GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
THE PATENT OFFICE

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BEFORE THE CONTROLLER OF PATENTS

THE PATENTS ACT, 1970

SECTION 15

In the matter of the Patents Act, 1970 (as amended)

& the Patents Rules, 2003 (as amended)

And

In the matter of Patent Application No. **201627008488** by

GILEAD SCIENCES, INC., U.S.A.

And

In the matter representation by way of opposition

under Section 25 (1) of the Patents Act by

Delhi Network of Positive People l(DNP+)

And

LOW COST STANDARD THERAPEUTICS, Vadodara, Gujarat- 390 001

D E C I S I O N

1. On 11/03/2016, the Applicant filed a PCT National Phase application for a patent bearing number **201627008488** in Patent Office, Mumbai entitled "COMBINATION FORMULATION OF TWO ANTIVIRAL COMPOUNDS". A request for examination under section 11-B was filed on 16/03/2016, and was assigned a Request No. R20162008036. As per the provision under Section 11-A of Patents Act, the said application was published on 15/07/2016.

2. Accordingly, said application was examined under sections 12 and 13 of the Patents Act, 1970 (as amended) and the First Examination report (hereinafter referred to as FER) was issued on 05/09/2019. The applicant's agent filed the reply to the FER on 18/02/2020. After

considering the reply in response to the FER, and the specification with amended claims 1-10 filed by the applicant's agent.

3. Two representations by way of opposition u/s 25 (1) of the Act (hereinafter referred to as the pre-grant opposition) were filed on 09-07-2018 and 28/12/2022 by Delhi Network of Positive People and LOW COST STANDARD THERAPEUTICS, Vadodara, Gujarat respectively against the grant of patent application. Statement of grounds, prior art and comparison of patent application with prior art in the said pre-grant opposition are available in the e-dossier as document named "201627008488-FORM7A(PREGRANT)--090718.pdf & 201627008488-FORM7A(PREGRANT)-090718.pdf and 201627008488-PRE GRANT OPPOSITION FORM [28-12-2022(online)].pdf & 201627008488-PRE GRANT OPPOSITION DOCUMENT [28-12-2022(online)].pdf. On 28-11-2019 and 24-04-2023 applicant's agent submitted reply Statements in support of the application under Rule 55(4) of the Patents Rules (as amended) to the representation by way of Oppositions by both of the Opponents, the said documents available in the e-dossier as document named 201627008488-Statement and Evidence (MANDATORY) [28-11-2019(online)].pdf & 201627008488-Statement and Evidence [24-04-2023(online)].pdf.

4. After considering the reply filed in response to the first examination report by the applicant's agent and the report of the examiner on such reply, the cited documents or grounds of the pre-grant oppositions, it was observed that the said patent application was not in order for grant. Keeping in view the provisions of the Patents Act, 1970 (as amended), a hearing notice under section 14 & 25(1) was issued to the applicant's agent as well as the opponent/opponent's agent vide email scheduled on 03/05/2023 through VC under rule 28(6) of the Patent Rules, 2003 (as amended) vide hearing notice dated 23/03/2023 which was extended to 05/07/2023 vide hearing notice dated 24/04/2023 as requested by opponent. Further, extended on 09/08/2023 as requested for adjournment of the scheduled hearing by filing a Request for Adjournment of Hearing under rule 129A of the Patents Rules, 2003 (as amended). Again, the scheduled hearing was adjourned as requested under rule 129A to 11/09/2022 vide hearing notice dated 07/08/2023. Further, adjourned on 27/09/2023 & 19/10/2023. In respect of the said hearing notice dated 11/09/2023, a hearing was duly held on 19/10/2023 and attended by all the parties (Applicant's agent as well as opponent's agents), However hearing could not be concluded on the aforesaid date. In continuation of said hearing two subsequent hearings were held on 22-12-2023 & 15/02/2024.

5. Meanwhile, on 12/10/2023 applicant's agent submitted a new declaration of Expert Dr. Eric Gorman on behalf of the Applicant GILEAD SCIENCES INC. LOWCOST STANDARD THERAPEUTICS ; Opponent 2 has submitted two Interlocutory Petitions in

against of Declaration of expert Dr. Eric Gorman filed by Applicant on 13/10/2023 & 15/10/2023.

6. On 03/11/2023 (DNP+) Opponent 1 has submitted an application for cross examination of DR. ERIC GORMAN on behalf of the opponent Delhi Network of Positive People (DNP+) regarding his affidavit.

7. Keeping in view the provisions of the Patents Act, 1970 (as amended) and with a view to provide natural justice to the applicant as well as to the both of the opponents sufficient opportunities were provided to hear all the arguments. Final Hearing Notice documents available in the e-dossier as document named 201627008488-PreGrant-ExtendedHearingNotice-(HearingDate-22-12-023).pdf & 201627008488-PreGrant-ExtendedHearingNotice-(HearingDate-15-02-2024).pdf .Since all these hearing notice documents are available in public domain, they are not reproduced here for the sake of brevity.

8. On the circumstances of the case, applicant's agent as well as both opponent's agents appeared for hearing on the above scheduled date and all the objections (hearing notice u/ s 14) as well as grounds of opposition u/ s 25(1) proceedings were discussed.

9. I now address the **two interlocutory petitions** filed by LOWCOST STANDARD THERAPEUTICS concerning the expert Dr. Eric Gorman's declaration that were submitted by the applicant on October 12, 2023 and further on 13-02-2024.

(i) LOWCOST STANDARD THERAPEUTICS filed a first interlocutory petition on October 13, 2023, challenging the expert Dr. Eric Gorman's declaration. The petition claimed that the declaration was time-barred because it was filed after the hearing notice was sent out, which was on June 28, 2023.

Opponent's agent submitted that

Thus, it is plainly evident that said affidavit was submitted much later than the issuance of the first hearing notice and is therefore in violation of the precedence established in **Pharmacyclics Llc vs Union Of India And Ors.** W.P.(C) 12105/2019 & CM APPLs. 49593/2019, 49594/2019, 49595/2019; paragraphs 39 to 44 (which is being reproduced herein below) (copy of the same being attached herewith as Annexure - A).

> *39. Therefore, the following general principles ought to be followed while dealing with a post-grant opposition:*
>
> *i)* ***The Opponent and the Applicant have adequate freedom to file their initial pleadings and evidence by relying upon all the documents and expert testimonies that they wish to****;*
>
> *ii) The Opponent"s rejoinder in Rule 59 ought to be strictly confined to the Patentee"s evidence;*
>
> *iii) Once the Opposition Board is constituted and the material is transmitted to the Board, further evidence is not permissible;*
>
> *iv)* ***Under Rule 60, if any further evidence comes to light which either party wishes to rely upon, the same can only be done prior to the issuance of notice of hearing, with the leave of the Controller****;*
>
> *v) Under Rule 62(4), only publicly available documents i.e. publications, can be considered provided they are served to the opposing party, five days prior to the hearing and the date/time of the publications as also the relevant portions are highlighted, so that the opposite side can deal with the same at the time of hearing. Any document the authenticity of which is in doubt would not be entertained;*
>
> *vii) The hearing, in the opposition would be usually granted upon request and Opposition Board Members may also be present in order to elicit their views and assist the Controller in deciding the post-grant oppositions.*
>
> *40.* ***In this background, the last question that arises is whether, if a hearing is adjourned, further evidence ought to be permitted or not prior to the next hearing. Clearly from the scheme of the Act, filing of further evidence would not be permissible after the first notice of hearing is issued. Thus, in***

terms of Rule 60, the hearing as contemplated in the said Rule would be the first notice of hearing. Such an interpretation would ensure that parties do not unduly delay the hearing of oppositions by seeking adjournments and utilising the adjourned period to dig up more evidence, especially as such evidence would in any case have not been considered by the Opposition Board.

41. ***The filing of further evidence prior to the hearing or reliance on publications under Rule 62(4) would not ordinarily permit an adjournment of the hearing.*** ...

42. ...

43. ...

44. ***For future, the conduct of post-grant oppositions by the Patent office shall be in accordance with the procedures laid down herein.*** *Long pendency of post-grant oppositions can have a cascading effect as it raises a question mark over the validity of the grant of the patent and could also severely delay adjudication of suits for infringement of patent, licensing and other forms of monetization of the patent as the overall term of patent is non- extendable i.e. 20 years. Following the above stipulated procedure would obviate delays in the adjudication of the same.*

In view of the above, it is humbly and most respectfully requested that the said declaration should not be taken on record as it would be unfair to the opponent and would set a precedent for future applicants to submit Affidavit documents subsequent to the relevant dates before which they can legally be submitted.

Now, I turn my attention to the rule 62(4) of the Patents Rule which rule is explicitly related to post grant proceedings state that

" *If either party intends to rely on any publication at the hearing not already mentioned in the notice, statement or evidence, he shall give to the other party and to the Controller not less than five days' notice of his intention, together with details of such publication."*

In present case Hearing held on 19/10/2023 and Dr. Eric Gorman's declaration was submitted by the applicant on October 12, 2023 which is 7 days before the actual date of hearing and communicated to the patent office as well as to both the opponents, therefore

the said document was taken on record as a part of proceedings. Therefore first interlocutory petition filed on October 13, 2023 is hereby disposed of.

(ii) The second Interlocutory Petition filed by Opponent Low Cost Standard Therapeutics on 17/10/2023 against the declaration of Expert Dr. Eric Gorman filed by the Applicant on October 12, 2023.Opponent submitted that ;

there are multiple new assertions that have been made by the applicant in declaration of Expert Dr. Eric Gorman which have never been the case of the Applicant as presented in patent application and prosecution thereof. It is submitted that the declaration of Expert Dr. Eric Gorman contains new contentions which are being brought into focus for the first time by way of said affidavit merely four working days before the scheduled hearing. The many instances in which completely new contentions regarding the claimed invention have been stated in the affidavit are as follows:

i. *In paragraph 6 of the declaration, it discusses the instability of both amorphous and crystalline agents, a concern not addressed in the specification.*

ii. *ii. Paragraphs 7-9 of the declaration outline various challenges encountered during the co formulation of amorphous and crystalline agents, such as compatibility degradation and stability issues, which are not mentioned in the specification.*

iii. *iii. Paragraph 10 of the declaration delves into different process parameters that impact the co-formulation process, yet the specification does not emphasize the significance of these parameters.*

iv. *Paragraph 13 of the declaration, focusing on Figure 1, highlights the superior performance of copovidone and Soluplus as the two best polymers for maintaining Compound I in solution. However, any such comparison and the comparative figure is absent in the specification.*

v. *Furthermore, paragraph 14 details the results of an in vitro dissolution test, showing that spray-dried dispersions (SDD) prepared with copovidone achieve a notably higher concentration (approximately 2 times) of Compound I dissolved in the media compared to SDD prepared with Soluplus (Figure 2). This critical data is conspicuously missing in the specification.*

vi. *Applicant has submitted a new post-dated document - 'J.J. Field et al.; Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection; December 31, 2015 N Engl J Med 2015; 373:2599-2607. This document is post dated; therefore, it should not to be considered.*

In view of the above, it is humbly and most respectfully requested that the said declaration should not be taken on record as the said declaration deals about the matters

which are not supported by the as filed specification. Additionally, the Applicant has cited a post dated document that should also not to be taken on record.

Therefore, we most respectfully request the Learned Controller to take said documents on record and keep the Opponent apprised of further developments in the matter.

In this context, I now focus on the para [0040] of the complete specification which state that

The selection of the polymer for the solid dispersion is based on the ***stability and physical characteristics of Compound I*** *in the solution. Polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol (Soluplus®) and* ***copovidone solid dispersions both showed adequate stability and physical characteristics****. In one embodiment, the polymer used in the solid dispersion is polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol (Soluplus®) or copovidone. Accordingly, in a certain embodiment, the polymer used in the solid dispersion is polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol (Soluplus®). In another embodiment, the polymer used in the solid dispersion is copovidone.*

Further, Page 34 of the specification provides Example 1 for tablet preparation and formulations, wherein monolayer and bilayer tablet preparation as per the claimed invention are enabled. Exhibit B/Annexure A/ Annexure B/Annexure C attached with the aforementioned affidavit(s) provided the experimental results of the study to identify the sustained virologic response in Patients with Genotype 1-6 HCV Infection treated with the combination of sofosbuvir (SOF) and Compound I solid dispersion which has clear support in the original specification in para [0140-0142] & Table 9.

So the question is whether the declaration can be considered for analysis or not. In this instance, I would like to rely on the judgement by High Court of Delhi in the matter of Astrazeneca AB & Anr Vs Intas Pharmaceuticals Limited (CS (COMM) No. 410/2020). In this case, the Court observed that

"*that post priority date evidence … to show technical advance can only be taken into account to confirm the existence of technical effect which is found embedded in the specification of IN 625 and is capable of being understood by a skilled person having common general knowledge and not to rely upon the same to establish its effect for the first time*".

In reference, the decision also cited paragraph from Generics (UK) Limited vs. Yeda Research and Development Company Limited ([2017] EWHC 2629 (Pat); [2018] R.P.C. 2), which mandated that *additional evidence can only be relied upon to confirm the existence of a technical effect which is plausible in the light of the specification and the skilled person's common general knowledge, and not to establish the existence of a technical effect for the first time.*

Upon a thorough examination of the entire specification, it is clear that the submitted affidavit directly relates to the stability aspect of the present invention, as well as to the experimental outcomes focusing on the sustained virologic response (SVR4) observed in patients infected with Genotype 1-6 HCV, treated using a combination of sofosbuvir (SOF) and Compound I in solid dispersion form. These elements were adequately covered in the original specification of the application. Thus, the detailed disclosure within the current application sufficiently supports the evidence presented in the submitted affidavit. Consequently, the affidavit provided by the applicant is hereby accepted and taken on record. Accordingly, the second interlocutory petition filed by Opponent 2 on October 17, 2023, is disposed of.

10. Regarding an application for cross examination of Expert affidavit of DR. ERIC GORMAN on behalf of the opponent Delhi Network of Positive People (DNP+) has been filed by their agent/ attorney which has been taken on record and discussed during the hearing on 22-12-2023.

Opponent's agent submitted *that_cross examination of expert for this affidavit - by filing an application dated 3 November 2023. However, the cross-examination application was dismissed by the Controller (without any written order) orally reasoning that the Opponent failed to submit any technical default/ error in the data included in the expert affidavit.*

We kindly bring to the notice of the learned Controller a decision of the Calcutta High Court (Natco Pharma Ltd vs. Union of India Ors; 05 April 2019) herein annexed, wherein it was held "In the event, the Controller decides on the application for grant of patent without allowing cross examination then the prejudice caused to the petitioner would be substantial. There is a scope to prevent such eventuality taking place. A quasi-judicial authority is obliged to decide an issue of law correctly. An erroneous decision on an issue of law would be an exercise beyond jurisdiction. When a quasi-judicial authority travels beyond jurisdiction or when there is every likelihood of it doing so, necessary directions can be issued to keep it within the parameters of its jurisdiction". The Opponent humbly requests the learned Controller to provide a speaking order on the same and grant an opportunity to cross examine the expert.

As per Section 79 of the Patents Act, 1970 (as amended),

"Subject to any rules made in this behalf, in any proceeding under this Act before the Controller, evidence shall be given by affidavit in the absence of directions by the Controller to the contrary, but in any case in which the Controller thinks it right

so to do, he may take oral evidence in lieu of, or in addition to, evidence by an affidavit, or may allow any party to be cross-examined on the contents of his affidavit."

In this regard, the it was explicitly asked during the hearing from the opponent's agent to present technical arguments regarding the application for cross-examination of the expert affidavit of DR. ERIC GORMAN on behalf of the opponent, Delhi Network of Positive People (DNP+). A party seeking cross-examination of experts of the other party must at the very least file evidence affidavits of its experts in reply to counter the evidence led by the other party. In the present case, the opponent has not filed any evidence affidavit and even though the opponent's agent gave sufficient opportunities for being heard regarding said matter. They made no arguments in the application filed on November 3, 2023, or during the oral proceedings in hearing held on 22-12-2023. Therefore, one more hearing was offered on 15-02-2024 to opponent to represent their arguments to identify any technical errors or deficiencies in affidavit. During the hearing opponent's agent withdrawn the application for cross examination. However opponent's agent represented their counter arguments regarding the non-allowability of the said expert affidavit of DR. ERIC GORMAN due to lack of support in the original specification. The aforementioned arguments were taken on record.

In this instance, I would like to rely on the judgment by High Court of Delhi in the matter of ISCHEMIX LLC Vs. THE CONTROLLER OF PATENTS (C.A. (COMM.IPD-PAT) No. 33/2022) & I.A.23186/2023. In this case, the Court observed that

"*clinical trial can be submitted- however, to only support the stand of the applicant in the Specification to demonstrate a significant enhancement of therapeutic efficacy*."

However, I already discussed in the above para 9 that the declaration can be considered for analysis as the complete speciation of the instant application clearly disclose the support for evidences provided in the aforementioned affidavit. Therefore, affidavit submitted by the applicant is taken on record.

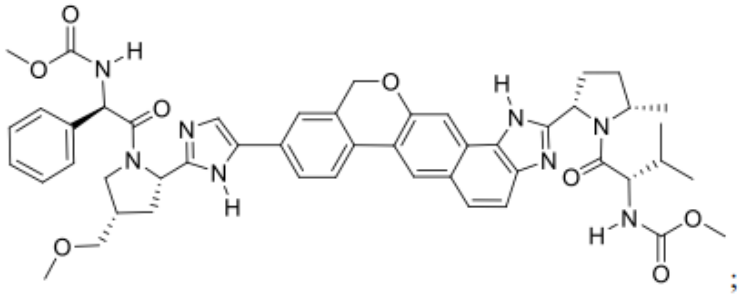
11. The hearing submissions along (oral arguments during hearing and written submissions after hearing) of the Opponent and the Applicant were considered carefully along with expert affidavits of DR. ERIC GORMAN by applicant and Dr. Jayamanti Pandit by LOW COST STANDARD THERAPEUTICS and dealt accordingly. It is noted that opponent as well as applicant have cited a number of grounds, few decisions given by Indian patent office and case law to establish their stand. Some of the points are irrelevant/superfluous and some of the points are relevant and worth discussing in the matter of the impugned application under pre-grant opposition. The plethora of preliminary issues, grounds, prior art documents, case law put forth by both the parties along with other Exhibits submitted

by applicant with written Submissions were considered but found not quite relevant in nature and all of them need not be addressed. However, I did take into consideration the relevant documents, relevant grounds of opposition and relevant case laws. My decision is based on the outcome of the invention disclosed in the complete specification and claims, analysis of the relevant documents and case laws, and the arguments made by the opponent and the Applicant.

12. After the hearings including hearing held on 15-02-2024 the applicant filed written submission to the hearing with amendment to the claims 1-7 which are as follows:

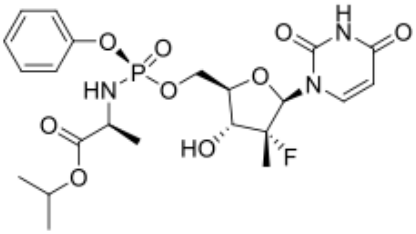
1. A pharmaceutical composition in the form of a tablet comprising:

a) from 15% to 25% w/w of a solid dispersion comprising Compound I dispersed within a polymer matrix formed by copovidone, wherein the weight ratio of Compound I to copovidone in the solid dispersion is 1:1 and wherein Compound I is substantially amorphous having the formula:



;

b) from 35% to 45% w/w of sofosbuvir characterized by XRPD 2θ-reflections (° ± 0.2θ) at : 6.1 and 12.7 or at 6.1, 20.1 and 20.8, wherein the sofosbuvir is crystalline having the formula:



c) from 30% to 40% w/w of microcrystalline cellulose;

d) from 1% to 5% w/w of croscarmellose sodium; and

e) from 0.5% to 2.5% w/w of magnesium stearate.

2. The pharmaceutical composition as claimed in claim 1, comprising 40% w/w of sofosbuvir.

3. The pharmaceutical composition as claimed in claim 1, comprising 20% w/w of the solid dispersion.

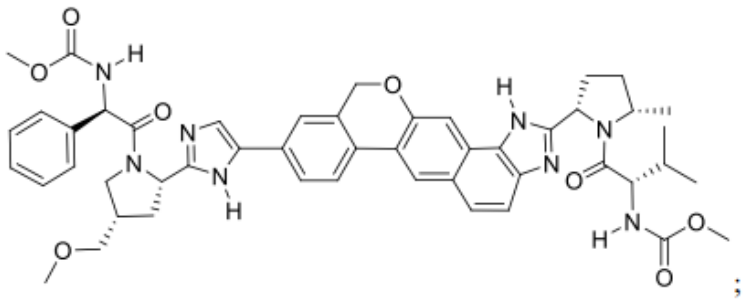
4. The pharmaceutical composition as claimed in claim 1, comprising 35.5% w/w of microcrystalline cellulose.

5. The pharmaceutical composition as claimed in claim 1, comprising 3% w/w of croscarmellose sodium.

6. The pharmaceutical composition as claimed in claim 1, comprising 1.5% w/w of magnesium stearate.

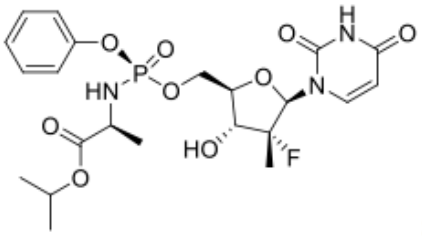
7. The pharmaceutical composition as claimed in claim 1 comprising:

a) 200 mg of a solid dispersion comprising Compound I dispersed within a polymer matrix formed by copovidone, wherein the weight ratio of Compound I to copovidone in the solid dispersion is 1:1 and wherein Compound I is amorphous having the formula:



;

b) 400 mg of sofosbuvir characterized by XRPD 2θ-reflections (° ± 0.2θ) at : 6.1 and 12.7 or at: 6.1, 20.1 and 20.8, wherein the sofosbuvir is crystalline having the formula:



;

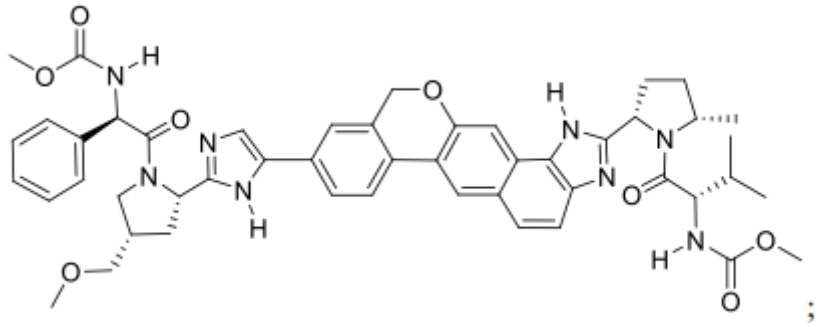
c) 355 mg of microcrystalline cellulose;

d) 30 mg of croscarmellose sodium; and

e) 15 mg of magnesium stearate.

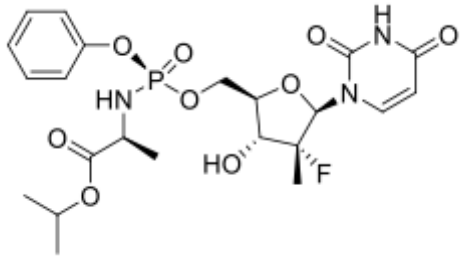
13. After going thoroughly to the complete specification of the impugned application under opposition, it is clear that the application relates to a pharmaceutical composition in the form of a tablet from 15% to 25% w/w of a solid dispersion comprising Compound I dispersed within a polymer matrix formed by copovidone wherein the weight ratio of

Compound I to copovidone in the solid dispersion is 1:1 and wherein Compound I is substantially amorphous having the formula:



;

from 35% to 45% w/w of sofosbuvir characterized by XRPD 2θ-reflections (° ± 0.2θ) at : 6.1 and 12.7 or at 6.1, 20.1 and 20.8, wherein the sofosbuvir is crystalline having the formula:



c) from 30% to 40% w/w of microcrystalline cellulose;

d) from 1% to 5% w/w of croscarmellose sodium; and

e) from 0.5% to 2.5% w/w of magnesium stearate

The complete specification para [008] of the present application discloses that the solid dispersions disclosed herein would demonstrate increased bioavailability, elimination of or reduced food-effect, reduced negative drug-drug interaction with acid suppressive therapies, reduced variability across patient populations, and/or improved dose linearity at higher doses when compared with administration of Compound I and/or sofosbuvir alone.

Basically, the present invention is a combination that is effective in treating hepatitis C virus claimed amount of Compound I (velpatasvir) in an amorphous form in a solid dispersion within a polymer matrix formed by copovidone, wherein the weight ratio of Compound I to copovidone in the solid dispersion is 1:1 and a claimed amount of sofosbuvir in a crystalline form with certain excipients in the claimed amounts. The claimed composition is a combination of velpatasvir and sofosbuvir is known as Epclusa®, which is a pangenotypic NS5A-NS5B inhibitor single-pill combination that for treatment of hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5, and 6.

14. The documents cited in the hearing Notice:

D1: WO2013075029A1; Condensed imidazolylimidazoles as antiviral compounds.	23/05/2013	The whole document
D2: WO2010017432A1; Pharmaceutical formulations of an hcv protease inhibitor in a solid molecular dispersion.	11/02/2010	The whole document
D3: WO2011156578A1; Solid compositions.	15/12/2011	The whole document
D4: WO2012068234A2; Antiviral compounds.	24/05/2012	The whole document
D5: WO2013059630A1; Methods for treating hcv comprising at least two direct acting antiviral agent, ribavirin but not interferon.	25/04/2013	The whole document
D6: Handbook of pharmaceutical excipients, 5th ed/edited by Raymond C. Rowe, Paul J. Sheskey, Sian C. Owen, ISBN 0-85369-618-7.		The whole document

Documents cited by the opponent 1 (DNP+):

Exhibit A: WO2013075029

Exhibit B: HANDBOOK of pharmaceutical excipients, 5th edition, Raymond C. Owen

Exhibit C: WO2010017432 (hereinafter referred to as "WO'432")

Exhibit D: WO2011156578 (hereinafter referred to as "WO'578")

Exhibit E: WO2013059630 (hereinafter referred to as "WO'630")

Documents cited by the opponent 2(LOW COST STANDARD THERAPEUTICS):

Annexure 3: US20130164260 (Annexure D of Dr Jayamanti Pandit's Affidavit) (corresponding of)

Annexure A: WO2010017432

Annexure B: US20130072528

Annexure C: WO2013101550

Annexure 6: Cheng et al.

Annexure G of Dr Jayamanti Pandit's Affidavit)

Annexure 4: US20130136776

Annexure E of Dr Jayamanti Pandit's Affidavit)

Annexure 5: Clinical trial data with (Annexure F of Dr Jayamanti Pandit's Affidavit)

Annexure H: Y. Takizawa et al

Documents details provided by applicant's agent;

Sr. NO.	Cited References	Delhi Network of Positive people (DNP+)	Low Cost standard therapeutics	Affidavit of Dr. Jayamanti Pandit by Low-Cost standard therapeutics	Ground	Hearing Notice
1	WO2013075029	Exhibit A	Annexure 3 (corresponding US20130164260)	Annexure D (corresponding US20130164260)	Novelty and Section 3(d)	D1
2	WO2010017432	Exhibit C		Annexure A	Inventive step	D2
3	WO2011156578	Exhibit D			Inventive step	D3
4	WO2013059630	Exhibit E			Inventive step	D5
5	US20130136776		Annexure 4	Annexure E	Inventive step	
6	US20130072528			Annexure B	Inventive step	
7	HANDBOOK of pharmaceutical excipients, 5th edition, Raymond C. Owen	Exhibit B			Inventive step	D6
8	WO2013101550			Annexure C	Inventive step	
9	NCT01909804 "Phase 2 Study of SOF + GS-5816 in Treatment Experienced Subjects With Chronic Genotype 3 HCV		Annexure 5	Annexure F	Inventive step	
10	Cheng et al., "GS-5816, a Second-Generation HCV NS5A Inhibitor With Potent Antiviral Activity, Broad Genotypic Coverage, and a High Resistance Barrier"		Annexure 6	Annexure G	Inventive step	
11	Y. Takizawa et al., International Journal of Pharmaceutics 453(2013)363–370 (Takizawa), published in June 2013			Annexure H	Inventive step Inventive step	
12	Tarik Asselah, Patrick Marcellin; "Interferon free therapy with direct acting antivirals for HCV"; Liver International 2013 Feb; 33 Suppl 1:93-104.		Annexure 2		Inventive step	

15. The grounds on which opponent 1 & 2 relied upon are considered carefully during the proceedings which are as below;

1. **GROUND: NOVELTY; UNDER SECTION 25(1) (b)**

That the invention so far as claimed in any claim of complete specification has been published before the priority date of the claim (section 25(l)(b))

2. **GROUND: OPPOSTION UNDER SECTION 25(1)(e); (Inventive Step u/s 2(1(ja));**

The invention as claimed in any of the claims of the complete specification is obvious and clearly does not involve any inventive step having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim (section 25 (l) (e)).

3. **GROUND: OPPOSTION UNDER SECTION 25(1)(f); (not patentable invention U/S 3(d) & 3(e))**

As far as the invention claimed in any of the claims falls under Section 25(1)(f) of the Act i.e. whether a patentable invention U/S 3(d) & 3(e) of the Act**.**

4. **GROUND : INSUFFICIENCY UNDER SECTION 25(1) (g);**

Section 25(1)(g) states that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed

Both Opponents have challenged the impugned application under opposition on the same ground, i.e. Under Section 25(1)(g) of The Patents Act, 1970 i.e. the impugned application under opposition does not sufficiently and fairly describe the invention in a manner so as to enable a person skilled in the art to perform or work the invention.

5. **GROUND: SECTION 25(1) (h) of The Patents Act**

that the applicant has failed to disclose to the controller the information required by section 8, and therefore objection is raised under section 25 (1)(h)

The details of these ground are available in public domain, they are not reproduced here for the sake of brevity.

GROUND: NOVELTY; UNDER SECTION 25(1) (b)

That the invention so far as claimed in any claim of complete specification has been published before the priority date of the claim (section 25(l)(b))

The determination of novelty, for a new invention to be patentable as specified in Section 2 (1)(j) of The Patents Act, 1970, is that the new invention has to be any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

To prove this ground of opposition (Novelty), Opponents 1 and 2 used the cited documents WO 2013/075029 and US 2013/0164260, respectively.

WO'029 discloses a pharmaceutical composition for use in treating Hepatitis C (HCV). WO'029 explicitly discloses in claims 31-34 a pharmaceutical composition comprising at least one nucleoside or nucleotide inhibitor of HCV NS5B polymerase, and at least one pharmaceutically acceptable carrier. WO'029 further discloses an interferon, a pegylated interferon, ribavirin or combinations thereof. Compound disclosed in claim 33 is Compound I (velpatasvir) of present invention and nucleotide inhibitor of HCV NS5B polymerase is sofosbuvir. WO'029 does not disclose particular pharmaceutical combination of Compound I (velpatasvir) in an amorphous form in a solid dispersion within a polymer matrix formed by copovidone, wherein the weight ratio of Compound I to copovidone in the solid dispersion is 1:1 and a claimed amount of sofosbuvir in a crystalline form with certain excipients in the claimed amounts. Therefore, Novelty of the claimed invention has been acknowledged in view of WO 2013/075029.

US'260 discloses a pharmaceutical composition comprising a pharmaceutically acceptable carrier, sofosbuvir, and a compound of the formula i.e Velpatasvir. US'260 also discloses polyvinylpyrrolidone (copovidone) as a one of the carriers in the composition. US'260 disclose formation of a solid dispersion of the active compound with a carrier such as polyvinylpyrrolidone (copovidone) i.e. it discloses a solid dispersion of Velpatasvir with copovidone. However , US'260 fail to disclose combination of **Compound I (velpatasvir) in an amorphous form** in a solid dispersion within a polymer matrix formed by copovidone, wherein the weight ratio of Compound I to copovidone in the solid dispersion is 1:1 and **sofosbuvir in a crystalline form** with certain excipients. Therefore Novelty of the claimed invention has been acknowledged in view of US 2013/0164260.

Hence the present invention is novel over the cited documents WO'029 or US'260. Therefore, ***I conclude that this ground of opposition is not validly established by Opponent(s).***

GROUND: OPPOSTION UNDER SECTION 25(1)(e); (Inventive Step u/s 2(1(ja));

Both of the opponents have challenged the impugned application under opposition on the same grounds i.e. The invention as claimed in any of the claims of the complete specification is obvious and clearly does not involve any inventive step having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim (section 25 (l) (e)).

The following documents which were analyzed:

1. **WO 2013/075029**
2. **US 2013/0164260**
3. **WO2010017432**
4. **WO2013059630**
5. **WO2013101550**
6. **WO2011156578**
7. **US20130136776**
8. **Cheng et al. (Annexure 6)**

Mandate of law

In view of the above, the instant application is to be looked as per Indian legislative provisions and jurisprudence regarding the requirement of "Inventive Step" for patentability of an "invention". Section 2(1)(j) of the Patents Act, 1970 (as amended) defines "invention" as:

""invention" means a new product or process involving an inventive step and capable of industrial application;"

Section 2(1)(ja) of the Patents Act, 1970 (as amended) defines "inventive step" as:

"inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;

Thus, as per Section 2(1)(ja) of the Patents Act, 1970 (as amended), to be inventive, an invention should:

(involve technical advance as compared to the existing knowledge

OR

have economic significance OR both) AND

be non-obvious to a person skilled in the art.

Based on various case laws and established Indian jurisprudence like *F. Hoffmann-La Roche Ltd vs Cipla Ltd case (2012)* by Hon'ble Delhi High Court *and Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444)* by Hon'ble Supreme Court,

the following analysis with regard to fulfilment of criteria for establishment of Inventive Step in the instant application has been carried out:

Step 1: Identification of the "person skilled in the art":

It is pertinent to mention that in the F. Hoffmann-La Roche Ltd vs Cipla Ltd case (2012), Hon'ble Delhi High Court had observed that the obviousness test is what is laid down in *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries Ltd (AIR 1982 SC 1444) and that "...Such observations made in the foreign judgments are not the guiding factors in the true sense of the term as to what qualities that person skilled in the art should possess. The reading of the said qualities would mean qualifying the said statement and the test laid down by the Supreme Court..."*

Hon'ble High Court further added "*...From the bare reading of the afore quoted observations of Supreme Court, it is manifest that the Hon'ble Supreme Court has laid down the test for the purposes of ascertaining as to what constitutes an inventive step which is to be seen from the standpoint of technological advancement as well as obviousness to a person who is skilled in the art. It is to be emphasized that what is required to be seen is that the invention should not be obvious to the person skilled in art. These are exactly the wordings of New Patents Act, 2005 u/s Section 2(ja) as seen above. Therefore, the same cannot be read to mean that there has to exist other qualities in the said person like unimaginary nature of the person or any other kind of person having distinct qualities.....Normal and grammatical meaning of the said person who is skilled in art would presuppose that the said person would have the knowledge and the skill in the said field of art and will not be unknown to a particular field of art and it is from that angle one has to see that if the said document which is prior patent if placed in the hands of the said person skilled in art whether he will be able to work upon the same in the workshop and achieve the desired result leading to patent which is under challenge. If the answer comes in affirmative, then certainly the said invention under challenge is anticipated by the prior art or in other words, obvious to the person skilled in art as a mere workshop result and otherwise it is not. The said view propounded by Hon'ble Supreme Court in Biswanath Prasad (supra) holds the field till date and has been followed from time to time by this Court till recently without any variance....Therefore, it is proper and legally warranted to apply the same very test for testing the patent; be it any kind of patent. It would be improper to import any further doctrinal approach by making the test*

modified or qualified what has been laid down by the Hon'ble Supreme Court in of Biswanath Prasad (supra).”

Hence, it is understood that the "person skilled in the art" is a competent craftsman or engineer as distinguished from a mere artisan. Hence, in the instant application, the "person skilled in the art" **is a person conversant in researching and developing antiviral drugs used in the treatment of hepatitis C (**HCV)**.**

Step 2: Identification of the relevant common general knowledge of that person at the priority date

WO 2013/075029

US 2013/0164260

WO2010017432

WO2013059630

WO2011156578

WO2013101550

US20130136776

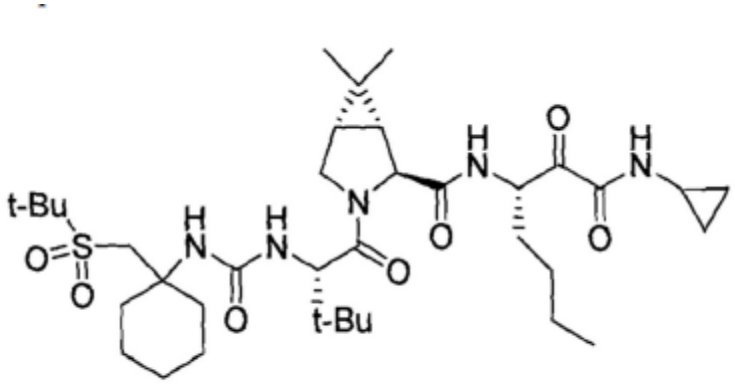
Cheng et al. (Annexure 6)

WO’029 discloses a pharmaceutical composition for use in treating Hepatitis C (HCV). WO’029 explicitly discloses in claims 31-34 a pharmaceutical composition comprising at least one nucleoside or nucleotide inhibitor of HCV NS5B polymerase, and at least one pharmaceutically acceptable carrier. WO’029 further discloses an interferon, a pegylated interferon, ribavirin or combinations thereof. Compound disclosed in claim 33 is Compound I (velpatasvir) of present invention and nucleotide inhibitor of HCV NS5B polymerase is sofosbuvir.

US’260 discloses a pharmaceutical composition comprising a pharmaceutically acceptable carrier, sofosbuvir, and a compound of the formula i.e Velpatasvir. US’260 also discloses polyvinylpyrrolidone (copovidone) as a one of the carriers in the composition. US’260 disclose formation of a solid dispersion of the active compound with a carrier such as polyvinylpyrrolidone (copovidone) i.e. it discloses a solid dispersion of Velpatasvir with copovidone. US’260 discloses that the preferred amount of the compound of the invention (which includes Velpatasvir) to be used is 50 or 100mg, and the most preferred amount is 100mg. The weight:weight ratio of 1:1 of active with carrier is taught in US’260. The claimed amount 400mg of sofosbuvir to be used in

combination with Valsartan formulation (i.e. solid dispersion of Valsartan) is also disclosed (see para 0151) US'260 discloses that tablet compositions may contain croscarmellose sodium, microcrystalline cellulose, and magnesium stearate (see para 0105).

WO432 (Annexure A of Dr. Pandit affidavit) related to a solid dispersion of particular HCV inhibitors. WO'432 discloses a pharmaceutical formulation comprising a Hepatitis C virus protease inhibitor having formula (I) in a solid dispersion with an excipient.



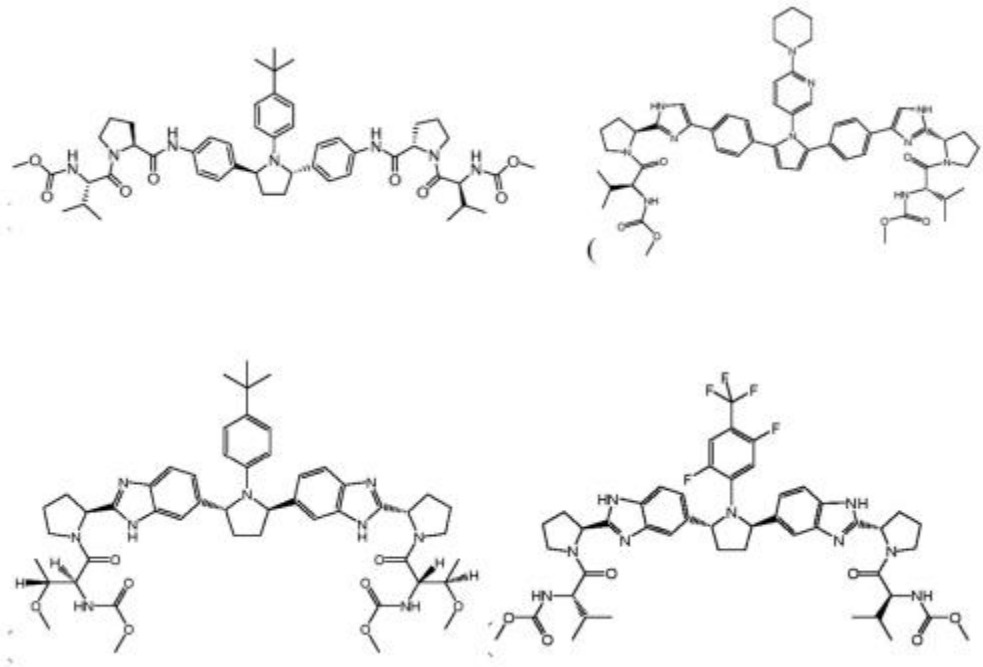
Formula (I)

Compound I is a Class IV compound, that is, a compound having low solubility and low permeability. Consequently, Compound I has relatively low bioavailability. Thus, pharmaceutical formulations of Compound I or a solvate thereof are needed that provide acceptable drug loading, dissolution, stability, and bioavailability for a treatment regimen wherein the number of doses administered per day to achieve the desired therapeutic plasma concentration could be reduced. WO432 also provided the ratio by weight of Compound I to polymer (Copovidone) in the solid dispersion is in the range of about 1:1 to about 1:3. WO 432 also teaches a solid dispersion of a compound in order to increase its bioavailability, reduce its dose, reduce it dosing regimen etc. by converting said compound into a solid dispersion by using a polymer.

WO'630 is related to a method of treating HCV infection by administering at least two direct acting antiviral agents and ribavirin for a duration of no more than twelve weeks. WO'630 discloses combination of PSI-7977 and PSI-938, a combination of BMS-790052 and BMS-650032, a combination of GS-5885 and GS-9451, a combination of GS-5885, GS-9190 and GS-9451, a combination of BI-201335 and BI-27127, a combination of telaprevir and VX-222, a combination of PSI-7977 and TMC-435, and a combination of danoprevir and R7128. Further it was disclosed that, at least two direct acting antiviral agents comprises a combination of PSI-7977 and BMS-790052 (daclatasvir). WO'630 discloses that the at least

two direct acting antiviral agents comprises a combination of PSI-7977 and BMS-650032 (asunaprevir). In another aspect, the at least two direct acting antiviral agents comprises a combination of PSI-7977, BMS-650032 (asunaprevir) and BMS-790052 (daclatasvir). In yet another aspect, the at least two direct acting antiviral agents comprises a combination of TMC-435 and daclatasvir. The said prior art also provides that , two or more drugs in a regimen can be co-formulated in amorphous forms or molecularly dispersed in a matrix comprising a water-soluble polymer and optionally a surfactant; for another instance, therapeutic agent 1 and ritonavir (RTV) are formulated in an amorphous form or molecularly dispersed in a matrix comprising a water-soluble polymer and optionally a surfactant, and therapeutic agent 3 is combined with amorphous Compound 1 and RTV in a single solid dosage form. For yet another instance, Compound 1 and RTV are formulated in a different dosage form than that of therapeutic agent 3. It is further disclosed that, 250 mg BID can be used for Compound 2 in lieu of 400 mg BID; it was unexpectedly discovered that by increasing the amount of the binder (e.g., copovidone) in a solid formulation of Compound 2 (or a pharmaceutically acceptable salt thereof), the bioavailability of Compound 2 (or said salt) can be significantly improved such that 250 mg Compound 2 (or said salt) in the improved formulation was bioequivalent to 400 mg Compound 2 (or said salt) in the original formulation.

WO'578 is directed to solid compositions comprising HCV inhibiting compounds selected from the group consisting of IA, IB, IC and ID having following structures:



WO'550 discloses a solid composition comprising an HCV inhibitor selected from telaprevir, BI-201335, TMC-435, vaniprevir, MK-5172, asunaprevir, daclatasvir, danoprevir, setrobuvir, tegobuvir, GS-9451, mericitabine, IDX-184, filibuvir, PSI-7977, PSI-352938, BIT-225, boceprevir, GS-5885 or GS-9256,a pharmaceutically acceptable hydrophilic polymer, and optionally a pharmaceutically acceptable surfactant, wherein said polymer is copovidone. (see para 0010), this document teaches that "Utilizing an amorphous solid dispersion (ASD) is attractive not only because it can increase the pharmacokinetic exposure of otherwise poorly absorbed drugs, but also because the final product may be delivered to the patient as a tablet or capsule, which may provide greater chemical stability and improved patient convenience compared to liquid dosage forms" (para 0026).WO550 also discloses that the selected HCV inhibitor used in solid dispersion is GS-5885 i.e. daclatasvir and the solid composition further comprises PSI-7977 i.e. Sofosbuvir (para 0115).

US'776 discloses a pharmaceutical composition comprising: a) about 25% to about 35% w/w of GS-7977; and b) at least one pharmaceutically acceptable excipient, wherein the crystalline GS-7977 has XRPD 2θ-reflections (°) at about: (1) 5.0, 7.3, 9.4, and 18.1; or (2) 6.1, 8.2, 10.4, 12.7, 17.2, 17.7, 18.0, 18.8, 19.4, 19.8, 20.1, 20.8, 21.8, and 23.3.

Annexure 6 of the opposition which was published on 28th April 2013 reports the use of GS-5816 (i.e. Valpatasvir which is the compound 1 of the impugned invention) along with Sofosbuvir to treat a broad range of HCV genotypes. Table 1 of Annexure 6 discloses that GS-5816 (Velpatasvir) has potent inhibitory activity against all 1 to 6 genotypes of HCV and the EC50 values of GS-5816 for all these genotypes ranges from 6 to 130 picomoles.

Step 3: Identification of the inventive concept of the claim(s) in question:

The **combination of sofosbuvir in a crystalline form with** specific excipients and Compound I **(velpatasvir) in an amorphous form** in a solid dispersion within a polymer matrix formed by copovidone, with a weight ratio of Compound I to copovidone in the solid dispersion of 1:1, is claimed to be effective for treating hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5, and 6. When compared to the administration of Compound I and/or sofosbuvir alone, the claimed combination increased bioavailability, decreased negative drug-drug interaction with acid suppressive therapies, reduced variability across patient populations, improved dose linearity at higher doses.

Step 4: Identification of what, if any, differences exist between the matters cited as forming part of the "state of the art" and the inventive concept of the claim(s):

The following documents which were found most relevant for deciding the patentability of the invention u/s 2(1) (ja) of the Act as well as from the view point of the opposition filed which has only been analyzed;

The difference lies in the present invention and WO'029 is that WO'029 does not disclose particular pharmaceutical combination of **Compound I (velpatasvir) in an amorphous form** in a solid dispersion within a polymer matrix formed by copovidone, wherein the weight ratio of Compound I to copovidone in the solid dispersion is 1:1 and a claimed amount of **sofosbuvir in a crystalline form** with certain excipients in the claimed amounts.

US'260 discloses pharmaceutical composition in the form of a fixed dose combination tablet comprising (a) 15% to 25% w /w of a solid dispersion of Compound I (velpatasvir) (see paras 0095, 0148, 0133) dispersed within the polymer matrix (see para 0097) formed by copovidone (see para 0107), wherein the weight ratio of Compound I to copovidone is 1:1 (see para 0112) (b) 35% to 45% w /w of the sofosbuvir, (see para 0151) (c) the microcrystalline cellulose (d) the croscarmellose sodium ; and (e) the magnesium stearate (see para 0151). However, the said document does not explicitly mention amorphous form of Compound I (Velpatasvir) and crystalline form of sofosbuvir in the composition; and the amount of croscarmellose sodium, microcrystalline cellulose, and magnesium stearate.

The difference lies in the present invention and WO432 that WO'432 does not disclose a pharmaceutical composition comprising specific amount of Compound I (velpatasvir) in an amorphous form in a solid dispersion and a specific amount of sofosbuvir in a crystalline form with certain excipients in specific amounts as claimed in the instant application. **WO'432** teaches that HCV inhibitors in an amorphous form is stable within the solid dispersion. Therefore, it teaches an amorphous form of HCV inhibitors can be stabilized within the solid dispersion.

The difference lies in the present invention and WO'630 that WO'630 teaches the composition comprising ribavirin, as one of the components for the treatment of HCV, however, the presently claimed invention aims at treatment of HCV with interferon free and ribavirin-free.

The difference lies in the present invention and WO'550 that WO'550 teachs that "Utilizing an amorphous solid dispersion (ASD) is attractive not only because it can increase the pharmacokinetic exposure of otherwise poorly absorbed drugs, but also because the final product may be delivered to the patient as a tablet or capsule, which may provide greater chemical stability and improved patient convenience compared to liquid dosage forms"(para 0026).WO550 also discloses that the selected HCV inhibitor used in solid dispersion is GS-5885 i.e. daclatasvir and the solid composition further comprises PSI-7977 i.e. Sofosbuvir (para 0115). Velpatasvir is not disclosed in this document.

The difference lies in the present invention and US'776 that US'776 discloses the composition of crystalline Form 6 is the most stable crystalline form of Sofosbuvir. US776 discloses that the preferred weight of Sofosbuvir is 400mg (see para 0074), the preferred weight of microcrystalline

cellulose is 356mg, preferred weight of croscarmellose sodium is about 60 mg, and the preferred weight of magnesium stearate is about 18mg in the composition comprising Sofosbuvir (para 0083). US776 teaches that when Sofosbuvir is used the preferred dose is 400mg in crystalline Form 6 as this is the most stable preferred crystalline form. The said prior art does not teach a pharmaceutical composition wherein the sofosbuvir is co-formulated with a solid dispersion of Compound I (velpatasvir) dispersed within the polymer matrix formed by copovidone.

The difference lies in the present invention and Annexure 6 that **i**t does not teach about a pharmaceutical composition comprising a solid dispersion of velpatasvir **in substantially amorphous form** dispersed within the polymer matrix formed by copovidone in 1:1 ratio, and co-formulated with crystalline sofosbuvir. However **Annexure 6** discloses that GS-5816 i.e. Velpatasvir or compound 1 of impugned application is the second generation HCV NS5A inhibitor which is more potent and has broader coverage of HCV genotypes as compared to first generation NS5A inhibitors (see first bullet point under the heading of "Conclusions" on page 247) and that GS-5816 i.e. Valpatasvir is developed to target HCV genotypes 1-6 and have broad polymorphism coverage.

Step 5: Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?

Applicant argued that co-formulation of amorphous agent with crystalline agent is the problem which applicant has solved by this invention, however justifying addition of this problem by the applicant at a later stage as the main theme of the invention may not arise. Nowhere was it mentioned in the complete specification which was produced in the declaration submitted on 12/10/2023. Further, Applicant **submitted** (Exhibit B included in Dr. Eric Gorman's Declaration) that

*several polymers were investigated to determine which polymers could be most effective in maintaining Compound I in solution. Copovidone and Soluplus® were determined to be the two best polymers for Compound I, as indicated in figure 1 of the aforementioned declaration. Compound I was produced as spray-dried dispersions (SDDs) with each of these polymers, and their performance was evaluated in both in vitro dissolution and in vivo dog exposure. The dissolution results are shown in figure 2, which shows that the SDD prepared with copovidone achieves a higher concentration (~2x) of Compound I dissolved in the media relative to the SDD prepared with Soluplus®. The dissolution and dog results were unexpected because based on the initial testing (Figure 1), the Soluplus® appeared to be equivalent or better than copovidone. Further, the data provided in Table 1 of the said declaration shows an improvement in bioavailability under fed conditions by a solid dispersion formulation as compared to the wet granulation formulation comprising a high dose of Compound I (e.g. 100 mg) and copovidone. As shown in Table 1, a wet granulation formulation comprising Tween 80 and copovidone exhibited a low AUC of 1161 hr*ng/mL and Cmax of 170*

*ng/mL in famotidine treated (fed) dogs. The Compound I solid dispersion formulation comprising copovidone almost doubled the AUC (2263 hr*ng/mL) and Cmax (369 ng/mL) in famotidine treated dogs. Whereas, similar bioavailability was observed for the wet granulation and Compound I solid dispersion formulation comprising copovidone in pentagastrin treated (fasting) dogs. The example 2 of the present specification demonstrate in table 6 that the claimed composition provided improved bioavailability in human patients for Sofosbuvir when given in combination with Velpatasvir as per the claimed composition. Sofosbuvir plasma exposures increased approximately 1.8-fold (Cmax) and 2.4-fold (AUC) when co-administered with Compound I (Velpatasvir).Example 3 of the present specification demonstrate in table 7 and 8 that the claimed composition provided improved bioavailability in human patients for Velpatasvir when given in combination with sofosbuvir as per the claimed composition. Example 4 of the specification provides the results of the study of the combination of sofosbuvir (SOF) and Compound I solid dispersion (Compound I: copovidone 1:1) in patients with genotype 1-6 HCV infection and experimental results provided in table 9 on page 46 of the specification.*

Now, I would like to focus on the components and known facts about the present invention;

COMPONENT	**Known Facts**
Compound I (Velpatasvir)(GS-5816)	a Second-Generation HCV NS5A Inhibitor With Potent Antiviral Activity against all 1 to 6 genotypes of HCV and the EC50 values of GS-5816 for all these genotypes ranges from 6 to 130 picomoles (**Annexure 6**)
Polymer matrix formed by copovidone	Copovidone-formed polymer matrix containing a solid dispersion of HCV inhibitor is well known as stability enhancer.(**WO'432**)
Crystalline form of sofosbuvir	**Well known antiviral medicine** to treat **hepatitis C (US'776)**
Combination of (sofosbuvir+ velpatasvir)+ copovidone	Already known (**WO'029** or **US'260**)
Technical effect of Combination of (sofosbuvir+ velpatasvir)	**Already Known (Annexure 6 or 5)**
Effect of amorphous solid dispersion (ASD) of HCV drugs	**Known for improvement of the pharmacokinetics or bioavailability (WO'432) or (WO'550)**
Particular solid dispersion of Compound I (velpatasvir)in substantially amorphous form dispersed within the polymer matrix formed by copovidone + crystalline form of sofosbuvir)	**Not known**
Is there any technical results provided in the complete specification by the use of Compound I (velpatasvir)in substantially amorphous form dispersed within the polymer	**YES** (As covered in more detail in the paragraphs that follow) The present invention provided increased bioavailability, decreased negative drug-drug interaction & functional aspect

matrix formed by copovidone + crystalline form of sofosbuvir)	of Antiviral Activity against all 1 to 6 genotypes of HCV (Tables 6-9 complete specification) & better dissolution results shown in figure 1 & 2 (as per declaration submitted by applicant)
Whether this is obvious to achieve the desired results:	**YES; This is obvious to a person skilled in the art** to **combine solid dispersion of Compound I (velpatasvir) in substantially amorphous form** dispersed within the polymer matrix formed by copovidone + crystalline form of sofosbuvir to achieve the desired results as **improved bioavailability**, **better dissolution profile** and **functional aspect** of working against with genotype 1-6 HCV infection.

In view of the above analysis and findings, I conclude that, it is clear from that combination of (sofosbuvir+ velpatasvir) with polyvinylpyrrolidone (copovidone) as a one of the carriers in the composition with croscarmellose sodium, microcrystalline cellulose, and magnesium stearate is already known from **WO'029 or US'260**. **Annexure 6** discloses that combination of Velpatasvir and Sofosbuvir when administered to patients is **safe and effective**. Valpatasvir and Sofosbuvir were combined and the administration of this combination was found to be effective against HCV genotype 1-6. **US'776** teaches the use of Sofosbuvir in preferred dose is 400mg in crystalline Form 6 for the treatment of hepatitis C virus. Teachings of a solid dispersion of amorphous form of HCV active compound within a polymer matrix formed by copovidone is well known from WO'630 and effect of amorphous solid dispersion (ASD) of HCV drugs to achieve the better dissolution, stability, and bioavailability also well-known from **(WO'432) or (WO'550).** Therefore it is obvious to a person skilled in the art to combine the teachings of WO'029 or US'260 or Annexure 6,with US776, WO'630 &(WO'432) or (WO'550) to achieve the dissolution results (as shown in figure 2, which shows that the SDD prepared with copovidone achieves a higher concentration (~2x) of Compound I dissolved in the media relative to the SDD prepared with Soluplus®) , doubled AUC (2263 hr*ng/mL) and Cmax (369 ng/mL) values in famotidine treated dog and plasma exposures 1.8-fold (Cmax) and 2.4-fold (AUC) as an improved bioavailability in human patients by the claimed composition. Therefore, pharmaceutical composition in the form of tablet of 15-25 % of solid dispersion of Compound I (velpatasvir) in substantially amorphous form dispersed within the polymer matrix formed by copovidone (in 1:1) with 35-45 % crystalline form of sofosbuvir is obvious for a person skilled in the art would optimize the teachings of know prior art(s) to arrive at the present invention to achieve the improved bioavailability, better dissolution profile & activity against genotype 1-6 HCV infection. Therefore, the invention as claimed in the

claim 1 and its dependent claims 2-7 of the present application not considered inventive over the teachings of all the cited prior arts **WO'029 or US'260 or Annexure 6 with US776, WO'630 &(WO'432) or (WO'550).** Therefore, Inventive step cannot acknowledged u/s 2(1)(ja) of the Act.

I conclude that such a ground of opposition is validly established by the Opponent(s).

GROUND: OPPOSTION UNDER SECTION 25(1)(f); (not patentable invention U/S 3(d) & 3(e))

As far as the invention claimed in any of the claims falls under Section 25(1)(f) of the Act i.e. whether a patentable invention U/S 3(d) & 3(e) of the Act**.**

3(d); *the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*

Explanation.--For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, **combinations** and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

3(e); *a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;"*

Judgment of the Supreme Court in Novartis AG v. Union of India and others, (2013) 6 SCC 1, the Supreme Court in the said judgment has held that "***even if an invention satisfies the criteria of Novelty and Inventive step, patent can be denied on the ground of Section 3(d)***. *Provisions of Section 3(d) exclude the patentability of a new form of a known substance if it does not result in enhancement of the known efficacy of that substance."*

Further, I would like to rely on the judgment by High Court of Delhi in the matter of W.P.(C)-IPD 11/2022 & CM 32/2022, 54/2022, 55/2022; BEST AGROLIFE LIMITED vs. DEPUTY CONTROLLER OF PATENTS, In this case, the Court observed that

Section 3(d) of the Patents Act provides that a known substance may include combination of known substances. The claims of the impugned application relate to a suspo-emulsion formulation comprising a combination of known substances i.e., Pyriproxyfen and Diafenthiuron with inactive excipients and therefore must fulfil the requirements of Section 3(d).

Section 3(d) provides that a mere discovery of a new form of a known substance which does not result in enhanced efficacy of that substance shall not be an invention. Explanation to the Section provides that 'combinations' shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy. Section 3(e) provides that a substance obtained by a mere admixture resulting only in the aggregation of properties of the components thereof shall not be an invention. There is merit in the contention of the Petitioner that the patent applicant has claimed a suspo-emulsion of admixture/combination of Diafenthiuron and Pyriproxyfen and therefore, ***the applicant would have to pass the test under both Section 3(d) and 3(e),*** *albeit on different aspects by showing enhanced efficacy over known combination of a suspo-emulsion qua Section 3(d) and synergistic effect over the mere additive effect of individual components of suspo-emulsion composition.*

In the present application, the applicant sought protection of **combination** of **Compound I (velpatasvir) in an amorphous form** in a solid dispersion within a polymer matrix formed by copovidone, wherein the weight ratio of Compound I to copovidone in the solid dispersion is 1:1 and **sofosbuvir in a crystalline form** with certain excipients.

US'260 or WO029 discloses a pharmaceutical composition comprising a pharmaceutically acceptable carrier, sofosbuvir, and a compound of the formula i.e Velpatasvir. US'260 also discloses polyvinylpyrrolidone (copovidone) as a one of the carriers in the composition. US'260 disclose formation of a solid dispersion of the active compound with a carrier such as polyvinylpyrrolidone (copovidone) i.e. it discloses a solid dispersion of Velpatasvir with copovidone. Therefore it is clear from US260 that a composition of solid dispersion of Velpatasvir in **combination** with Sofosbuvir was known.

Further **Annexure 6** discloses that combination of Velpatasvir and Sofosbuvir when administered to patients is **safe and effective**. Valpatasvir and Sofosbuvir were combined and the administration of this combination was found to be effective against HCV genotype 1-6.

Table 1 of the **Annexure 6 clearly discloses that** GS-5816 i.e. Valpatasvir was found to be effective against HCV genotype 1-6.

Table 2 of the **Annexure 6 has shown additive to synergistic activity when** combined **with** Sofosbuvir.

Annexure 5 specifically discloses that that combination of GS-5816 i.e. Valpatasvir and Sofosbuvir was found to be effective against HCV in clinical trial Phase I and were being tested in clinical trial Phase II as shown below:

Study Status

Record Verification:	July 2013	July 2013
Overall Status:	Recruiting	Recruiting
Study Start:	June 2013	June 2013
Primary Completion:	October 2013 [Anticipated]	October 2013 [Anticipated]
Study Completion:	April 2014 [Anticipated]	April 2014 [Anticipated]
First Submitted:	July 17, 2013	July 17, 2013
First Submitted that Met QC Criteria:	July 26, 2013	July 26, 2013

First Posted:	July 29, 2013 [Estimate]	July 29, 2013 [Estimate]
Last Update Submitted that Met QC Criteria:	July 26, 2013	July 26, 2013
Last Update Posted:	July 29, 2013 [Estimate]	July 29, 2013 [Estimate]

Sponsor/Collaborators

Sponsor:	Gilead Sciences	Gilead Sciences
Responsible Party:	Sponsor	Sponsor
Collaborators:		

Oversight

U.S. FDA-regulated Drug:		
U.S. FDA-regulated Device:		
Data Monitoring:	No	No

Study Description

Brief Summary:	This study will evaluate sofosbuvir (SOF)+GS-5816 for the treatment of chronic genotype 3 Hepatitis C Virus (HCV) infection in treatment experienced subjects.	This study will evaluate sofosbuvir (SOF)+GS-5816 for the treatment of chronic genotype 3 Hepatitis C Virus (HCV) infection in treatment experienced subjects.
Detailed Description:		

Conditions

Conditions:	Hepatitis C	Hepatitis C
Keywords:	Hepatitis HCV Genotype 3	Hepatitis HCV Genotype 3

Study Design

Study Type:	Interventional	Interventional
Primary Purpose:	Treatment	Treatment
Study Phase:	Phase 2	Phase 2
Interventional Study Model:	Factorial Assignment	Factorial Assignment
Number of Arms:	4	4
Masking:	None (Open Label)	None (Open Label)
Allocation:	Randomized	Randomized
Enrollment:	200 [Anticipated]	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: SOF+GS-5816(25mg) SOF 400 mg + GS-5816(25 mg) once daily for 12 weeks	Drug: Sofosbuvir (SOF)+GS-5816
Experimental: SOF+GS5816(25mg)+RBV SOF 400 mg + GS-5816(25 mg) + RBV (1000 or 1200 mg/day in a divided daily dose) for 12 weeks	Drug: Sofosbuvir (SOF)+GS-5816 and Ribavirin
Experimental: SOF+GS-5816(100mg) SOF(400 mg) + GS-5816(100 mg) once daily for 12 weeks	Drug: Sofosbuvir (SOF)+GS-5816
Experimental: SOF+GS-5816(100mg)+RBV SOF 400 mg + GS-5816 100mg+ RBV (1000 or 1200 mg/day in a divided daily dose) for 12 weeks	Drug: Sofosbuvir (SOF)+GS-5816 and Ribavirin

Outcome Measures

Primary Outcome Measures:

1.	Efficacy 12 weeks post dosing [Time Frame: 12 weeks]	Efficacy 12 weeks post dosing [Time Frame: 12 weeks]
	The proportion of patients with a sustained virologic response (SVR) 12 weeks after discontinuation of therapy	The proportion of patients with a sustained virologic response (SVR) 12 weeks after discontinuation of therapy

https://clinicaltrials.gov/ct2/history/NCT01909804?A=1&B=1&C=Side-by-Side#StudyPageTop

2.	Safety and tolerability of SOF+GS-5816 with or without Ribavirin as measured by review of the accumulated safety data [Time Frame: Safety and tolerability on treatment and 30 days post last dose]	Safety and tolerability of SOF+GS-5816 with or without Ribavirin as measured by review of the accumulated safety data [Time Frame: Safety and tolerability on treatment and 30 days post last dose]
	Frequency and severity of adverse events.	Frequency and severity of adverse events.

Secondary Outcome Measures:

1.	Efficacy 4 and 24 weeks post dosing [Time Frame: 4 and 24 Weeks]	Efficacy 4 and 24 weeks post dosing [Time Frame: 4 and 24 Weeks]

	2. Safety and tolerability of SOF+GS-5816 with or without Ribavirin as measured by review of the accumulated safety data [Time Frame: Safety and tolerability on treatment and 30 days post last dose] Frequency and severity of adverse events.	Safety and tolerability of SOF+GS-5816 with or without Ribavirin as measured by review of the accumulated safety data [Time Frame: Safety and tolerability on treatment and 30 days post last dose] Frequency and severity of adverse events.
Secondary Outcome Measures:		
	1. Efficacy 4 and 24 weeks post dosing [Time Frame: 4 and 24 Weeks] To determine the proportion of subjects who attain SVR at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)	Efficacy 4 and 24 weeks post dosing [Time Frame: 4 and 24 Weeks] To determine the proportion of subjects who attain SVR at 4 and 24 weeks after discontinuation of therapy (SVR4 and SVR24)
	2. Amount of plasma HCV RNA [Time Frame: 24 weeks] To evaluate the kinetics of plasma HCV RNA during treatment and after treatment discontinuation	Amount of plasma HCV RNA [Time Frame: 24 weeks] To evaluate the kinetics of plasma HCV RNA during treatment and after treatment discontinuation
	3. Characterization of viral resistance [Time Frame: 24 weeks] To evaluate the emergence of viral resistance to SOF+GS-5816 during treatment and after treatment discontinuation	Characterization of viral resistance [Time Frame: 24 weeks] To evaluate the emergence of viral resistance to SOF+GS-5816 during treatment and after treatment discontinuation

▼ Eligibility

Minimum Age:	18 Years	18 Years
Maximum Age:		
Sex:	All	All
Gender Based:		
Accepts Healthy Volunteers:	No	No
Criteria:	Inclusion Criteria: • Male or female, age ≥ 18 years • Body mass index (BMI) ≥ 18 kg/m2 • HCV RNA ≥ 10000 IU/mL at Screening • Prior treatment failure to a regimen including interferon with or without RBV • HCV Genotype 3 • Chronic HCV infection • Cirrhosis determination • Use of highly effective contraception methods if female of childbearing potential or sexually active male Exclusion Criteria • Current or prior history of clinically significant illness other than HCV • Screening ECG with clinically significant abnormalities • Prior exposure to HCV specific direct acting antiviral agent • Pregnant or nursing female or male with pregnant female partner • Chronic liver disease of non-HCV etiology • Hep B • Active drug abuse • Use of any prohibited concomitant medications	Inclusion Criteria: • Male or female, age ≥ 18 years • Body mass index (BMI) ≥ 18 kg/m2 • HCV RNA ≥ 10000 IU/mL at Screening • Prior treatment failure to a regimen including interferon with or without RBV • HCV Genotype 3 • Chronic HCV infection • Cirrhosis determination • Use of highly effective contraception methods if female of childbearing potential or sexually active male Exclusion Criteria • Current or prior history of clinically significant illness other than HCV • Screening ECG with clinically significant abnormalities • Prior exposure to HCV specific direct acting antiviral agent • Pregnant or nursing female or male with pregnant female partner • Chronic liver disease of non-HCV etiology • Hep B • Active drug abuse • Use of any prohibited concomitant medications

Therefore, it is proved from above paragraphs that **combination of Velpatasvir with Sofosbuvir** is **known substance** with respect to the present invention.

The applicant has provided table 9 in the complete specification as given below:

Table 9: SVR4 in Patients Treated with SOF + Compound I for 12 Weeks

HCV genotype	SOF (400mg) + Compound I (25mg)	SOF (400mg) + Compound I (100mg)
GT1	96% (26/27)	100% (28/28)
GT2	91% (10/11)[a]	100% (10/10)
GT3	89% (24/27)[a]	100% (27/27)
GT4	100% (7/7)	86% (6/7)[a]
GT5	100% (1/1)	-
GT6	100% (4/4)	100% (5/5)

a. One patient per group was lost to follow-up prior to posttreatment week 4.

Above Table 9 of the complete specification was not sufficient to prove improved therapeutic efficacy of the claimed combination. Therefore, to support such facts, applicant's agent submitted declaration by Dr. Eric Gormen and said declaration is carefully considered and taken on record. In this declaration it was submitted that the rate of sustained virologic response among patients who received 12 weeks of sofosbuvir-velpatasvir was 99% (95% confidence interval [CI], 98 to >99), which was significantly superior to the prespecified performance goal of 85% (P <0.001) as shown in below table 2. None of the 116 patients in the placebo group had a sustained virologic response. Further, Annexure B of the declaration of Expert Dr. Eric Gorman provided the efficacy in terms of sustain virologic response i.e HCV RNA level of less than 15 IU per milliliter at 12 weeks after the end of the treatment.

Table 2. Response during and after Treatment.*

Response	Sofosbuvir–Velpatasvir (N=624)
HCV RNA <15 IU/ml	
During treatment period — no. (%)	
At wk 2	355 (57)
At wk 4	564 (90)
At 12 wk after treatment period — no./total no. (%)	
Any genotype	618/624 (99)
1a	206/210 (98)
1b	117/118 (99)
2	104/104 (100)
4	116/116 (100)
5	34/35 (97)
6	41/41 (100)
Virologic failure — no. (%)	
During treatment	0
After treatment	2 (<1)
Other reason for classification as failure — no. (%)	
Loss to follow-up	2 (<1)
Withdrawal of consent	1 (<1)
Death	1 (<1)

* None of the patients receiving placebo had an HCV RNA level of less than 15 IU per milliliter at any time point. Additional data about response according to subgroup are provided in Tables S2 and S3 in the Supplementary Appendix.

Further, the data provided in above table 2 which is taken from Exhibit B "The new england journal of medicine" Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection. It is observed that no where it is disclosed in the said document that results of 624 patients who received treatment with sofosbuvir–velpatasvir is related to the present claimed composition i.e. Claimed composition involves the solid dispersion of Compound I (velpatasvir) in a substantially amorphous form, dispersed within the polymer matrix formed by copovidone, combined with the crystalline form of sofosbuvir. It is noted that there is no mention in the aforementioned paper of the relationship between the alleged composition of the claimed combination of (**amorphous velpatasvir+crystalline sofosbuvir**) and the outcomes of 624 patients who were treated with **sofosbuvir-velpatasvir**.

I have carefully reviewed the affidavit and annexures provided, specifically focusing on the sustained virologic response data outlined in relation to the combination tablet containing 400 mg of sofosbuvir and 100 mg of velpatasvir administered orally once daily for 12 weeks. However, it appears that the information provided does not explicitly attribute the stated virologic response to the administration of amorphous velpatasvir + crystalline sofosbuvir (the claimed composition).

The documentation consistently refers to the combination as velpatasvir and sofosbuvir, a combination that is already well-documented in Annexures 5 or 6 of opposition. In order to assess the claimed composition's enhancement of therapeutic efficacy over prior art, it is imperative to have credible and specific information regarding the therapeutic efficacy of amorphous velpatasvir + crystalline sofosbuvir.

As it stands, the lack of explicit identification of sustained virologic response outcomes achieved through the administration of amorphous velpatasvir + crystalline sofosbuvir raises concerns about the relevance and applicability of the provided data to the unique formulation under consideration in the present claim. Without clear evidence of the therapeutic efficacy of the claimed composition, the provided data for enhancement of efficacy over the teachings of the art cannot be considered relevant.

Moreover, after a meticulous examination of the aforementioned declaration, it is discerned that the declaration provides comparative evidence related to the 12-week treatment activity for HCV genotype 2 or 3, involving both sofosbuvir-velpatasvir and sofosbuvir-ribavirin, as illustrated in Figure 1. It is crucial to note that sofosbuvir-ribavirin is not a relevant or known substance in connection with the present invention. The inclusion of sofosbuvir-ribavirin in the comparison raises concerns about its applicability and relevance to the unique aspects of the presently claimed invention.

(Fig. 1). Sustained virologic response did not appear to be correlated with the IL28B genotype or early viral kinetics.

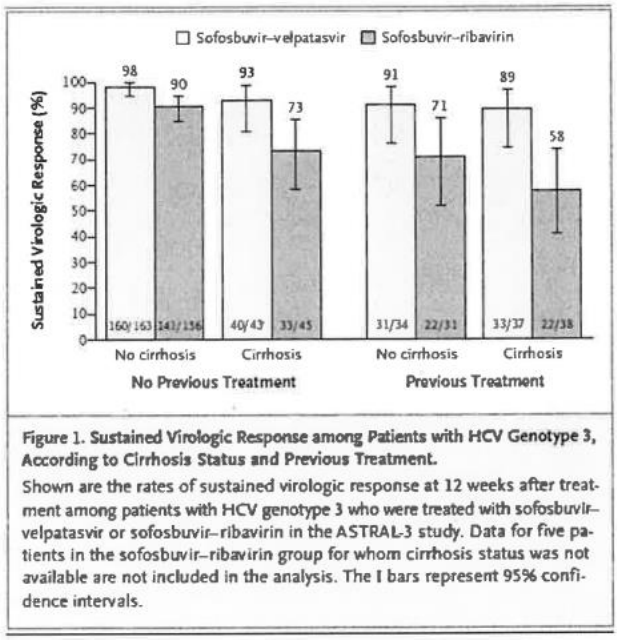


Figure 1. Sustained Virologic Response among Patients with HCV Genotype 3, According to Cirrhosis Status and Previous Treatment.

Shown are the rates of sustained virologic response at 12 weeks after treatment among patients with HCV genotype 3 who were treated with sofosbuvir–velpatasvir or sofosbuvir–ribavirin in the ASTRAL-3 study. Data for five patients in the sofosbuvir–ribavirin group for whom cirrhosis status was not available are not included in the analysis. The I bars represent 95% confidence intervals.

Among patients with HCV genotype 2 or 3 with or without previous treatment, including those with compensated cirrhosis, 12 weeks of treatment with sofosbuvir–velpatasvir resulted in rates of sustained virologic response that were superior to those with standard treatment with sofosbuvir–ribavirin.

Further, it is well known from the Annexures 5 & 6 cited by the opponent that efficacy of combination of sofosbuvir–velpatasvir is well known. Therefore, combination of Compound I **(velpatasvir) in substantially amorphous form** dispersed within the polymer matrix formed by copovidone **combined with crystalline form of sofosbuvir** present claimed invention to be patentable should be showing enhanced efficacy and that to unexpected enhanced therapeutic efficacy for treatment of HCV Genotype 1, 2, 4, 5, and 6 Infection. The comparative data, which has been placed on record, relates to the improved dissolution, absorption, and bioavailability which can't be correlated with the enhanced therapeutic effect unless data relating to the improved efficacy of combination of Compound I **(velpatasvir) in substantially amorphous form combine with crystalline form of sofosbuvir** is given. Further, there is no comparative data given in the complete specification or in declaration when non-amorphous or other form of **velpatasvir was used in the** treatment of HCV Genotype 1, 2, 4, 5, and 6 Infection. Table 6 only compared compound I's bioavailability statistics with the current combination. Table 9 provides only functional aspect of the claimed combination not improved therapeutic efficacy over known combination. The therapeutic

efficacy of the known combination of Velpatasvir and Sofosbuvir might have also been compared since the applicant was fully aware of the published clinical trial data of that combination.

Data related to improved bioavailability and dissolution test would not constitute enhancement in therapeutic efficacy of known combination unless it shows significant enhancement in known therapeutic efficacy in terms of comparative efficacy results. In the absence of any such credible evidence regarding enhanced therapeutic effect of the claimed combination of **substantially amorphous form combine - sofosbuvir** is considered new form of known combination of Velpatasvir and Sofosbuvir not patentable u/s 3(d) of the Act. Therefore, the objection U/S 3(d) is maintained and not met by the applicant.

Regarding section 3(e), Applicant has provided synergy in terms of bioavailibity as shown in table 6-7 of the complete specification. *As sofosbuvir plasma exposures increased approximately 1.8-fold (Cmax) and 2.4-fold (AUC) when coadministered with Compound I. SOF metabolite I Cmax and AUC increased approximately 1.6- and 1.8-fold, respectively, when SOF was coadministered with Compound I (solid dispersion, Compound I copovidone 1:1). approximately 1.8-fold (Cmax) and 2.4-fold (AUC) when coadministered with Compound I.*

With respect to the HCV Genotype 1, 2, 4, 5, and 6 studies, applicant's agent argues that " *table 1 of Annexure 6 provides EC50 values in picomoles for individual drug Velpatasvir in cell lines. In this regard, it is important to note that the example 3 of the present specification demonstrate in table 7 and 8 that the claimed composition provided* ***improved bioavailability in human patients*** *for Velpatasvir when given in combination with sofosbuvir as per the claimed composition. It is submitted that bioavailability is known factor to consider therapeutic efficacy.Further, the table 2 of Annexure 6 depicts that mere combination of Velpatasvir and Sofosbuvir has additive effect, not synergistic. It does not talk about crystalline sofosbuvir at all".*

As mentioned above, section 3(e) precludes the patenting of a formulation or composition if there is only aggregation of properties of the individual component. Therefore, section 3(e) requires that in a composition, of the known substances, with well-known pharmaceutical activity, if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features. In other words it can said that if the effectiveness of the formulation, as a whole, produces greater effects than the sum of the individual effects, the combination or formulation is said to exhibit more than a mere aggregation of the features i.e. Composition is said to possesses synergistic effect. Thus it can be said that presence of synergistic effect is the essential requirement of

section 3(e) of the Act. In my opinion, in pharmaceutical formulation it is the potency and/or efficacy of the formulation over the individual components determine the presence or absence of synergistic effect.

Applicant, in response to the objection under section 3(e) could only submit that *"present combinations demonstrates an enhanced technical effect, i.e. bioavailability. Further applicant's agent argued that annexure 6 which shows mere additive effect of Velpatasvir and Sofosbuvir combination, the present invention clearly demonstrates synergistic effect of the claimed composition comprising a pharmaceutical composition comprising a solid dispersion of velpatasvir dispersed within the polymer matrix formed by copovidone in 1:1 ratio, and co-formulated with crystalline sofosbuvir*".

However, the description of present application also fails to disclose any data to establish that the present formulation possesses greater affects i.e. efficacy, than the sum of the individual effects, as discussed above. Applicant also could not provide any such to establish synergistic effect in terms of therapeutic effect. Thus, in absence of any such data it is concluded that present pharmaceutical formulation of present claims 1-7 fails to fulfil the requirement section 3(e) of the Act.

I conclude that this ground of opposition 25(1)(f) of the Act) (non-patentability u/s 3(d), 3(e)) is validly established by opponent(s).

GROUND : INSUFFICIENCY UNDER SECTION 25(1) (g);

Section 25(1)(g) states that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed

Both Opponents have challenged the impugned application under opposition on the same ground, i.e. Under Section 25(1)(g) of The Patents Act, 1970 i.e. the impugned application under opposition does not sufficiently and fairly describe the invention in a manner so as to enable a person skilled in the art to perform or work the invention.

In this regard, the complete specification meets the statutory requirement as mandated under Section 10(4) of The Patents Act, 1970 and that the person skilled in the art would be sufficiently enabled to work on the claimed invention without undue experimentation by simply relying on the disclosure made in the complete specification. The question of insufficiency of disclosure does not arise even if a single working example for performing the invention is disclosed in the complete specification and the law is clear in this regard. In the present case, the complete specification is supported with working example which sufficiently describes the invention and the manner in which it is to be performed. Thus, it is my considered view, that the present application under opposition sufficiently

and fairly describe the invention in a manner so as to enable an ordinary person skilled in the art to perform or work the invention and is therefore not leading to any insufficiency of disclosure and also does not violate any provisions of Section 10(4) of the Patents Act, 1970.

I conclude that this ground of opposition is not validly established by Opponent(s).

GROUND: SECTION 25(1) (h) of the Patents Act

that the applicant has failed to disclose to the controller the information required by section 8, and therefore objection is raised under section 25 (1)(h)

In this regard applicant's agent submitted updated Form-3 to the Patent Office with current status of corresponding applications along with petition under rule 137 on February 18, 2020 for condoning the irregularity of the procedure envisaged by Section 8. This has been taken on record and the said objection does not withstand.

16. In view of the hearing submissions & deletion of other claims other objections raised in hearing notice are met.

17. The instant application does not meet the requirements of section 2(1)(ja) and sections 3(d) & 3(e) of the Patents Act based on the findings from the investigation as well as from the matter presented by the opponents in the pre-grant opposition proceedings as discussed above. Therefore, it is hereby ordered that the invention disclosed and claimed in the instant application 201627008488 entitled "COMBINATION FORMULATION OF TWO ANTIVIRAL COMPOUNDS" has been refused to proceed further under section 15 of the Act and simultaneously, I dispose of both the pre-grant oppositions as per the provision under Section 25(1) of the Act and corresponding Rules made thereunder.

Dated this 05-03-2024

(Dr. (Miss) Latika Dawara)
Asst. Controller of Patents & Designs
Patent Office Mumbai