 articles published in periodicals and 3 patents.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 29.07.2019.</td></tr>
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Granted 17.05.2022</td></tr>
<tr><td>Russian Federation</td><td>28.10.2019</td><td>2019134197</td><td>Granted 15.03.2021</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018206466</td></tr>
<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited</td></tr>
<tr><td>Priority Date</td><td>08.05.2017</td></tr>
<tr><td>Details</td><td>The application claims sanfetrinem, a pharmaceutically acceptable salt or ester prodrug thereof for use in the treatment of tuberculosis, either alone or in combination with beta-lactamase inhibitors and other agents. This is an application for a new use of a known compound, and its known prodrug (sanfetrinem cilexetil). Sanfetrinem is a beta-lactam containing compound which inhibits bacterial cell wall synthesis.</td></tr>
<tr><td>Claims</td><td>The application has 27 claims (9 independent and 18 dependent), all of which are secondary claims. Of these, 1 claim is for formulation, 6 for salt forms, 18 claims for use, 9 claims for the method of treatment and 7 claims pertaining to combination. All the claims (except the 9 method of treatment claims) are drafted as compounds/composition/combinations for use as the application claims a new use for a known compound. Of the 6 claims for specific forms, 2 claims are for the ester prodrug of sanfetrinem, 2 claims are for sanfetrinem cilexetil and 2 claims are for the sodium salt of sanfetrinem. Of these 6 claims, 3 are drafted as method of treatment claims. The claims generally claim the compounds for use in the treatment of a disease resulting from a mycobacterial infection, mycobacterial infection, mycobacterium tuberculosis infection and also specifically for use in treatment of tuberculosis disease.</td></tr>
<tr><td>ISR</td><td>The ISR had 8 documents, of which 1 attacked novelty and 7 were general state of the art documents.</td></tr>
<tr><td>TPO</td><td>The TPO had 8 documents, 1 of which was an ISR document. Of these 8 documents, 1 document attacked inventive step and 7 dislodged novelty and inventive step of the application. All these 8 documents were articles published in periodicals.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 09.09.2019.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><td>Australia</td><td>21.10.2019</td><td>2018265192</td><td>Published 07.11.2019</td></tr>
<tr><td>China</td><td>07.11.2019</td><td>201880030277.5</td><td>Published 06.03.2020</td></tr>
<tr><td>Japan</td><td>07.11.2019</td><td>2019561315</td><td></td></tr>
<tr><td>Unites States of America</td><td>08.11.2019</td><td>16611908</td><td>Published 17.09.2020
Granted 22.02.2022</td></tr>
<tr><td>Brazil</td><td>19.11.2019</td><td>112019023322</td><td>Refused 18.01.2022</td></tr>
<tr><td>EPO</td><td>09.12.2019</td><td>2018721053</td><td>Granted 27.07.2022</td></tr>
<tr><td>Russian Federation</td><td>09.12.2019</td><td>2019139864</td><td>Published 09.06.2021</td></tr>
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	Serbia	01.08.2022	P-2022/0731	Granted 31.08.2022	
	India		201917045452	Published 13.12.2019	
	Republic of Korea		1020197032729	Published 10.01.2020	

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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019034700</td></tr>
<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited and BioVersys AG</td></tr>
<tr><td>Priority Date</td><td>16.08.2017</td></tr>
<tr><td>Details</td><td>The application claims spiroisoxazoline compounds and their use in treatment of mycobacterial infections or treatment of diseases caused by mycobacterium such as tuberculosis, primarily to potentiate the action of ethionamide. More specifically, it claims a compound very similar to SMARt-420, a known spiroisoxazoline compound for use as ethionamide booster in the treatment of TB.</td></tr>
<tr><td>Claims</td><td>The application has 22 claims (1 independent and 21 dependent), of which 13 claims are secondary claims. The application has 1 claim for formulation, 5 claims for uses, 2 claims for method of treatment, and 5 claims for combination. Of the 5 claims for use, 4 are drafted as claiming the compound or its pharmaceutically acceptable salt for use. The application generally claims treatment of mycobacterial infection or disease caused by infection with mycobacterium. It specifically claims treatment of Mycobacterium tuberculosis infection and tuberculosis.</td></tr>
<tr><td>ISR</td><td>The ISR had 6 documents, and all dealt with the general state of the art which is not considered to be of particular relevance and therefore does not attack the novelty or inventive step of the molecule.</td></tr>
<tr><td>TPO</td><td>The TPO had 5 documents, of which 1 was an ISR document. Of these 5 documents, 2 attacked inventive step and 3 dislodged both novelty and inventive step. The TPO used 3 documents published in periodicals and 2 patent documents.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 16.12.2019.</td></tr>
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<tr><td>Israel</td><td>09.02.2020</td><td>272562</td><td></td></tr>
<tr><td>New Zealand</td><td>10.02.2020</td><td>761518</td><td>Published 28.02.2020</td></tr>
<tr><td>Canada</td><td>12.02.2020</td><td>3072838</td><td></td></tr>
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<tr><td>Mexico</td><td>14.02.2020</td><td>MX/a/2020/001808</td><td>Published 24.11.2020
Granted 19.07.2022</td></tr>
<tr><td>Philippines</td><td>14.02.2020</td><td>12020500339</td><td></td></tr>
<tr><td>Thailand</td><td>14.02.2020</td><td>2001000850</td><td></td></tr>
<tr><td>United States of America</td><td>14.02.2020</td><td>16639192</td><td>Published 04.02.2021
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<tr><td>China</td><td>17.02.2020</td><td>201880053326.7</td><td>Published 10.04.2020</td></tr>
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	EPO	16.03.2020	2019752171	Granted 29.09.2021
	Russian Federation	16.03.2020	2020109677	Published 16.09.2021
	Serbia	15.12.2021	P-2021/1543	Granted 31.01.2022

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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019034729</td></tr>
<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited</td></tr>
<tr><td>Priority Date</td><td>17.08.2017</td></tr>
<tr><td>Details</td><td>The application appears to specifically claim a preclinical compound, GSK839, a tetrazole benzene sulfonamide, which is identified by the Working Group for New TB Drugs as a pipeline compound.</td></tr>
<tr><td>Claims</td><td>The application has 26 claims (1 independent and 25 dependent), of which 15 claims are secondary claims. There is 1 claim for formulation, 7 claims for uses, 2 claims for treatment, and 5 claims for combination. Of the 7 claims for use, 6 are drafted as claiming the compound or its pharmaceutically acceptable salt for use. The application generally claims treatment of mycobacterial infection or disease caused by infection with mycobacterium. It specifically claims Mycobacterium tuberculosis infection and tuberculosis.</td></tr>
<tr><td>ISR</td><td>The ISR had 6 documents and all dealt with the general state of the art which is not considered to be of particular relevance and therefore does not attack the novelty or inventive step of the molecule.</td></tr>
<tr><td>TPO</td><td>The TPO had 4 documents, of which 1 was an ISR document. Of these, 2 documents attacked inventive step and the other 2 documents dislodged both novelty and inventive step. The TPO made use of 3 articles published in periodicals and 1 patent document.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 17.12.2019.</td></tr>
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<tr><td>EPO</td><td>17.03.2020</td><td>2018755815</td><td>Granted 23.06.2021</td></tr>
<tr><td>Russian Federation</td><td>17.03.2020</td><td>2020110818</td><td>Published 17.09.2021</td></tr>
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TPO No.	55
Appl. No.	PCT/EP2018/077222: WO2019068910
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019068910
Applicants	Quretech Bio Ab and Washington University in St. Louis
Priority Date	05.10.2017
Details	The application relates to ring-fused thiazolino 2-pyridone compounds and, in particular, combinations of such ring-fused thiazolino 2-pyridones with other known anti-TB agents for treating various types of tuberculosis infections.
Claims	The application has 46 claims (2 independent and 44 dependent), of which there are 45 secondary claims. Of these, there are 2 claims for formulation, 5 claims for salt forms, 9 claims for use, 4 claims for method of treatment, 45 claims for combination and 3 other claims. There are 2 independent claims, 1 for combination and 1 for specific compounds. All claims except 1 (claim 46) are drafted as combination claims wherein parent/derived Markush structures of Formula I (imidazopyridines; acting on cytochrome b subunit of the bc1 complex) and Formula II (ring-fused thiazolino 2-pyridone compounds) are claimed in combination with each other and also with further other known anti-TB agents for the treatment of infections caused by mycobacteria. However, 1 independent claim is directed to 34 specific ring-fused thiazolino 2-pyridone (Formula II) compounds. Therefore, this application is being treated as a basic molecule application. The Markush structures are claimed as part of the combination claims and not separately as Markush structures per se. Of the 11 Markush structures, 3 are for imidazopyridines, of which 1 is a primary Markush structure (Formula I) and 2 are derivative Markush structures. Of the 11 Markush structures, 8 Markush structures are ring-fused thiazolino 2-pyridone structures, of which 1 is a primary Markush structure (Formula II) and 7 are derivative Markush structures. Of the 7 derivative Markush structures, 2 are directly derived from Formula II (Formula IIa and IIb), 2 (Formula IIIa and IIIb) specifically claim various nicotinic hydrazide salt forms of Formula IIa and IIb, and the other 3 (Formula IV, IVa, IVb) specifically claim Markush structures derived from Fomula II bonded with an nicotinamide moiety. Two additional derivative structures (Formula IIa51 and Formula IVa5; claims 4 and 8) have not been counted as separate Markush structures because they differ from their parent Markush structures (Formula IIa and Formula IVa) only in terms of their stereochemistry. Thirty-four specific ring-fused thiazolino 2-pyridone (Formula II) compounds are claimed in the independent claim. In a combination claim, 87 specific ring-fused thiazolino 2-pyridone (Formula II) compounds (which include the 34 mentioned above) are claimed as part of the claimed combination. Of the 5 claims for forms, 3 are claims for the nicotinic hydrazide salt forms of compounds of Formula II and 2 are claims for stereoisomers of certain derivative Marksush structures of Formula II. As regards the 3 claims for the salt forms, 2 broad claims (claims 1 and 2) include within them the nicotinic hydrazide salt form specifically and therefore are counted as claims for "forms". One claim (claim 5) specifically claims Markush structures (Formula IIIa and IIIb) for different nicotinic hydrazide salt forms wherein the compounds differ in the substitution of various anionic groups (A-) on the parent Markush structure. Of the 9 use claims, 4 are drafted as use claims per se and 5 are drafted as claims to combination for use. Of the 3 "other" claims, 1 claim is a combination wherein the claimed drug is profiled in a test and 2 claims are for the claimed combination in a kit (apart from composition).

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<tr><td>ISR</td><td>The ISR had 3 documents, of which 1 document and an additional document (published after the priority date, but before the filing date) attacked the novelty of the application and 1 document was a general state of the art document.</td></tr>
<tr><td>TPO</td><td>The TPO had 3 documents, of which 1 was an ISR document. All the TPO documents attacked both novelty and inventive step. The TPO made use of 1 document published in a periodical and 2 patent documents.</td></tr>
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Granted 28.09.2021</td></tr>
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<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019175737</td></tr>
<tr><td>Applicants</td><td>University of Notre Dame Du Lac</td></tr>
<tr><td>Priority Date</td><td>12.03.2018</td></tr>
<tr><td>Details</td><td>The application claims imidazopyridine and pyrazolopyridine compounds wherein carbon hydrogen bonds have been replaced with isotopic carbon-deuterium bonds, syntheses thereof, compositions thereof, and methods of using such compounds and compositions for killing and/or inhibiting the growth of M. tuberculosis and/or M. avium. In this application, deuterated imidazopyridine and pyrazolopyridine compounds are broadly claimed for the treatment of tuberculosis mycobacterial and non-tuberculosis mycobacterial infection, without mentioning the specific diseases.</td></tr>
<tr><td>Claims</td><td>The application has 11 claims (2 independent and 9 dependent), all of which are secondary claims. The application has 4 claims for formulation and 3 claims for method of treatment. The application is not considered as an application for basic molecule as all the compounds claimed are deuterated forms of known imidazopyridine compounds and the process of deuteration is known to a person skilled in the art. The secondary claims of the application relate to 4 Markush structures. Of the 4 Markush structures, 2 structures have imidazopyridine core [wherein 1 Markush structure has the core and substituents deuterated (A deut) and the other Markush structure has the linker too at deuterated] and 2 structures have a pyrazolopyridine core [wherein 1 Markush structure has the core and substituents deuterated (B deut) and the other Markush structure has the linker too deuterated]. The application claims 130 specific deuterated compounds of certain known compounds, wherein H is replaced with D at various positions and substituents. These include deuterated forms of known drugs such as Q203 and TB-47. However, as all compounds are deuterated analogues of known compounds, and the process of deuteration itself is known, the number of specific compounds is counted as 0. Of the 4 formulation claims, 1 is a composition claim per se and the other 3 are method of treatment of infection caused by mycobacterium by administration of the claimed compounds or composition.</td></tr>
<tr><td>ISR</td><td>The ISR had 2 documents. Both these documents attacked the inventive step of the application.</td></tr>
<tr><td>TPO</td><td>The TPO had 9 documents, all of which attacked the inventive step of the application. The TPO used 3 documents published in periodicals, 5 patent documents and 1 book reference.</td></tr>
<tr><td>Date of Filing TPO</td><td>The TPO was filed on 30.03.2020.</td></tr>
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PART D: Case Summaries: Applications claiming HIV, HCV and TB treatments

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<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited</td></tr>
<tr><td>Priority Date</td><td>20.12.2016</td></tr>
<tr><td>Details</td><td>The application discloses IDO (indoleamine dioxygenase) inhibitor compounds derived from a scaffold comprised of a pyridine core and pharmaceutically acceptable salts thereof, their pharmaceutical compositions, their methods of preparation, and methods for their use in the prevention and/or treatment of diseases.</td></tr>
<tr><td>Claims</td><td>The application has 16 claims (2 independent and 14 dependent claims), of which 9 are secondary claims wherein 2 claims are for formulation, 2 are for use and 6 for method of treatment. Of the 2 formulation claims, 1 overlaps with a method of treatment claim as the composition is claimed for treatment. The application claims a single Markush structure with the core being pyridine ring is substituted at positions 2 and 3 with an amine group, wherein the amine itself is further substituted and also includes an acid group substitution at position 5. A single compound has also been claimed specifically; having this pyridine core wherein the amine at position 2 is substituted with an alkyl chain of 3 carbon atoms and a tetrahydropyran ring and the amine at position 3 is substituted with another pyridine ring; and an acidic functional group substitution at position 5. The application claims compounds/pharmaceutical composition containing these compounds for treating chronic viral infections such as HIV and HCV and bacterial infections such as TB by modulating activity of IDO.</td></tr>
<tr><td>ISR</td><td>The ISR has 2 documents, of which 1 was listed for novelty (X) and also listed for inventive step (Y). The other ISR document was published after the priority date of the present application but before the international filing date (P) and was listed only for inventive step (Y).</td></tr>
<tr><td>TPO</td><td>The TPO was filed on 23.04.2019 and comprised 6 prior art documents. Of the 6 documents, only 1 was uploaded to the WIPO website. Five of the 6 documents were patent applications and 1 was a periodical article. Four documents were used for both novelty and inventive step, and 2 were used only for inventive step. In the TPO, 2 of the documents used had a publication date after the priority date of the present application (P documents) but before the international filing date. Of the two P documents, 1 document was used for both novelty and inventive step and 1 document was used for only inventive step.</td></tr>
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<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited</td></tr>
<tr><td>Priority Date</td><td>20.12.2016</td></tr>
<tr><td>Details</td><td>The application discloses IDO (indoleamine dioxygenase) inhibitor compounds derived from a scaffold comprised of a pyridine core and pharmaceutically acceptable salts thereof, their pharmaceutical compositions, their methods of preparation, and methods for their use in the prevention and/or treatment of diseases.</td></tr>
<tr><td>Claims</td><td>The application has 19 claims (2 independent and 17 dependent claims), of which 9 are secondary claims wherein 2 claims are for formulation, 2 are for use and 6 for method of treatment. Of the 2 formulation claims, 1 overlaps with a method of treatment claim as the composition is claimed for treatment. The application claims a single Markush structure with the core being pyridine ring is substituted at positions 2 and 3 with an amine group, wherein the amine itself is further substituted and also includes an acid group substitution at position 5. (The Markush structures claimed in WO’107 and WO’108 are identical.) A single compound has also been claimed specifically; having this pyridine core wherein the amine at position 2 is substituted with an alkyl chain of 3 carbon atoms and a tetrahydropyran ring and the amine at position 3 is substituted with an thiadiazole ring (the only difference in the compounds claimed in both WO’107 and WO’108 is the presence of a different heteroaryl ring at this position); and an acidic functional group substitution at position 5. The application claims compounds/pharmaceutical composition containing these compounds for treating chronic viral infections such as HIV and HCV and bacterial infections such as TB by modulating activity of IDO.</td></tr>
<tr><td>ISR</td><td>Even though the Markush scaffolds claimed in both WO’107 and WO’108 are identical, there is no overlap in the ISR documents across both the applications. The ISR for the present application has 4 documents, of which 2 were published after the priority date (P documents) but before the international filing date. Of these 2 documents, 1 was listed for both novelty and inventive step (X) and the other document was listed to describe only the general state of the art and is not considered to be of particular relevance (A). Of the remaining 2 documents, 1 was an X document and the other an A document.</td></tr>
<tr><td>TPO</td><td>The TPO was filed on 23.04.2019 and comprised 6 prior art documents. Of the 6 documents, only 1 was uploaded to the WIPO website. Of the 6 documents used in the TPO, 5 were patent applications and 1 was a periodical article. Also, 5 documents were used for both novelty and inventive step and 1 was used only for inventive step. In the TPO, 2 of the documents used had a publication date after the priority date of the present application (P documents) but before the international filing date. Both the P documents were used to assail novelty and inventive step. The prior art documents used across WO’107 and WO’108 were identical.</td></tr>
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<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited</td></tr>
<tr><td>Priority Date</td><td>28.06.2017</td></tr>
<tr><td>Details</td><td>The application claims compounds with a Markush structure which modulate indoleamine 2,3-dioxygenase (IDO1), which is associated with chronic viral infections such as HIV, HCV and HBV, autoimmune disorders, neurodegenerative disorders and chronic bacterial infections such as tuberculosis.</td></tr>
<tr><td>Claims</td><td>The application has 16 claims, 1 independent and 15 dependent claims consisting of 1 Markush structure claim. There are 9 secondary claims, of which 1 is a formulation claim, 2 are claims for use and 6 are claims for methods of treatment. The compounds claimed as indoleamine modulators are used for the treatment of HIV, HCV and TB, and for diseases like Parkinson’s disease, Huntington’s disease and prosthetic joint infection.</td></tr>
<tr><td>ISR</td><td>The ISR/WOSA/IPRP were published, with the European Patent Office, Rijswijk, Netherlands, being the ISA. The ISR listed 3 documents, comprising 2 which dislodged the novelty claims in the application (1 of them being a document published after the priority date, but before the filing date of the application) and 1 other document (E document).</td></tr>
<tr><td>TPO</td><td>The TPO filed 4 prior art documents, none from the ISR. All 4 documents dislodged the inventive step arguments of the claims in the application. 1 prior art document used was a periodical article and 3 were patent documents. It is interesting to note that the scaffolds claimed in the application were similar to the scaffolds and compounds claimed in WO’108 and WO’107 – for which TPOs were filed earlier.</td></tr>
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<tr><td>Japan</td><td>26.12.2019</td><td>2019572171</td><td></td></tr>
<tr><td>China</td><td>27.12.2019</td><td>201880043633.7</td><td>Published 11.02.2020</td></tr>
<tr><td>Brazil</td><td>31.12.2019</td><td>112019027363</td><td>Withdrawn 21.12.2021</td></tr>
<tr><td>EPO</td><td>28.01.2020</td><td>2018749513</td><td>Published 06.05.2020
Withdrawn 08.06.2021</td></tr>
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<tr><td>Applicants</td><td>GlaxoSmithKline Intellectual Property Development Limited</td></tr>
<tr><td>Priority Date</td><td>30.10.2017</td></tr>
<tr><td>Details</td><td>The application claims compounds with a Markush structure comprising a spirocyclic core which modulate indoleamine 2,3-dioxygenase (IDO1), which is associated with chronic viral infections such as HIV, HCV and HBV, autoimmune disorders, neurodegenerative disorders and chronic bacterial infections such as tuberculosis.</td></tr>
<tr><td>Claims</td><td>The application has 14 claims (1 independent and 13 dependent claims), wherein 9 claims are secondary claims. Of the 9 secondary claims, 7 are for formulation, 2 are for use and 6 are method of treatment claims. Of the 7 claims for formulation, 1 is for composition per se and the other 6 claims are for the dependent method of treatment claims comprising administration of the claimed composition for treatment of diseases/conditions by modulation of IDO activity. Of the 6 method of treatment claims, 2 specifically characterise the disease/condition to be treated in terms of biomarkers of IDO activity. The application broadly claims treatment of conditions such as cancer, chronic viral and bacterial infections and neurological disorders, and also specifically claims method of treatment of diseases related to these conditions such as HBV, HCV, tuberculosis and Parkinson’s disease via modulation of IDO activity. Thus, the number of diseases is given as > 10. Of the 2 claims for use, 1 claim is drafted as “compound or salt for use” and the other claim is drafted as a claim for use of “compound or salt for manufacture of medicament for treating diseases”.</td></tr>
<tr><td>ISR</td><td>The ISR comprises 3 documents, all of them listed to describe only the general state of the art and not considered to be of particular relevance (A). Also, one of the A documents was published after the priority date of the present application but before the international filing date (P).</td></tr>
<tr><td>TPO</td><td>The TPO was filed on 02.03.2020 and comprises 5 prior art documents. Of the 5 documents, 4 are patent applications and 1 is a periodical article. Also, 2 documents were used for both novelty and inventive step and 3 documents were used only for inventive step. One of the patent documents in the prior art (WO 2019/078968), used to assail both novelty and inventive step, was published after the priority date of the present application but before the international filing date (P, X). In the TPO, the 1 additional document uploaded is a periodical document (Arrumugam et al.) to support a periodical document cited (Mbongue et al.) for which a note was written.</td></tr>
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TPO No.	62
Appl. No.	PCT/US2018/061117: WO2019099564
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019099564
Applicants	Children's Medical Center Corporation and Dana-Farber Cancer Institute, Inc
Priority Date	14.11.2017
Details	The application is a basic molecule application as well as a biologic application for HIV, HCV and TB. It claims imidazopyrimidine compounds and their derivatives as enhancers or modifiers of an immune response and thus useful in treating and/or preventing diseases, as adjuvants in a vaccine for various diseases (e.g., proliferative disease, inflammatory disease, autoimmune disease, infectious disease or chronic disease), or as stand-alone anti-infective or immune response modifying agents. It also claims pharmaceutical compositions, kits, methods and uses including or using the claimed compounds. The diseases listed include HIV, HCV and TB as well as several other diseases such as influenza, cancer, allergy, HPV, HBV, smallpox, yellow fever, mumps, etc. The mechanism of action of the claimed compounds is immune response enhancing/modifying activity as well as stand-alone anti-infective activity. In the description, the applicant discloses that commercial libraries were screened for activation of human immune cells and adjuvant activity and that the SAR of known imidazopyrimidine compounds was studied for the generation of the claimed compounds present in the pharmaceutical composition/vaccine of the present application.
Claims	The application has 67 claims, of which 1 is an independent claim and the remaining 66 are dependent claims. It claims 3 Markush structures and 38 specific compounds. Of the 3 Markush structures, 1 is a primary Markush structure and 2 are derivative Markush structures. However, the derivative Markush structures are not numbered specifically. The applicant also specifically disclaims 6 compounds in 1 of the claims. From the description, it appears that these compounds were part of the imidazopyrimidine compounds that were screened by the applicant. The application claims the imidazopyrimidine compounds as well as their pharmaceutically acceptable salts. There are 52 secondary claims, of which 52 are formulation claims, 2 are dosage claims, 3 are use claims, 46 are method of treatment claims, 51 are combination claims and 1 is an "other" claim. Of the 52 claims for formulation, 2 claims are for pharmaceutical composition per se. All the 46 method of treatment claims, 3 use claims and 1 "other" claim all relate to either the claimed compounds or the claimed compositions. Thus, all the secondary claims have been counted as formulation claims too. The 2 dosage claims, which disclose frequency of dosing, of the claimed composition have been drafted as method of treatment claims. The 1 "other" claim relates to a kit comprising the claimed compound or the claimed pharmaceutical composition.

	Of the 3 claims for use, 2 claims are drafted as use of compound/pharmaceutical composition as medicament (also specifically as immunomodulator); 1 claim is drafted as use of compound/pharmaceutical composition for treating diseases. All 46 method of treatment claims relate either to the claimed compounds, compositions thereof or where the claimed compound is an adjuvant in a vaccine. Of these, 28 claims relate to the treatment of various diseases/conditions or protection against a range of pathogens (claims 18-45). Two claims relate to frequency of dosing, 1 claim relates to route of administration, 12 claims relate to targeted patient, condition and time of administration. Two claims relate to administration of the claimed composition as a prophylactic (n = 1) and as combination therapy (n = 1). One claim relates to method of enhancing an immune response in a subject. Of the 51 claims for combination, 1 claim is drafted as a composition claim per se and another claim is drafted as a method of treatment claim wherein the claimed composition is administered as part of combination therapy. All the secondary claims (except 1 formulation claim) impliedly include a reference to the claimed combination and have therefore been counted as combination claims too. The application broadly claims method of treatment with claimed compounds/pharmaceutical compositions thereof of various conditions such as proliferative, inflammatory, autoimmune, viral, bacterial and paediatric infections and specifically lists certain diseases, including influenza, HIV, HCV and TB.
ISR	The ISR, WOSA and IPRP have been published; the USPTO is the ISA. The ISR cites 5 documents, of which 2 are X documents, 1 is a Y document and 2 are A documents. In the ISR, one of the documents listed for novelty (X) was also listed for inventive step (Y). The search strategy has been separately published.
TPO	Two TPOs were filed. The first TPO cites 6 documents. Of these 6 documents, 3 documents are used to assail inventive step and 3 documents are used to assail both novelty and inventive step. Two of these documents are periodicals and 4 are patent documents. In the first TPO, 7 further/additional documents (5 periodical prior art documents and 2 patent documents) were cited along with the main documents cited for which notes were written. Of the 7 additional documents, (i) 2 additional periodical articles each were cited in support of a periodical article and a patent document (n = 4), (ii) 1 additional periodical article was cited in support of a patent document, and (iii) 1 additional patent document each was cited in support of 2 patent documents (n = 2). A second TPO with a note on 1 patent document (which was used as an additional/supporting document in the first TPO) was also filed on the same day. “Additional comments” were also filed with this TPO. In the description, the applicant discloses and admits that commercial libraries were screened for activation of human immune cells and adjuvant activity and that the SAR of known imidazopyrimidine compounds was studied for the generation of the claimed compounds present in the pharmaceutical composition/vaccine of the present application. Thus, 1 of the additional documents is an “additional comment” which highlights the admissions by the applicant in the description to point out that the claimed imidazopyrimidine compounds lack inventive step.

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<tr><td>Republic of Korea</td><td>12.06.2020</td><td>1020207016955</td><td>Published 22.07.2020</td></tr>
<tr><td>EPO</td><td>15.06.2020</td><td>2018879326</td><td></td></tr>
<tr><td>China</td><td>30.06.2020</td><td>201880084871.2</td><td>Published 13.11.2020</td></tr>
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TPO No.	63
Appl. No.	PCT/US2018/061135: WO2019099578
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019099578
Applicants	Children's Medical Center Corporation and Dana-Farber Cancer Institute, Inc
Priority Date	14.11.2017
Details	The application is a biologic application for HIV, HCV and TB. The application claims compositions comprising an antigen and imidazopyrimidine compound for enhancing human immune response and/or as adjuvants in vaccines. It also claims methods of enhancing immune response in a subject by administering the imidazopyrimidine compounds per se. The diseases listed include HIV, HCV and TB as well as several other diseases such as influenza, cancer, allergy, HPV, HBV, smallpox, yellow fever, mumps, etc. The mechanism of action of the claimed compounds is immune response enhancing activity. In the description, the applicant discloses that commercial libraries were screened for activation of human immune cells and adjuvant activity and that the SAR of known imidazopyrimidine compounds was extensively studied for the generation of compounds present in the pharmaceutical composition/vaccine of the present application.
Claims	This application claims pharmaceutical compositions/vaccine containing imidazopyrimidine compounds and an antigen. This application was filed on the same day as WO2019099564 by the same applicant (for which TPO #62 above was filed). The descriptions of both the applications are almost identical. However, the 6 compounds specifically disclaimed in WO2019099564 have been specifically claimed in the pharmaceutical compositions and method of treatment claims of the present application. The application has 143 claims, of which 7 are independent claims and 136 are dependent claims. Of the 7 independent claims, 2 are formulation claims, 3 are method of treatment claims and 2 are use claims. All 143 claims relate to either pharmaceutical composition, method of treatment and use of imidazopyrimidine compounds as an adjuvant along with an antigen or method of enhancing immune response with imidazopyrimidine compound per se. Therefore, this is primarily a secondary application. The application does not claim the Markush structures per se. However, the secondary claims (formulation and method of treatment claims) relate to 3 Markush structures and 42 specific imidazopyrimidine compounds (or their salts). Of the 3 Markush structures, 1 is a primary Markush structure (Formula I) and the other 2 are derivative Markush structures. The 2 derivative Markush structures are not numbered specifically. There are 47 formulation claims, 2 use claims, 94 method of treatment claims and 131 combination claims. Of the 47 formulation claims, 1 independent formulation claim is for a composition comprising an antigen and an imidazopyrimidine compound, 13 dependent claims list the antigens for the claimed composition, 16 dependent claims define the Markush structures or the imidazopyrimidine compounds for the claimed composition, 13 dependent claims further define the composition itself (i.e., conjugation of

	imidazopyrimidine compound to the antigen; adsorption onto alum, vaccine and possible second adjuvants). The second independent formulation claim relates to a vaccine comprising an antigen and an imidazopyrimidine compound as an adjuvant and 3 dependent claims further define the vaccine composition, including adjuvant system. Of the 2 use claims, 1 is for use of an imidazopyrimidine compound as an adjuvant in a vaccine and the second claim is for use of an imidazopyrimidine compound to enhance immune response in a subject. Of the 94 method of treatment claims, 82 claims relate to method of enhancing immune response with a composition comprising imidazopyrimidine compound and an antigen (wherein specific antigens and imidazopyrimidine compounds along with other adjuvants are claimed), 1 claim relates to method of vaccinating a subject with the claimed composition or vaccine, 1 claim relates to method of treating a disease with the claimed composition or vaccine and 10 claims relate to a method of enhancing immune response by administration of the claimed imidazopyrimidine compounds alone. Apart from the 2 use claims claiming use of imidazopyrimidine compounds as adjuvants and enhancing immune response and 10 method of treatment claims for enhancement of immune response by administration of imidazopyrimidine compounds alone, all the other claims (i.e., n = 131) have been considered as combination claims. With respect to diseases, the application broadly claims method of treatment with claimed compounds/pharmaceutical compositions thereof of various conditions such as proliferative, inflammatory, autoimmune, viral, bacterial and paediatric infections and specifically lists certain diseases, including influenza, HIV, HCV and TB. Therefore, the number of diseases is counted as > 10.
ISR	The ISR, WOSA and IPRP have been published; the USPTO is the ISA. The ISR cites 9 documents, of which 7 are X documents, 1 is a Y document and 1 is an A document. In the ISR, one of the documents listed for novelty (X) was also listed for inventive step (Y). The search strategy has been separately published.
TPO	The TPO cites 7 documents. Of these 7 documents, 3 documents are used to assail inventive step and 4 documents are used to assail both novelty and inventive step. Of these 7 documents, 3 are periodicals, 3 are patent documents and 1 is a book. Five additional documents were cited in the TPO. Of these, 1 was a book chapter to support another book chapter itself; 1 patent document each was cited in support of a periodical article and a patent document (i.e., n = 2); and 1 periodical article was cited in support of a patent document. As mentioned earlier, 1 document, i.e., “additional comments”, was also uploaded along with the TPO. “Additional comments” were filed along with the TPO pointing out how the imidazopyrimidine compounds claimed in the composition and method of treatment claims are not novel (previously known compounds) or lack inventive step. Given the commonality of the descriptions of WO2019099564 and this application, 2 patent documents (i.e., WO2012088411 and WO2006033703) were used as common prior art documents for both these TPOs.

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<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 16.03.2020.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>United States of America</td><td>13.05.2020</td><td>16763847</td><td>Published 10.09.2020</td></tr>
<tr><td>Japan</td><td>14.05.2020</td><td>2020526547</td><td></td></tr>
<tr><td>Republic of Korea</td><td>12.06.2020</td><td>1020207016958</td><td>Published 22.07.2020</td></tr>
<tr><td>EPO</td><td>15.06.2020</td><td>2018878690</td><td></td></tr>
<tr><td>China</td><td>13.07.2020</td><td>201880086316.3</td><td>Published 25.08.2020</td></tr>
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PART E: Case Summaries: Applications claiming HIV and TB treatments

<table>
<tr><td>TPO No.</td><td>60</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/057126: WO/2019/084020</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsfdocId=WO2019084020</td></tr>
<tr><td>Applicants</td><td>Gilead Sciences, Inc.</td></tr>
<tr><td>Priority Date</td><td>24.10.2017</td></tr>
<tr><td>Details</td><td>The application claims treatment of a patient co-infected with a viral disease (HIV or HBV) and tuberculosis with a combination of tenofovir alafenamide fumarate (TAF) and an antimycobacterial agent, more specifically rifampicin.</td></tr>
<tr><td>Claims</td><td>The application has 31 claims (2 independent and 29 dependent claims); wherein all 31 claims are secondary claims. All 31 claims are also combination, method of treatment and dosage claims. Of the 31 claims, 3 claims are specifically for formulation. All the claims are for method of treatment for treating a patient with a viral condition (HIV or HBV) co-infected with TB with a combination of TAF and an anti-mycobacterial agent, more specifically rifampicin. One of the independent claims is for a combination of TAF and anti-mycobacterial agent. The second independent claim is for a combination of TAF, bictegravir and emtricitabine in combination with rifampicin. The 3 formulation claims are the method of treatment claims claiming treatment with a single tablet; of these, 2 claims also refer to the doses of the therapeutic agents. Both the independent claims refer to the dosage and/or dose and therefore, all 31 claims are counted as dosage claims too. Of these dosage claims, the 2 formulation claims specifically refer to the doses. Thirteen method of treatment claims characterise the pharmacokinetic parameters, i.e., TAF and TFV exposure.</td></tr>
<tr><td>ISR</td><td>The ISR comprises 5 documents. One of them is listed to describe only the general state of the art and not considered to be of particular relevance (A) and 4 of them are listed as Y documents, wherein the claimed invention cannot be considered to involve an inventive step when the said document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</td></tr>
<tr><td>TPO</td><td>The TPO was filed on 24.02.2020 and comprises 7 prior art documents. Of the 7 documents, 1 is a patent application, 5 are periodical articles and 1 is an “other” prior art document. Also, 1 document was used only for novelty, 1 was used for both novelty and inventive step and 5 documents were used only for inventive step. In the TPO, the 1 "other" prior art document used is a report of a conference proceeding. An additional document was uploaded to establish the date of the report. The US Department of Health and Human Services (DHHS) guidelines are referred to as a supporting document. However, it was not uploaded. The 1 document used to assail only novelty is a PX document, a report of a conference proceeding.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 24.02.2020.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><td>EPO</td><td>25.05.2020</td><td>2018800413</td><td>Withdrawn 19.12.2020</td></tr>
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PART F: Case Summaries: Applications claiming HIV and HCV treatments

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<tr><td>TPO No.</td><td>28</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/024288: WO2018183171</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018183171</td></tr>
<tr><td>Applicants</td><td>Bristol-Myers Squibb Company</td></tr>
<tr><td>Priority Date</td><td>27.03.2017</td></tr>
<tr><td>Details</td><td>The compounds in the application are substituted isoquinoline derivatives as immunomodulators, used for the treatment of cancer and infectious diseases, HIV, HCV, etc. The compounds are inhibitors of protein PD-1 and PD-L1 and CD80/PD-L1 protein interactions.</td></tr>
<tr><td>Claims</td><td>There are a total of 15 claims, of which 1 claim has a Markush structure, while there are 5 specific compounds claimed. One specific compound has been listed twice, as two of its isomeric forms have also been claimed. Fourteen claims are dependent on one claim. There is one formulation claim and 9 method of treatment claims, 2 of which overlap with the 2 combination claims.</td></tr>
<tr><td>ISR</td><td>The ISR/WOSA/IPRP were published, with the European Patent Office, Rijswijk, Netherlands, being the ISA. Two prior art documents were listed in the ISR – one document that affected the novelty of the application and the same document was also listed as a general document.</td></tr>
<tr><td>TPO</td><td>The TPO contained both the ISR documents and 1 additional document – totalling 3 prior art documents, 2 of which would affect the novelty and inventive step, whereas 1 prior art document was used that affects the inventive step claimed in the application. The 3 prior art documents used were prior patent applications.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 29.07.2019.</td></tr>
<tr><td>National Phase as of 07.10.2022</td><td>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>Japan</td><td>26.09.2019</td><td>2019553088</td><td></td></tr>
<tr><td>China</td><td>27.09.2019</td><td>201880022254.X</td><td>Published 15.11.2019</td></tr>
<tr><td>United States of America</td><td>17.09.2019</td><td>16499009</td><td>Published 11.06.2020
Granted 29.06.2021</td></tr>
<tr><td>Republic of Korea</td><td>23.10.2019</td><td>1020197031232</td><td>Published 03.12.2019</td></tr>
<tr><td>EPO</td><td>28.10.2019</td><td>2018716873</td><td></td></tr>
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TPO No.	30
Appl. No.	PCT/US2018/027969: WO2018195075
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018195075
Applicants	Aquinnah Pharmaceuticals, Inc.
Priority Date	19.04.2017
Details	The application makes claims of compounds, compositions used for modulation of TDP-43 inclusion formation and stress granules in cells, used in the treatment of HIV, HCV and other diseases such as neurogenerative, musculoskeletal, ophthalmological diseases or disorders, cancer, etc.
Claims	The application has 51 claims, of which 1 is an independent claim and 50 are dependent claims. The application claims a patent on 4 Markush structures (1 main formula and 3 derived from the main Markush) and 22 specific compounds. There are 23 secondary claims, all of which are for formulation; 22 claims are also for use of the compounds. The secondary claims are also characterised by the mechanism of action, that is, modulation of TDP-43 inclusion formation and stress granules.
ISR	The ISR/WOSA/IPRP were published, with USPTO being the ISA. There were 4 documents listed in the ISR, of which 3 were general documents and 1 was a document affecting the novelty – though published after the priority date of the application, but before the filing date.
TPO	The TPO used only 1 of the ISR documents and added another 3 documents as prior art challenging the inventive step and the novelty claims in the application. One document was used only for inventive step and 3 documents were used for both novelty and inventive step challenges. All 4 documents used as prior art were patent documents.
Date of Filing of TPO	The TPO was filed on 19.08.2019.
National Phase as of 07.10.2022	No national phase entries.

TPO No.	32
Appl. No.	PCT/IB2018/052936: WO2018198084
Link to Appl.	https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2018198084
Applicants	Lupin Limited
Priority Date	27.04.2017
Details	The application claims cyclic di-nucleotide compounds with tricyclic nucleobases, their tautomeric forms, stereoisomers, pharmaceutically acceptable salts, and their combination with suitable medicament, by the use of STING modulators, for the treatment of HIV, HCV and cancer, among other diseases.
Claims	There are 25 claims, which consist of 2 independent claims and 23 dependent claims. The application contains 3 Markush structures and about 30 specific compounds. The application claims the salt forms, the tautomeric, stereoisomeric forms, and its pharmaceutically accepted hydrate, solvate, or its prodrug. There are about 12 secondary claims, of which 4 are claims for formulations, 2 claims are for the use of the compounds, whereas 6 claims are for method of treatment. There are 3 claims for the combination of the compounds, and all 3 are drafted as composition claims – thus overlapping with the formulation claims.
ISR	The ISR/WOSA/IPRP were published, with the European Patent Office, Rijswijk, Netherlands, being the ISA. The ISR quoted 4 prior art documents, of which 3 were general documents and 1 document was a document affecting novelty of the application, though it was published after the priority date but prior to the filing date of the application. The document affecting the novelty of the claims in the application was also listed as a general document.
TPO	The TPO used 1 of the ISR documents and 3 additional documents that would affect the inventive step and the novelty of the application. The document used after the priority date would affect both novelty and inventive step. The TPO used 1 periodical article and 3 patent documents as prior art documents to challenge the claims in the application.
Date of Filing of TPO	The TPO was filed on 27.08.2019.
National Phase as of 07.10.2022	No national phase entries.

<table>
<tr><td>TPO No.</td><td>50</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/052180: WO2019060692</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019060692</td></tr>
<tr><td>Applicants</td><td>Chimerix, Inc.</td></tr>
<tr><td>Priority Date</td><td>21.09.2017</td></tr>
<tr><td>Details</td><td>The application claims crystalline hemihydrate forms of an antiviral compound which is claimed for antiviral infections, including norovirus, HIV and HCV. The claimed compound appears to be a derivative, a CMX-521, which is presently being developed for treatment of norovirus. It is a secondary application, and no mechanism of action has been disclosed. Crystallisation conditions using water activity as a parameter have been claimed. It may be noted that as per Adis Insight, CMX-521 is tagged as DNA-directed RNA polymerase modulators, nucleoside reverse transcriptase inhibitors and polymerase inhibitors.</td></tr>
<tr><td>Claims</td><td>The application has 43 secondary claims, of which 15 are independent claims and 28 are dependent claims. There are 2 formulation claims, 21 claims of the crystalline form of the compounds (1 of which is a claim of the hemihydrate form of compound A, and 6 are claims of forms of compounds B to G), 4 claims for the use of the compounds and 3 claims for method of treatment. There are 13 process claims too in the application.</td></tr>
<tr><td>ISR</td><td>The ISR/WOSA/IPRP were published, with the European Patent Office, Rijswijk, Netherlands, being the ISA. The ISR has only 1 document against the novelty claims of the application.</td></tr>
<tr><td>TPO</td><td>The TPO used 3 prior art documents, none from the ISR. Two of the documents in the prior art were for inventive step and one was for both inventive step and novelty. Two of the documents used in the TPO were periodical articles and 1 was a book.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 21.01.2020.</td></tr>
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<tr><th>Office</th><th>Entry Date</th><th>National Number</th><th>National Status</th></tr>
<tr><td>United States of America</td><td>10.03.2020</td><td>16645876</td><td>Published 03.09.2020
Granted 07.09.2021</td></tr>
<tr><td>EPO</td><td>21.04.2020</td><td>2018808140</td><td></td></tr>
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<tr><td>TPO No.</td><td>52</td></tr>
<tr><td>Appl. No.</td><td>PCT/CN2018/106983: WO2019057158</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019057158</td></tr>
<tr><td>Applicants</td><td>Jiangsu Hengrui Medicine Co., Ltd and Shanghai Hengrui Pharmaceutical Co., Ltd</td></tr>
<tr><td>Priority Date</td><td>22.09.2017</td></tr>
<tr><td>Details</td><td>The application claims compounds and pharmaceutical compositions containing fused heteroaryl derivatives acting as TLR-7 agonists for the treatment of many viral diseases, HIV, HCV, HPV, HBV, SARS, Zika virus, cancer, etc.</td></tr>
<tr><td>Claims</td><td>The application has 26 claims, 2 independent and 24 dependent claims. The claims contain 10 Markush structures, with 8 specific compounds, and 9 secondary claims. The tautomer, racemate, enantiomer, diastereomer or mixtures of the compounds are also claimed. One claim is for a formulation, 5 are for the use of the compounds, and 3 are other claims for process.</td></tr>
<tr><td>ISR</td><td>The ISR/WOSA/IPRP were published, with the China State Intellectual Property Office being the ISA. The ISR has 6 prior art documents, 2 of which are against the novelty, and 4 are general documents against claims of the application.</td></tr>
<tr><td>TPO</td><td>The TPO annexed only 1 document, not from the ISR. The TPO, however, refers to 2 documents of the ISR (1 general and 1 novelty-challenging document) in the note. The TPO referred to only 1 periodical document, but along with it, filed an additional periodical document. The prior art was against the novelty and inventive step claims of the application.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 22.01.2020.</td></tr>
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Granted 23.08.2022</td></tr>
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<tr><td>TPO No.</td><td>54</td></tr>
<tr><td>Appl. No.</td><td>PCT/US2018/053871: WO2019070643</td></tr>
<tr><td>Link to Appl.</td><td>https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2019070643</td></tr>
<tr><td>Applicants</td><td>Bristol-Myers Squibb Company</td></tr>
<tr><td>Priority Date</td><td>03.10.2017</td></tr>
<tr><td>Details</td><td>The application claims macrocyclic peptides which inhibit the PD-1/PD-L1 and PD-L1/CD80 protein/protein interaction, and thus are useful for the amelioration of various diseases, including cancer and infectious diseases, like HIV, HCV, HBV, herpes virus, influenza, etc.</td></tr>
<tr><td>Claims</td><td>There are 16 claims, 1 independent claim and 15 dependent claims. One claim has a Markush structure, whereas there are 12 secondary claims. All 12 secondary claims are method of treatment claims, and 4 are claims for combinations.</td></tr>
<tr><td>ISR</td><td>The ISR/WOSA/IPRP were published, with the European Patent Office, Rijswijk, Netherlands, being the ISA. The ISR has only 1 document against the novelty claims of the application.</td></tr>
<tr><td>TPO</td><td>The TPO referred to 2 prior art documents, none from the ISR. One document was against only inventive step and the other was against both novelty and inventive step. One document was a patent document and the other was a book.</td></tr>
<tr><td>Date of Filing of TPO</td><td>The TPO was filed on 03.02.2020.</td></tr>
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<tr><td>China</td><td>25.02.2020</td><td>201880055279.X</td><td>Published 21.04.2020</td></tr>
<tr><td>Japan</td><td>02.04.2020</td><td>2020519054</td><td></td></tr>
<tr><td>United States of America</td><td>03.04.2020</td><td>16753666</td><td>Published 17.09.2020</td></tr>
<tr><td>EPO</td><td>04.05.2020</td><td>2018793327</td><td></td></tr>
<tr><td>Republic of Korea</td><td></td><td>1020207012116</td><td>Published 27.05.2020</td></tr>
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