

10.	Exhibit-H- Order dated 16.12.2020 of the Assistant Controller of Patents & Designs in patent application no. 1554/CHENP/2013	530-545
11.	Form 26	

Dated this 8th day of September, 2021

Priyam Lizmary Cherian

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TO
THE CONTROLLER OF PATENTS
PATENT OFFICE, DELHI

FORM 7A
THE PATENTS ACT, 1970
and
THE PATENT RULES, 2003
REPRESENTATION FOR OPPOSITION TO GRANT OF PATENT

WE, Delhi Network of Positive People (DNP+) with our office at Flat No. A1-5, House No 141, Gali No 3, Near IGNOU, Neb Sarai, New Delhi 110068, hereby give representation by way of opposition to the grant of patent in respect of Indian Patent Application No. **201818021052** titled **ANTIVIRAL COMPOUND** filed by **Abvie Bahamas Ltd.**, on 05.06.2018 in India and published on 14.09.2018.

The patent application is opposed on the following grounds:

1. Section 25(1)(e)-That the invention claimed is obvious and does not involve any inventive step; it
2. Section 25(1)(f)-That the subject of the claims of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act ;
3. Section 25(1)(g)- That the complete specification does not clearly and sufficiently describe the method by which the invention is to be performed.

Our address for service in India is:

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Dated this the 8th day of September 2021

Opponent

To

The Controller,

The Patent Office

DELHI

**BEFORE THE CONTROLLER OF PATENTS,
THE PATENT OFFICE, DELHI**

IN THE MATTER OF A PRE- GRANT
OPPOSITION UNDER SECTION 25 (1)
AND RULE 55 OF THE PATENTS ACT,
1970

And

IN THE MATTER OF PATENT
APPLICATION NO. **201818021052**
TITLED ‘ANTI-VIRAL COMPOUNDS’
FILED BY Abbvie Bahamas Ltd. Filed on
05.06.2018 APPLICANT

And

IN THE MATTER OF REPRESENTATION
BY WAY OF OPPOSITION FILED BY
THE DELHI NETWORK OF POSITIVE
PEOPLE (DNP+)OPPONENT

REPRESENTATION BY WAY OF OPPOSITION

U/S 25(1), PATENTS ACT 1970

1. A pre-grant opposition under Section 25(1), Patents Act, 1970 is hereby being filed by the Delhi Network of Positive People (DNP+) (hereinafter, “the Opponent”) in the patent application no. **201818021052** (hereinafter, the “Present Application”) titled ‘ANTI-VIRAL COMPOUNDS’ filed by

Abbvie Bahamas Ltd. (hereinafter, “the Applicant”), filed before the Indian Patent Office on 05.06.2018.

OPPONENT’S BACKGROUND & *LOCUS STANDI*

2. The Opponent is a network of people living with HIV (PLHIV) working extensively in the area of access to medicines particularly Anti-Retroviral (ARV) medicines and those related to opportunistic infection such as Hepatitis C and Tuberculosis. The Opponent’s work includes but is not limited to service delivery, treatment literacy and community empowerment. The Opponent believe that every individual should have access to affordable medicines and no one should suffer and die due to lack of medicines and/ or treatment.
3. Section 25(1), provides that an opposition to grant of a patent to an application may be instituted by “any person” when the application has been published but a patent has not been granted.
4. The Opponent herein is non-profit organisation representing the needs of the PLHIV. Given that any person may institute an opposition to the grant of patent under Section 25(1), the Opponent has the *locus standi* to file the present opposition.
5. The INPASS system indicates the status of the Present Application as “Reply Filed. Application in amended examination”. That is, the Present Application is published and examined and has not been granted a patent. Hence, this opposition to grant of patent to the Present Application is maintainable before the Hon’ble Patent Office, Delhi.

GENERAL BACKGROUND

6. The Present Application covers compounds used for treatment of Hepatitis. The WHO Global Hepatitis Report, 2017 estimated 325 million people worldwide to be living with chronic Hepatitis B or C virus infection. The report indicates that 71 million people are estimated to be with chronic Hepatitis C infection with majority of them having limited access to life

saving HCV testing and treatment. Increasing mortality rates due to Hepatitis C Viral (HCV) infection when compared with HIV and Tuberculosis deaths is a cause of concern. In 2015, viral hepatitis reportedly caused 1.34 million deaths.

7. Hepatitis C is a blood borne virus, the infection spreads from exposure to infected blood which may be during unsafe injection practice, injecting drug use, and transfusion of unscreened and unsafe blood products. In India, a rough estimate indicates there are 10 to 15 million chronic carriers of HCV (Bhattacharya PK, Roy A (2015) Management of Hepatitis C in the Indian Context: An Update. J Liver 4:187).
8. The absence of surveillance system to track HCV infection in India and presence of PLHIV community with undetected HCV co-infection further necessitates the need to ensure early access to HCV care and treatment. Though Hepatitis C is red flagged as a major public health concern and termed as a ticking time bomb by the World Health Organisation, access to treatment and medicines continues to be abysmally low for people with hepatitis C infection with patent posing as a major barrier in accessing affordable HCV medicines.

ACCESS TO MEDICINES AND STRICT INTERPRETATION OF INDIAN PATENTABILITY STANDARDS

9. Competition plays a significant role in ensuring low and affordable medicines in the market. A patent creates a market monopoly, allowing the patent holder to set monopolistic prices. It therefore becomes imperative that patents are not granted for non-inventive or incremental improvements- leading to ever-greening, and are not eligible for a patent in India.
10. While the Patents Act 1970 lays down strict standards for patent eligibility, a study showed that in a cohort of 2,293 pharmaceutical patents granted between 2009 and 2016, about 72 per cent of patents granted are secondary patents, not eligible for patent under Indian law, but granted for marginal improvements over previously known drugs for which primary patents exist.

That is, the patent applications were not properly scrutinised following the strict standards laid down in the Patents Act, 1970 under Section 3. (See Dr. Feroz Ali et al, *Pharmaceutical Patents Granted in India: How our safeguards against ever-greening have failed, and why the system must be Reformed*, Accessibsa, 2018).

11. The Opponent firmly believes that a proper application of the patentability standards set out in Section 3 of the Patents Act, as well as those embodied in Section 2(1)(j) and Section 2(1)(j)(a) of the Patents Act, will result in the rejection of the Present Application in its entirety. The decision on the grant of patent to the Present Application will have an impact of affordability of life saving drugs for a large number of People Living with HCV.

THE PARENT APPLICATION

12. The Present Application purports to be a divisional application stemming from patent application no. 1310/DELNP/2013 (hereinafter referred to as “IN ’310 application”). IN ’310 application was filed in India with the same 22 claims as filed with in the original PCT Publication No. WO2012051361 in respect of Markush formula. bearing a priority date of 13.10.2010 from US application no. 12/093,822, priority date of 09.12.2010 from US application no. 12/964,027, and priority date of 25.02.2011 from US patent application no. 61/446,800, and priority of 04.05.2011 from US application no. 13/100,827.
13. IN ’310 application was examined in 2017 and a First Examination Report (FER) was issued on 07.12.2017. It may be noted that the FER pointed out the claims IN’310 application to be lacking unity of invention. The FER noted,
*‘Claim(s) 1-22 lack(s) unity of invention as the claims do not relate to a single invention or to a group of inventions linked so as to form a single inventive concept:
The two separate groups of "inventions" in the application are the following, being independent from each other:*

(1) Claims 1, 11, 13 and 14 (all of them partly), i.e. compounds of formula I wherein X is a carbocycle, the corresponding pharmaceutical compositions, methods and process for preparation

(2) Claims 1, 11, 13 and 14 (all partly), 2-10,12 and 15-22 (completely), i.e. the compounds of formula I wherein X is a heterocycle the corresponding pharmaceutical compositions, methods and process for preparation.'

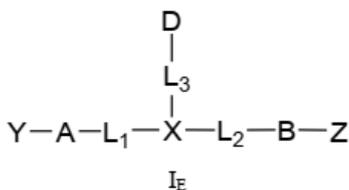
14. The Applicant filed a response to the FER in IN'310 application on 07.06.2018 and also amended/deleted several claims. After amendment, the total number of claims came down to 3. The three new claims covered a specific compound – which compound was the subject of original claim 15 as filed during national phase entry of IN'310 application.
15. An opposition under Section 25(1) of the Patents Act was filed against IN '310 application in July 2018. IN '310 application is currently pending, and there has been no hearing in the opposition filed against the application.

PRESENT APPLICATION

16. The Present Application was filed in India on 05.06.2018 with 18 claims. The Present Application purports to be a divisional application stemming from IN'310 application and claims a priority date of 13.10.2010. The Present Application was published on 14.09.2018. A FER was issued in the Present Application on 30.01.2020. The Applicant filed a response to the FER on 29.10.2020.
17. The 18 claims of the Present Application are described below:-

Claim 1: Claim 1 covers a compound with Markush Formula I_E, and its pharmaceutically acceptable salt. The claims goes on to describe of the substitutions in the Markush formula.

The compound of Formula I_E is reproduced below:



Claims 2 to 9 are dependent on claim 1 and elaborate the substitutions to the compound I_E.

Claims 10 to 11 are dependent on claim 9 and elaborate specific substitutions to the compound I_E.

Claim 12 is dependent on claim 11 and covers specific substitutions to compound of claim 11.

Claim 13 identifies a specific compound resulting from substitution on compound of claim 1. Claim 13 thus covers a compound with a chemical formula methyl {(2S,3R)-1-[(2S)-2-{5-[(2R,5R)-1-{3,5-difluoro-4-[4-(4-fluorophenyl) piperidin-1-yl]phenyl}-5-(6-fluoro-2-[(2S)-1-[N-(methoxycarbonyl)-O-methyl-L-threonyl]pyrrolidin-2-yl)-1H-benzimidazol-5-yl]pyrrolidin-2-yl]-6-fluoro-1H-benzimidazol-2-yl]pyrrolidin-1-yl]-3-methoxy-1-oxobutan-2-yl} carbamate.

Claim 14 covers a composition comprising the compound of claim 13 or its pharmaceutically acceptable salt.

Claim 15 identifies a specific compound resulting from substitution on compound of claim 1. Claim 15 thus covers a compound with a chemical formula methyl {(2S)-1-[(2S)-2-{5-[(2S,5S)-1-{4-[4-(2,6-difluorophenyl)piperazin-1-yl]-3,5-difluorophenyl}-5-{6-fluoro-2-[(2S)-1-[(2S)-2-[(methoxycarbonyl)amino]-3-methylbutanoyl]pyrrolidin-2-yl]-1H-benzimidazol-5-yl]pyrrolidin-2-yl]-6-fluoro-1H-benzimidazol-2-yl]pyrrolidin-1-yl]-3-methyl-1-oxobutan-2-yl} carbamate.

Claim 16 covers a composition comprising the compound of claim 15 or its pharmaceutically acceptable salt.

Claim 17 identifies a specific compound resulting from substitution on compound of claim 1. Claim 15 thus covers a compound with a chemical formula dimethyl ((2*R*,5*R*)-1- {3,5-difluoro-4- [4-(4-fluorophenyl) piperidin-1-yl] phenyl} pyrrolidine -2,5-diyl]bis {(6-fluoro-1*H*-benzimidazole-5,2 diyl) (2*S*) pyrrolidine-2,1-diyl}[(1*S*)-2-oxo-1-(tetrahydro-2*H*-pyran-4-yl)ethane-2,1-diyl]) biscarbamate.

Claim 18 covers a composition comprising the compound of claim 17 or its pharmaceutically acceptable salt.

18. The IPO examined these 18 claims and the same Controller (who had also examined the parent 1310) issued a FER for present '1052 application on 30/Jan/2020 along with the following notes/ objections:

'5. Claims 2-11 were absent in parent application no. 1310/DELNP/2013.

...

8. The instant application has been filed as a purported divisional application out of the purported parent application no. 1310/DELNP/2013 u/s 16 of The Patents Act, 1970 (as amended). There is no distinction between the subject matter of the set of claims of the purported parent application. Hence the instant application does not deserve the merit of a divisional application. In view of this, the filing of the present application as a division alone is infructuous and cannot be allowed as a divisional application when section 16 is read with the provision of sub-section 5 of section 10 of the Act.'

19. On 29.10.2020, the Applicant replied to the FER and amended the claims. The amendment introduced 4 new claims that were completely beyond the scope of the parent IN '310 application.

no. 61/446,800, and priority of 04.05.2011 from US application no. 13/100,827.

SUMMARY OF GROUNDS FOR OPPOSITION

23. The Opponent brings this representation by way of opposition to grant of patent on the following grounds, each of which is without prejudice to the other:
- a. **Section 25(1)(1)(e)**: That claims 1-4 of the Present Application, lack inventive step. Therefore claims 1-4 fail under Section 2(1)(j) and Section 2(1)(ja) of the Patents Act.
 - b. **Section 25(1)(f)**: That claims 1-4 of the Present Application does not cover an invention within the meaning of the Patents Act.
 - c. **Section 25(1)(g)**: That the complete specification does not clearly and sufficiently describe the method by which the invention is to be performed.

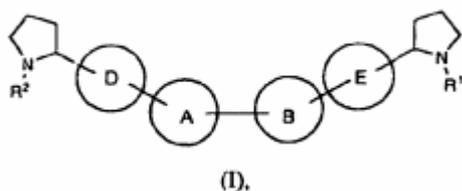
DETAILED GROUNDS

- a. Claims 1-4 of the Present Application lack inventive step and must be rejected under S.25(1)(e) of the Patents Act**
24. Section 2(1)(j), mandates that an invention be either a new product or a process involving an inventive step and capable of industrial application (emphasis supplied). Further, 'Inventive step' is defined in Section 2(1)(ja) as '*a feature of an invention that involves technical step as compared to existing knowledge ...*'(emphasis supplied).
25. It is submitted that the claims 1-4 of the Present Application lack inventive step and therefore must be refused.
26. It is submitted that the following was known before the priority date of the Present Application and has been admitted by the Applicant:
- a. Computer modelling to design or select NS5A inhibitors was known (see Present Application, internal page 3, lines 32-33)

- b. To improve interaction with the NS5A protein, many NS5A inhibitors have been designed to have dimeric or dimer-like structures (see Present Application, internal page 3, lines 34-35 and internal page 4, page 5);
- c. Biphenyl linker between the imidazole moieties in NS5A inhibitors was known (see Present Application, internal page 6, lines 5-9).

WO2008/144380

- 27. The Opponent relies on patent publication no. WO2008/144380 (hereinafter “WO’380” and annexed herewith as **Exhibit-A**) titled “Hepatitis Virus Inhibitors” published on 27.11.2008. Given that the publication has been published before the priority date claimed in the Present Application, the same can be relied on as a prior art document for the purposes of S. 25(1)(e).
- 28. WO ’380 discloses compound of formula I or a pharmaceutically acceptable salt thereof, “*wherein A and B are each phenyl; D and E are each five-membered aromatic rings containing one, two, or three i hcteroatoms independently selected from nitrogen, oxygen, and sulfur; provided that , at least one of D and E is other than imidazole; compositions and methods for the treatment of Hepatitis C virus (HCV) infection.*” (see WO ’380 at abstract)



- 29. In particular, a preferred embodiment includes one where one of D and E is imidazole. (see WO’380, internal page 115, claim 2, claim 7)
- 30. Further, WO ’380 discloses composition comprising the compound of formula I, or a pharmaceutically acceptable salt thereof, further comprising one or two additional compounds having anti-HCV activity (WO’380, internal page 4, lines 26-28) This is also a preferred embodiment and claimed in claim 9 of WO’380 (see internal page 115). Further, the additional compound could be selected from a group that is effective to inhibit function

of a target including HCV serine protease (see WO'380, internal page 117 at claim 13 and internal page 118 at claim 19)

31. WO '380 teaches the type of pharmaceutically acceptable salts that could be used in the context of the invention therein. It provides, "*The term "pharmaceutically acceptable salt," as used herein, represents salts or zwitterionic forms of the compounds of the present disclosure which are water or oil-soluble or dispersible, which are, within the scope of sound medical judgment, suitable for use in contact with the tissues of patients without excessive toxicity, irritation, allergic response, or other problem or complication commensurate with a reasonable benefit/risk ratio, and are effective for their intended use. The salts can be prepared during the final isolation and purification of the compounds or separately by reacting a suitable nitrogen atom with a suitable acid. Representative acid addition salts include acetate, adipate, alginate, citrate, aspartate, benzoate, benzenesulfonate, bisulfate, butyrate, camphorate, camphorsulfonate; digluconate, glycerophosphate, hemisulfate, heptanoate, hexanoate, formate, fumarate, hydrochloride, hydrobromide, hydroiodide, 2 -hydroxy ethanesulfonate, lactate, maleate, mesitylenesulfonate, methanesulfonate, naphthylenesulfonate, nicotinate, 2-naphthalenesulfonate, oxalate, palmoate, pectinate, persulfate, 3-phenylpropionate, picrate, pivalate, propionate, succinate, tartrate, trichloroacetate, trifluoroacetate, phosphate, glutamate, bicarbonate, para-toluenesulfonate, and undecanoate. Examples of acids which can be employed to form pharmaceutically acceptable addition salts include inorganic acids such as hydrochloric, hydrobromic, sulfuric, and phosphoric, and organic acids such as oxalic, maleic, succinic, and citric.*" (see WO'380, internal page 14, lines 31-33, and internal page 15, lines 1-18)
32. WO '380 also teaches the preparation of the salt form of the compound, indicating, "*Basic addition salts can be prepared during the final isolation and purification of the compounds by reacting a carboxy group with a suitable base such as the hydroxide, carbonate, or bicarbonate of a metal cation or with ammonia or an organic primary, secondary, or tertiary*

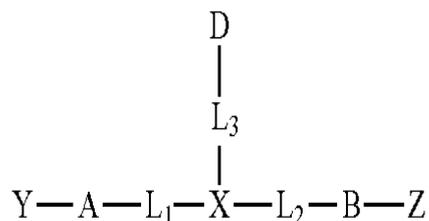
amine. The cations of pharmaceutically acceptable salts include lithium, sodium, potassium, calcium, magnesium, and aluminum, as well as nontoxic quaternary amine cations such as ammonium, tetramethylammonium, tetraethylammonium, methylamine, dimethylamine, trimethylamine, triethylamine, diethylamine, ethylamine, tributylamine, pyridine, N,N-dimethylaniline, N-methylpiperidine, N-methylmorpholine, dicyclohexylamine, procaine, dibenzylamine, N,N-dibenzylphenethylamine, and N,N'-dibenzylethylenediamine. Other representative organic amines useful for the formation of base addition salts include ethylenediamine, ethanolamine, diethanolamine, piperidine, and piperazine.” (WO’380 internal page 15, lines 19-31)

33. Particularly, WO ’380 discloses a composition comprising a compound of Formula I, or a pharmaceutically acceptable salt thereof, a pharmaceutically acceptable carrier, and “*one or two additional compounds having anti-HCV activity, wherein least one or two additional compounds is effective to inhibit the function of a target selected from HCV metalloprotease, HCV serine protease, HCV polymerase, HCV helicase, HCV NS4B protein, HCV entry, HCV assembly, HCV egress, HCV NS5A protein, and IMPDH for the treatment of an HCV infection.*” (see WO ’380, internal page 5, lines 9-16)
34. Hence, a persons skilled in the art (POSITA) on reading WO’380 would be taught that a compound such that of formula I with imidazole substitutions to be useful in treating hepatitis infections. The POSITA would also be taught that such compounds or their pharmaceutically acceptable salts could be used in a composition with other inhibitors such as HCV protease inhibitor.

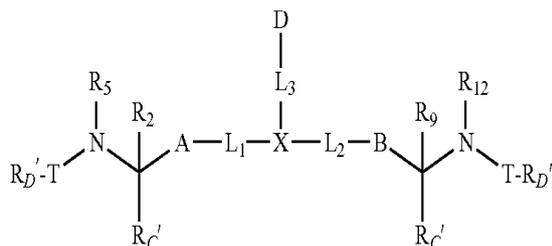
US2010/0317568

35. The Opponent relies on patent publication no. US2010/0317568 (hereinafter “US’568” and annexed herewith as **Exhibit-B**) filed on 10.06.2010. Given that the publication US ’568 has been published before the priority date claimed in the Present Application, the same can be relied on as a prior art document for the purposes of S. 25(1)(e).

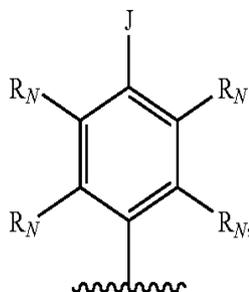
36. US '568 describes compounds effective in inhibiting replication of Hepatitis C Virus. (see US'568, abstract). It discloses a compound of Formula I, a Markush formula and its pharmaceutically acceptable salt thereof (see US '568, internal page 1, para 0012)



37. It also discloses specific substitutions to the compound and discloses a compound of formula I_B (See US'568, internal page 32, para [0114]). The structure of compound of formula I_B is reproduced below for reference:

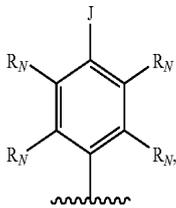
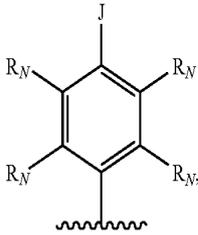


38. In particular, one of the preferred embodiments the substitution at D is disclosed (see US'568, internal page 44, LHS) The preferred substitution disclosed is reproduced below:



39. In fact, US'568 specifically teaches (see internal page 1, para [0006] and internal page 328 para [1010]) and claims combination of the Markush with another anti-HCV agent (including HCV protease inhibitors) and compositions containing such compounds (internal page 337, claim 18). This disclosure makes the present claims of the impugned application obvious in light of common Markush formula, similar substitutions in the Markush formula and use of these compounds and combination of such compounds with another HCV agent for the treatment of HCV infection.
40. Therefore, a POSITA on reading US'568 would be taught about a compound of formula I having anti-HCV properties. The POSITA would also be taught about various substitutions that can be made to the compound of formula I.
41. US'568 discloses a Markush formula of a compound similar to the compound claimed in the Present Application of formula I_B. The table below provides a comparison of the substitutions disclosed in US'568 that are similar to the substitutions disclosed in the Present Application. A comparative table is produced below for easy reference:

<p style="text-align: center;">US2010/0317568 Exhibit-B</p>	<p style="text-align: center;">Present Application</p>
$ \begin{array}{c} D \\ \\ L_3 \\ \\ Y-A-L_1-X-L_2-B-Z \end{array} $ <p style="text-align: center;">Formula 1</p>	$ \begin{array}{c} D \\ \\ L_3 \\ \\ Y-A-L_1-X-L_2-B-Z \end{array} $ <p style="text-align: center;">Formula 1</p>
$ \begin{array}{c} D \\ \\ L_3 \\ \\ R_5 \quad R_2 \quad R_9 \quad R_{12} \\ \quad \quad \quad \\ R_D'-T \quad N \quad A-L_1-X-L_2-B \quad N \quad T-R_D' \\ \quad \quad \quad \\ R_C' \quad R_C' \quad R_C' \quad R_C' \end{array} $ <p style="text-align: center;">Formula I_B</p>	$ \begin{array}{c} D \\ \\ L_3 \\ \\ R_5 \quad R_2 \quad R_9 \quad R_{12} \\ \quad \quad \quad \\ R_D'-T \quad N \quad A-L_1-X-L_2-B \quad N \quad T-R_D' \\ \quad \quad \quad \\ R_C' \quad R_C' \quad R_C' \quad R_C' \end{array} $ <p style="text-align: center;">I_B Formula I_B</p>

 <p>Refer page no.44, substitution of D</p>	 <p>Refer page no. 25, substitution of D</p>
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42. Both, WO'380 and US'568 disclose numerous NS5A inhibitors with same Markush formula as that claimed in the Present Application. They also disclose the importance of substituting the Markush formula to improve the anti-HCV activity of such compounds and possible positions at which these substitutions should be applied. Both the prior art documents also teach use of NS5A inhibitor compounds with other HCV agents (including protease inhibitors) and compositions containing such combinations thus rendering the compound of claim 1 of the Present Application as obvious and lacking inventive step. Given that claims 204 are dependent on claim 1, these claims are also rendered obvious and as lacking inventive step.
43. On reading the WO'380 and US'568, a POSITA would be taught that the compound of formula I or its pharmaceutically acceptable could be used for treating hepatitis and could be used in combination with other HCV protease inhibitors.

b. Subject of claims 1-4 are not patentable under S. 25(1)(f) of the Patents Act 1970

44. Without prejudice to the grounds raised above, the Opponent submits that the subject matter of the claims of the Present Application are not patentable under the Act on following counts.
45. Section 25(1)(f) of the Patents Act provides that grant of a patent may be opposed on the ground that the claimed subject matter is not an invention within the meaning of the Act. In summary are addressed in the paras below.

- i. The Present Application is not a valid divisional application wherein the claims do not appropriately relate to an invention different from the parent application, and therefore the Present Application is not patentable;
- ii. Claims 1-4 of the Present Application are outside the ambit of amendments allowed under Section 59(1) and hence are not patentable;
- iii. The claims 1-4 do not meet the test of Section 3(e) and therefore not patentable.

i. The Present Application is not a valid divisional application

46. Section 16 of the Patents Act lays the basis for filing a divisional application. The provision states:

“(1) A person who has made an application for a patent under this Act may, at any time before the grant of the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.

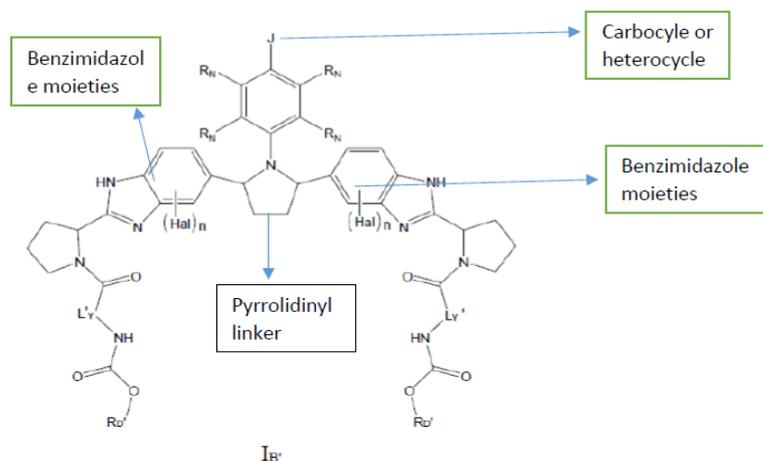
(2) The further application under sub-section (1) shall be accompanied by a complete specification, but such complete specification shall not include any matter not in substance disclosed in the complete specification filed in pursuance of the first mentioned application.

(3) The Controller may require such amendment of the complete specification filed in pursuance of either the original or the further application as may be necessary to ensure that neither of the said complete specifications includes a claim for any matter claimed in the other.

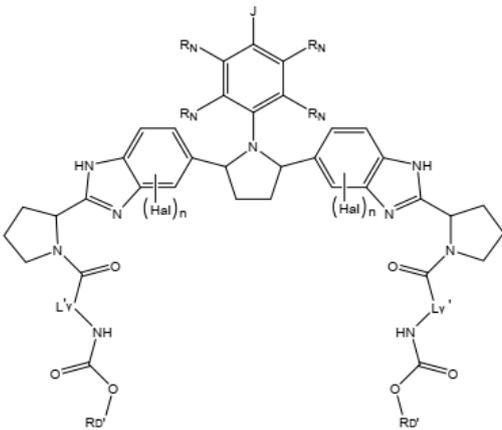
Explanation.—For the purposes of this Act, the further application and the complete specification accompanying it shall be deemed to have been filed on the date on which the first mentioned application had been filed, and the

further application shall be proceeded with as a substantive application and be examined when the request for examination is filed within the prescribed period.”

47. That is, a division of patent application can be filed by an applicant on their own volition or with an objective to remedy the objections raised by the Controller that the claims of the complete specification relate to more than one invention.
48. Para 06.01.01 of ‘The Manual of Patent Office Practice and Procedure’ states:
‘vi. Claims of divisional application(s) shall be based on the claims of first mentioned (or earlier application for that matter) from which instant application is divided out and no addition of claims, which do not fall within the scope of said claims, is allowable.’
49. In the case of the purported parent application IN '310 of the Present Application, the Controller had noted in the FER that there are two separate groups of invention, i.e. one where the compound of Formula I with X being a carbocycle and the other being where the compound of Formula I with X being a heterocycle (emphasis supplied).
50. Thus, in order to ensure that the application on division related to one invention, one application should have limited claims to the compound of Formula I with X being a carbocycle and the other application should have limited the claims to the compound of Formula I with X being a heterocycle.



51. The Applicant, however amended/deleted the claims and opted to focus on the compound which was earlier identified in claim 15 (new claim 1) in parent IN'310 application.
52. The Applicant, on applying for division of application vide the Present Application opted to focus on Compound of Formula I_{B'} (which corresponds to original claim 2 of the parent IN '310 application). The claims of the Present Application do not correspond to overcoming Controller's objection in FER, to ensure unity of invention. Instead, the Applicant is prosecuting similar compounds in both, the parent IN'310 application and the Present Application.
53. Importantly, the Applicant continues to claim a specific compound in the Present Application and the parent IN'310 application: -

<p align="center">Claims 1 and 2 of the Present Application</p>	<p align="center">Amended/ new claim of parent '1310 (07/June/2018)</p>
<p>13. A compound of Formula I_{B'} or a pharmaceutically acceptable salt thereof and a HCV protease inhibitor</p> <div style="text-align: center;">  <p>I_{B'}</p> </div> <p>Amongst the several substitutions claimed in the claims, the following may be taken note of:</p>	<p>1. Methyl {(2S,3R)-1-[(2S)-2-{5-[(2R,5R)-1-{3,5-difluoro-4-[4-(4-fluorophenyl) piperidin-1-yl]phenyl}-5-(6-fluoro-2-{(2S)-1-[N-(methoxycarbonyl)-O-methyl-L-threonyl]pyrrolidin-2-yl}-1H-benzimidazol-5-yl)pyrrolidin-2-yl]-6-fluoro-1H-benzimidazol-2-yl}pyrrolidin-1-yl]-3-methoxy-1-oxobutan-2-yl} carbamate</p>

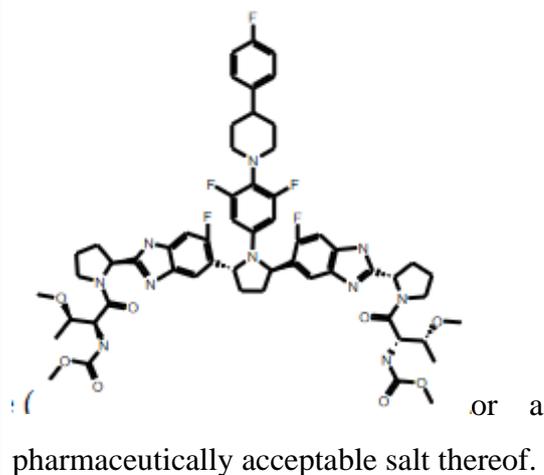
J is a six membered heterocycle substituted with two R_A

Where one R_A is a halogen

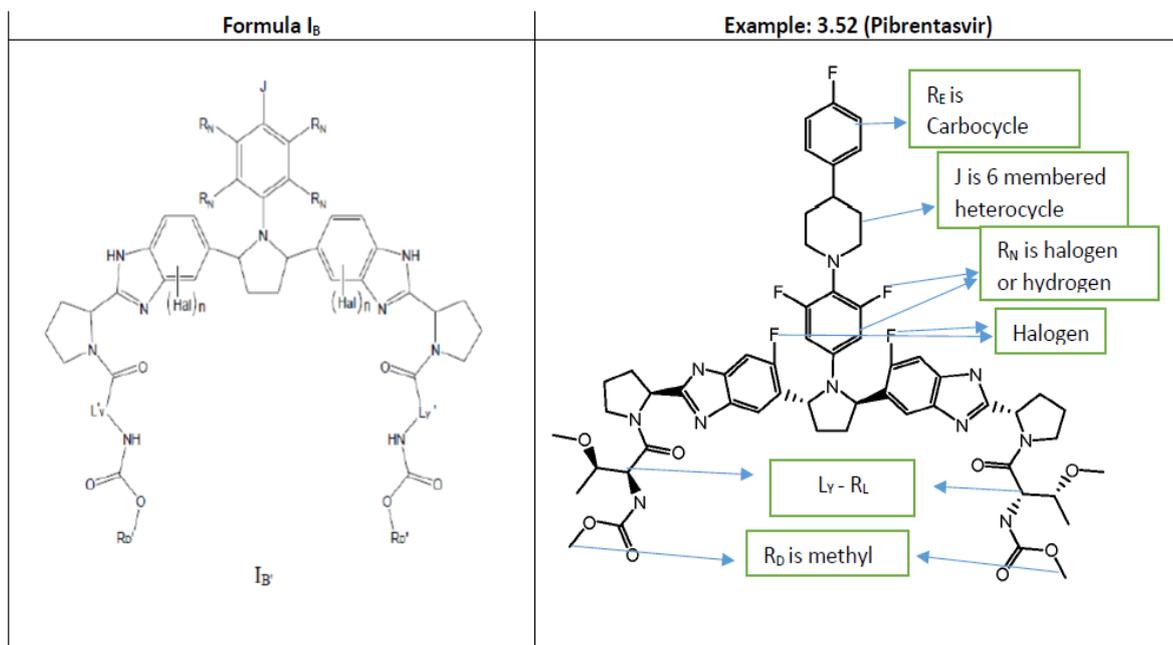
The other R_A is $-L_S-R_E$

Where L_S is a bond and R_E is a C_2-C_6 haloalkenyl

$n=1$

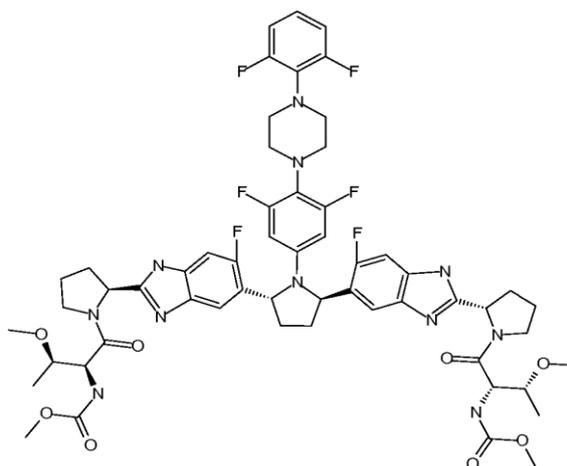


56. Compound **I_B** claimed in the Present Application also covers compounds listed in example 3.48 (Present Application, internal page 322), example 3.52 (Present Application, internal page 325), example 4.38 (Present Application, internal page 349), and example 5.1 (Present Application, internal page 363). Example 3.52 covers Pibrentasvir that has also been claimed in the parent IN'310 application (claim 1).

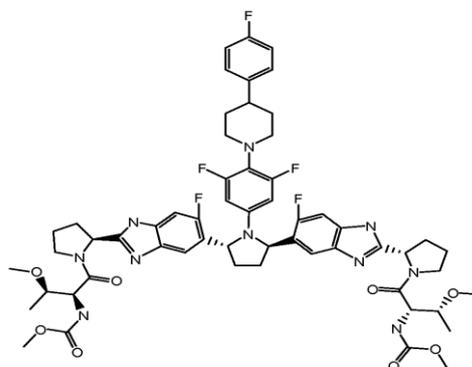


The examples that are covered by Compound I_B' are reproduced below for easy reference:

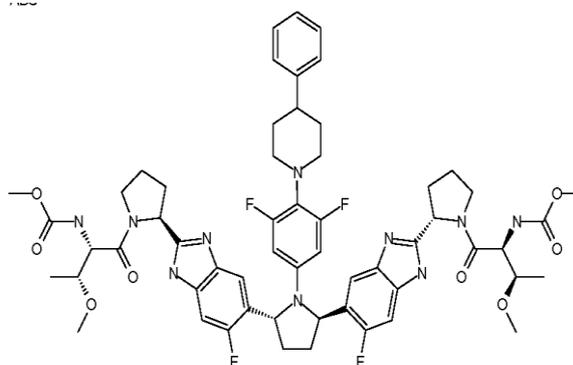
Example: 3.48



Example: 3.52

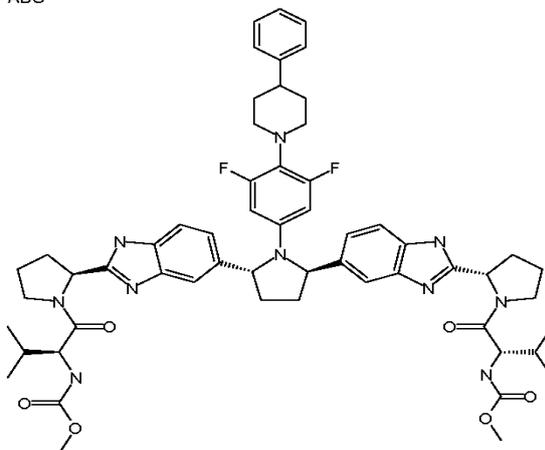


Example: 4.38



Example: 5.1

ABS



57. In fact, the claims of application of the divisional and the original application have to show considerable difference. The Hon'ble Patent Office in an order rejecting the divisional application no. 7863/DELNP/2014, noted, "*In other words, pharmaceutical vehicle is used for transportation/administration of single active compound (in present case), there is no role of vehicle in enhancement of therapeutic efficacy of the composition but remain same as of the efficacy of single active pharmaceutical ingredient and considered as compound of claim 1. The compound claimed in parent application is individual and independent claims as independent compound and belongs to same broad category based on the chemical structure where substituted alpha amino acid moiety is absent. However, as applicant tried to show chemical structure differences in his written submission the chosen differences are not a valid reason for filing separate /further/ divisional application...*" (see internal page 19 of the S.15 order dated 28.09.2020 in patent application no. 7863/DELNP/2014 annexed as **Exhibit-C**)
58. In an order refusing claims in divisional application no. 201718032849, the Hon'ble Patent Office had noted, that, "*In the present case, in pending claim*

I a proviso is added to exclude the subject matter which has been granted in parent application, but in dependent claim applicant claiming the same pharmaceutical composition with same components i.e. pharmaceutical composition comprising as an active ingredient...” A copy of the order of the Patent Office in application no. 201718032849 dated 01.03.2021 is annexed herewith as **Exhibit-D**, (see internal page 4).

59. The Patent Office in rejecting a divisional application no. 507/DELNP/2010 had noted, “*Thus, in my view divisional application must be filed only when the claims of the complete specification in parent application relate to more than one invention and divisional application should not include a claim for any matter claimed in parent application. In present application, essential technical feature of formulation and article of manufacture comprising 420mg recombinant humanized monoclonal antibody rhuMAb 2C4, wherein rhuMAb 2C4 comprising the variable light and variable heavy amino acid sequences of SEQ ID NOs. 3 and 4, respectively, and human light and heavy IgG1 (non-A allotype) constant region sequences has already been claimed in claim 1,3 and 5 of parent application...*” (emphasis supplied; see **internal page 5** of the order dated 05.09.2018 in application no. 507/DELNP/2010, herein annexed as **Exhibit-E**)
60. Hence, the Present Application claims the same invention as than in the parent IN’310 application and therefore does not qualify to be a filed as a divisional application. On that account the Present Application has to be rejected.

ii. **The amendment of claims in the Present Application violates Section 59(1) of the Patents Act**

61. S. 59(1) that deals with provisions as to amendment of application or specification, states:

‘(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no

*amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that **any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.***

62. It has been pointed out above that the Applicant in response to the FER amended the claims in a manner that do not fall within the scope of the claims of the complete specification, before the amendment. Originally, the claims were directed at a single compound with a Markush structure. However, the amended claims, cover a composition of two compounds as noted in the FER, which was not contemplated under the original claims.
63. Therefore, the present set of amended 4 claims of the Present Application runs afoul of S.59(1) as these claims do not fall wholly within the scope of any of the claims of the specification.
64. The Indian Patent Office in refusing to allow to amended claims in 357/CHENP/2010 noted that, *'In this instance, the initially filed claims were only for crystal Forms, but later the applicant proceeded to voluntarily amend the claims to method of preparing the crystal forms. It is not acceptable since the scope of the amended claims is not within the scope of claims in the originally filed divisional application. I am referring to the scope of the claims rather than its support in the complete specification/ working examples. Thus, the amended claims 1-4 filed on 31/01/2018 are not allowable because the claims of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.'* (see page 2, order dated 02.03.2018 in application number 357/CHENP/2010, herein annexed as **Exhibit-F**)
65. In the matter of application no. 4973/CHENP/2012, the Patent Office rejecting the change of scope of claims from a method claim to a product claim had noted, *"The originally filed application has 15 claims which refer to method of treatment of treating or preventing otitis externa infection and*

sequelae thereof by topical administration. The subject matter of these claims is directed to method of diagnosis of human beings or animals, which are statutorily barred from the patentability under Section 3 (i) of the Patent Act, 1970. This objection was communicated in the FER itself. Upon amendment, the applicant has replaced the word A method for with A pharmaceutically acceptable composition for use in.

*It was explained in the hearing notice as well as at the time hearing that the scope of the amended claims have changed and are not allowed under section 59 of Patents Act 1970, as the amendments are not by the way of disclaimer, correction or explanation, rather it changes the scope of a claim before the amendment.” (see order dated 28.12.2008 in application no. 4973/CHENP/2012, internal page 5, herein annexed as **Exhibit-G**)*

66. The claims in patent application no. 1554/CHENP/2013 were refused on the ground that the scope of the claims was not within the original claims. The Patent Office had noted, *“It is pertinent to mention here that the applicant reworded the claims, where the entire scope of the invention has been changed when compared with the claims filed in international phase or while entering the national phase. The applicant reworded the claims, where the entire scope of the invention has been changed. In the present case, neither in the international phase, nor at national phase entry the application had a claim for A method of making a genetically modified mouse. So from the above discussion, it is amply clear that the claim which is not claimed at the time of filing is disclaimed and such amendments of claims are not allowable under section 59(1) of the Act...”* (see internal page 15 of the order dated 16.12.2020 in patent application no. 1554/CHENP/2013, herein annexed as **Exhibit-H**)

67. The claims 1-4 of the Present Application therefore are liable to be rejected.

iii. Claims of the Present Application are not an invention under s.3(e)

68. Without prejudice to the grounds raised above, it is submitted that the claims of the Present Application do not meet the test of Section 3(e) of the Patents Act.
69. Claims 1-4 of the Present Application seeks to claim a compound of formula I_B and an HCV protease inhibitor. The complete specification, however fails to provide any data to indicate that these two compounds when used together show any synergistic interaction or give a result that are beyond a simple aggregation of these two components.
70. The burden of proof to show that an invention meets the standards laid down in Section 3(e) lies on the Applicant. This has not been fulfilled by the Applicant. Therefore, the claims 1-4 of the Present Application must be rejected.

c. That the claims of the Present Application must be rejected as the complete specification does not sufficiently and clearly describe the invention

71. Without prejudice to the grounds raised above, the Opponent raises an objection to the grant of patent to the Present Application under Section 25(1)(g).
72. It is submitted that the claim 1 of the Present Application claims a compound of Formula I_B, or a pharmaceutically acceptable salt thereof and a HCV protease inhibitor. It is unclear whether the claim covers each of these compounds separately, or as a composition, or as a combination. Such construction of claims, renders the scope of the claim vague and broad.
73. Further, the claims also do not specify their scope. The claims vaguely identify the pharmaceutically acceptable salt or the HCV protease inhibitor. There is no suggestion or teaching on which is the most preferred salt or HCV protease inhibitor, rendering the scope of the claim to be very broad and ambiguous.
74. Further, even if it is to be assumed that the Applicant has claimed a composition, the complete specification does not teach how this composition

is to be made, or what percentage or by weight each of the components to be used in the composition.

75. The claims 1-4 of the Present Application therefore must be rejected for not being sufficiently described.

PRAYER

In view of the above said references Opponent prays as follows:

- a) To be granted a hearing and be allowed to lead evidence (documentary and oral) before any order is passed;
- b) To reject the claims 1-4 of Application No. 201818021052 *in toto*;
- c) To allow the Opponent to file further submissions / documents as evidence, if necessary, to support the averments;
- d) To allow the Opponent to make further submissions in case the Applicant amends the claims;
- d) To be provided with a copy of any and all further submissions/ claim amendments /response by the Applicant;
- e) To allow amendment of the opposition as and when the need may arise;
- f) For costs in this matter;
- g) For any further and other relief in the facts and circumstances that may be granted in favour of the Opponent in the interest of justice.

Dated this the 8th day of September 2021.



Priyam Lizmary Cherian
Counsel for the Opponent

To
The Controller,
The Patent Office Branch
NEW DELHI