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. 201917029812 by

ATEA PHARMACEUTICALS INC., U.S.A.

And

In the matter representation by way of opposition

under Section 25 (1) of the Patent Act

by **SANKALP REHABILITATION TRUST, Mumbai**

Present: Agent for the Applicant- Archana Shanker (**IN/PA 149**) & Dr. Sachin Malik **(IN/PA-3246)**

Agent for the Opponent: Pragya Singh Thakur (IN/PA – **3329**)

D E C I S I O N

1. On 23/07/2019, the Applicant filed a PCT National Phase application for a patent bearing number 201917029812 in Patent Office, Delhi entitled "NUCLEOTIDE HEMI-SULFATE SALT FOR THE TREATMENT OF HEPATITIS C VIRUS". A request for examination under section 11-B was filed on 29/01/2021, and was assigned a Request No. R20211003186. As per the provision under Section 11-A of Patents Act, the said application was published on 18/10/2019.
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 19/03/2021. The applicant's agent filed the reply to the FER on 26/08/2022.(As per Hon'ble Supreme Court's order, the revised deadline for filing the response to the FER)

3. One representation by way of opposition u/s 25 (1) of the Act (hereinafter referred to as the pre-grant opposition) was filed on 28/09/2022 by **SANKALP REHABILITATION TRUST, Mumbai** 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 201917029812-FORM7A(PREGRANT)-041022.pdf, "201917029812-PRE GRANT OPPOSITION FORM [28-09-2022(online)].pdf and 201917029812-PRE GRANT OPPOSITION DOCUMENT [28-09-2022(online)].pdf.

4. On 19/10/2023 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 Opposition by the Opponent, the said documents available in the e-dossier as document named 201917029812-Statement and Evidence [09-10-2023(online)].pdf.

5. 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 opposition, 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's agent vide email scheduled on 16/04/2024 through VC under rule 28(6) of the Patent Rules, 2003 (as amended) vide hearing notice dated 06/03/2024 after two adjournments. Since all these hearing notice documents are available in public domain, they are not reproduced here for the sake of brevity. In respect of the said hearing notice dated 06/03/2024, a hearing was duly held on 16/04/2024 and attended by Applicant's agent as well as opponent's agents.

6. 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 the opponent sufficient opportunities were provided to hear all the arguments. Final Hearing Notice document available in the e-dossier as document named 201917029812-PreGrant-ExtendedHearingNotice-(HearingDate-16-04-2024).pdf. On the circumstances of the case, applicant's agent as well as 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.

7. The hearing submissions (oral arguments during hearing and written submissions after hearing) of the Opponent and the Applicant, Affidavit of Mr. STEVEN S. GOOD, SECOND DECLARATION OF MR. STEVEN GOOD, ATTACHMENT A to D and EXHIBITS-1-10 submitted on 30-05-2024 which are being considered taken on record to arrive a decision as under but the documents which were found most relevant for deciding

the patentability of the invention as well as from the view point of the opposition filed which have only been analyzed and all of them need not be addressed.

8. It is noted that opponent as well as applicant have cited a number of grounds, few decisions or 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 all submissions 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.

9. Hearing Notice dated 14/03/2024 with the following objections:

Objections

Formal Requirement(s)

1. Pregnant opposition hearing has been scheduled on the said date & time, Applicant/opponent are therefore, required to appear before the Controller for the hearing on the said date and time. You are also requested to prior confirm to the office as well opponnet/applicant for attending the same.

Invention u/s 2(1)(j)

1. Document D1, US20160257706A1, (WO2016144918A1; cited by the pre-grant opponent) discloses the impugned molecule and its pharmaceutically acceptable salts like sulphate salt. The said document not only encompassed the mono salt but also encompassed the hemi-salt of the compound claimed in the present application.

   D1 further discloses the pharmaceutical compositions that comprise an anti-HCV virus effective amount of β-D-2'-deoxy-2'-α-fluoro-2'-β-methyl-N 6 -methyl2,6-diaminopurine nucleoside phosphoramidate compound, optionally in combination with a pharmaceutically acceptable carrier, additive, or excipients. In addition to this, it further discloses that the said composition optionally is in combination with at least one other antiviral, such as an anti-HCV agent.

   Hence, the subject matter of amended claims 1-19 is not novel over the disclosure of D1. Thus, said claims do not meet the requirements of section 2(1)(j) of the Patents Act.

Invention u/s 2(1)(ja)

1. In addition, document D4 (Chang et al.: "Discovery of PSI-353661, a Novel Purine Nucleotide Prodrug for the Treatment of HCV Infection" ACS Med. Chem. Lett. 2011, 2, 2, 130–135) on page no. 131 discloses the compounds 8-31 which encompasses the compound claimed in the present application (see table 2, compound 31).

   The present application differs from compound 31 of D4 in that the present compound has a methyl group instead of an iso-propyl group attached to the N-atom of the pyrimidine. However, a person skilled in the art working in the same field can easily arrive at the present compound, because both the compounds (i.e. present compound and compound 31 of D4) are used for the treatment of the same type of disease.

   Document D5 (cited by the opponent as D2- G. Steffen Paulekuhn et al; Trends in Active Pharmaceutical Ingredient Salt Selection based on Analysis of the Orange Book Database, J. Med. Chem. 2007, 50, 6665–6672) discloses the concepts and importance of salt selection of active pharmaceutical ingredient. Salt formation is a well-known technique to modify and optimize the physical chemical properties of an ionisable research or development compound. Properties such as solubility, dissolution rate, hygroscopicity, stability, impurity profiles, and crystal habit can be influenced by using a variety of pharmaceutically acceptable counter ions. The crystal structure of a salt is usually completely different from the crystal structure of the conjugate base or acid and also differs from one salt to another. The modification of physical chemical properties, mainly solubility and dissolution rate, may also lead to changes in biological effects such as pharmacodynamics and pharmacokinetics, including bioavailability and toxicity profile.

   Document D6 (cited by the opponent as D3- Herve Rebiere et al; Determination of 19 antiretroviral agents in pharmaceuticals or suspected products with two methods using highperformance liquid chromatography; Journal of Chromatography B, 850 (2007) 376–383) discloses the list of various antiviral drugs, the sulfate salt is one of the common salt for antiviral drugs. Therefore, it would motivate to a person skilled in the art to opt sulphate salt for antiviral drugs.

   Document D7 (cited by the opponent as D4- US 2014/0187773) discloses the hemi-salt of tenofovir which is an antiviral drug. This document teaches the importance of hemi-salt over mono-salt of tenofovir alafenamide. The hemifumarate form of tenofovir alafenamide can be more readily and easily separated from impurities than the monofumarate form. Other major advantages of tenofovir alafenamide hemifumarate over the monofumarate form include improved thermo dynamic and chemical stability (including long-term storage stability), Superior process reproducibility, Superior drug product content uniformity, and a higher melting point. The hemifumarate form of tenofovir alafenamide was compared with the monofumarate form. Under identical conditions, the hemifumarate form of tenofovir alafenamide was chemically more stable and exhibited better long-term storage stability, with significantly less degradation (%Total Deg. Products) than the monofumarate form.

   By combining all the technical features disclosed in the documents cited above, a person skilled in the art can easily arrive at the present application. Therefore, amended claims 1-19 are not inventive u/s 2(1)(ja) of the Patents Act.

Non-Patentability u/s 3

1. Any salt of a known compound is not allowable u/s 3(d) of the Patents Act (see D1). Therefore, amended claims 1-2 are not allowable.

   The composition claimed in amended claims 3-9 is a mere admixture resulting only in the aggregation of the properties of

the components thereof. The addition of the carrier to the compound does not lead to a new composition but rather only increases the stability of the compound and also does not lead to enhanced therapeutic efficacy. It is a routine experiment in the field of pharmaceutical chemistry to adopt new carriers/excipients to increase the stability of any drug to be delivered by studying the different physical parameters like polarity, solvent-solute interaction, etc. Hence, claims 3-9 attract section 3(e) of the Patents Act.

Other Requirement(s)

1. The reply filed by the applicant for FER is beyond the stipulated time period. Further, no proper clarification has been given by the applicant.

   Without prejudice to the above objection, the instant applicant is examined.

   Amended claims 10-19 refer to the intended use or application of the so-called compound/composition and accordingly, are not allowable. Industrial application is inherent/intrinsic to any application wherein the industrial application is already acknowledged.

2. Hearing u/s 25(1) of the Patent act has been scheduled for the said case, Therefore applicant/ opponent are required to appear on the said date.

3. 1. Kindly confirm whether the applicant/agent will be/ will not be attending the scheduled hearing as required u/r 28 (4) of the Patents Rules.

   2. Valid Power of attorney in respect of the person who is attending the hearing should be submitted online before the date of hearing.

   3. While filing amended claims (if any) the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, not to add subject matter, which extends beyond the content of the application as originally filed. If any corrections/amendments are made on any page of the specification that page should be freshly typed and filed in duplicate along with a marked copy clearly highlighting the corrections/amendments made in originally filed claims. If any amendment is carried out based on above observation the subject-matter of the present application has to be clearly and convincingly be distinguished over the cited prior art knowledge. When filing new claims, as precautionary measure, the attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed and application after amendment full fill the requirement of section 59(1) of the Act. Furthermore, if any amended set of claims is filed on the basis of the above observation, the applicant should clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and clearly indicate the passages of the application as filed on which these amendments are based.

   4. The claims should be restricted to be within the scope of examples disclosed in the specification /s 10(4)(a)/(b) of the Act.

   5. Details regarding application for Patents which may be filed outside India from time to time for the same or substantially the same invention should be furnished within Six months from the date of filing of the said application under clause(b) of sub section(1) of section 8 and rule 12(1) of Indian Patent Act.

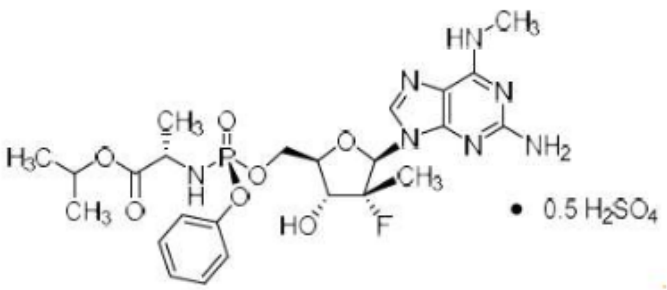
Sufficiency of Disclosure u/s 10 (4)

1. 1. Complete specification shall have a field of the invention, a background of the invention and which technical problem it is facing, how the present invention resolves the problem and a summary of the invention as per section 10(4a) of The Patents Act,1970, hence present invention fails to meet this criterion, therefore it shall attracts section 10(4a) of The Patents Act,1970.

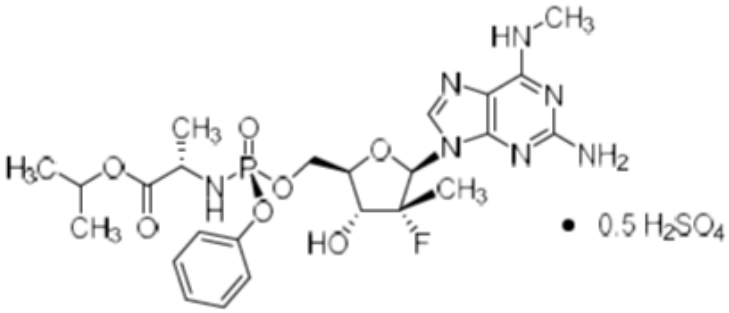
   2. Claims of the instant application are nowhere exemplified in the description in the form of examples, therefore it shall attract section 10(4b) of The Patents Act,1970.

10. After the hearing including hearing the applicant filed written submission to the hearing with amendment to the claims 1-3 which are as follows:

1. A compound of the formula:



2. A pharmaceutical composition comprising from 10 to 1000 mg of a compound of the formula



in a pharmaceutically acceptable carrier.

3. The pharmaceutical composition as claimed in claim 1, wherein the pharmaceutically acceptable carrier is in the form of a tablet.

11. Documents cited in Hearing Notice:

D1: US 2016/0257706 A1; Atea Pharmaceuticals Inc; 08/09/2016(D1: WO2016144918A1; cited by the pre-grant opponent)

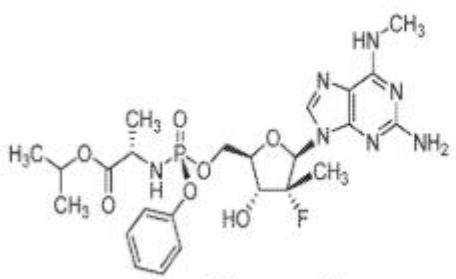
D4: Chang et al.: "Discovery of PSI-353661, a Novel Purine Nucleotide Prodrug for the Treatment of HCV Infection" ACS Med. Chem. Lett. 2011, 2, 2, 130–135

D5: G. Steffen Paulekuhn et al; Trends inActive Pharmaceutical Ingredient Salt Selection based onAnalysis of the Orange Book Database, J. Med. Chem. 2007, 50, 6665–6672)((cited by the opponent as D2)

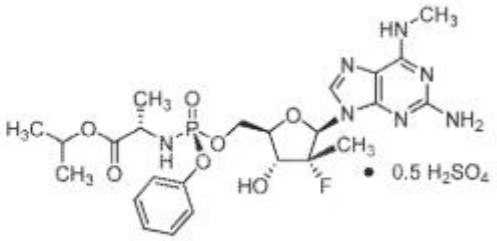
D6: Herve Rebiere et al; Determination of 19 antiretroviral agents in pharmaceuticals or suspected products with two methods using highperformance liquid chromatography; Journal of Chromatography B, 850 (2007) 376–383)(cited by the opponent as D3)

D7: US 2014/0187773((cited by the opponent as D4)

12. After going thoroughly to the complete specification of the impugned application under opposition, it is clear that the application relates to the hemisuifate salt of Compound 1(free base) which is provided below as Compound 2. Compound 2 is referred to as the hemi - sulfate salt of isopropyl((S)-(((2R,3R,4R,5R)-5-(2-amino-6-(methylamino)-9.Hpurin-9-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl)-Z-alaninate and its pharmaceutical composition for the of treatment of a hepatitis C infection.



Compound 1



Compound 2

13. The opponent filed representation with the following grounds of opposition;

(a) Section 25(1)(b): Lack of novelty

(b) Section 25(1)(e): Lack of inventive step

(c) Section 25(1)(f): Invention is not patentable under section 3(d) and 3(e) (d)

Section 25(1)(g): The complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed. **(Dropped by opponent)**

(e) Section 25(1)(h): Failed to disclose to the Controller the information required by section 8. **(Dropped by opponent.**

14. The documents relied upon by the opponent are as follows:

D1- WO2016144918A1 (WO'918) published on 15 September 2016

D2- G. Steffen Paulekuhn et al; Trends in Active Pharmaceutical Ingredient Salt Selection based on Analysis of the Orange Book Database, J. Med. Chem. 2007, 50, 6665–6672

D3- Herve Rebiere et al; Determination of 19 antiretroviral agents in pharmaceuticals or suspected products with two methods using highperformance liquid chromatography; Journal of Chromatography B, 850 (2007) 376–383

D4: US 2014/0187773 (US'773) published on 03 July 2014

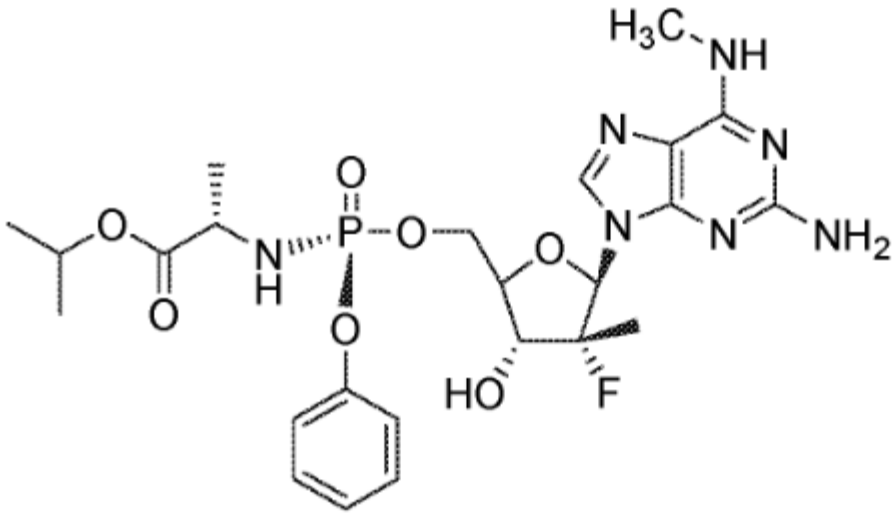
15. **GROUND:NOVELTY ; UNDER SECTION 25(1) (b)**

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. Thus, it is a well settled law in patents that in order to destroy the novelty of an invention each and every particular feature of the invention must be disclosed in a single document.

To prove this ground of opposition (Novelty), opponent relied on the cited document D1: WO 2016144918. D1 discloses the compound of formula 1 (Free base in table 7, compound 5-2 as given below) for the treatment of a host infected with a HCV virus via administration of an effective amount of the compound or its pharmaceutically acceptable salt.



Document **D1 does not disclose the particular hemi-sulfate salt of Compound 1** as D1 teaches a free base form of the compound, but does not teach 0.5 H2SO4 salt, hence the present invention is novel over cited document D1. Therefore Novelty of the invention has been acknowledged Under Section 2 (1)(j) of The Patents Act, 1970.

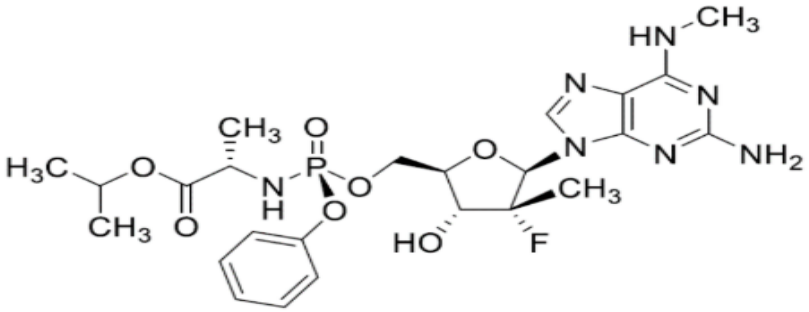
I conclude that such a ground of opposition is not validly established by the Opponent.

16. GROUND: OPPOSTION UNDER SECTION 25(1)(e), Opponent has challenged the impugned application under opposition on the ground i.e. (i) that 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 (under Section 25 (l)(e));

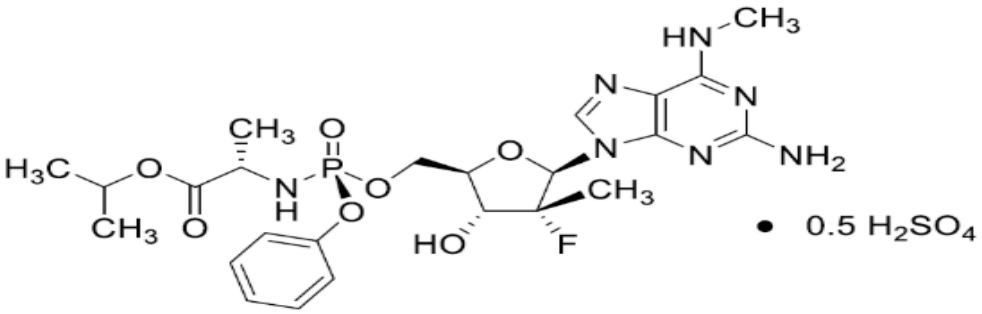
Referring to this ground, opponent cited some documents to establish their claim of lack of inventive step in the invention claimed in the instant application. The documents relied upon by the opponent are as follows:

D1- WO2016144918A1 (WO'918) published on 15 September 2016
D2- G. Steffen Paulekuhn et al; Trends in Active Pharmaceutical Ingredient Salt Selection based on Analysis of the Orange Book Database, J. Med. Chem. 2007, 50, 6665–6672
D3- Herve Rebiere et al; Determination of 19 antiretroviral agents in pharmaceuticals or suspected products with two methods using highperformance liquid chromatography; Journal of Chromatography B, 850 (2007) 376–383
D4: US 2014/0187773 (US'773) published on 03 July 2014

The antiviral prodrug compound is known as AT-511 (Compound 1 of D1) and the salt form of AT-511 which has been claimed in the present application is known as AT-527. AT-527 is the hemi-sulphate salt of AT-511(compound 2). **Compound 2 of the instant Application (compound of Document D1) is referred as Compound 1.** The structures of AT-511 and At-527 are shown below:



AT-511 (also known as Compound 1 in the impugned application and also known as Compound 5-2 in the prior art document WO 2016144918)



AT-527 (also known as Compound 2 in the impugned application)

AT-527 is the hemi-sulfate salt of the prodrug AT-511, this salt form in itself also acts as a prodrug. Thwe claimed compound AT-527 hemi-sulfate salt form of prodrug AT-511 is also a prodrug.

Mandate of law: 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;" [Emphasis Added]

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 fulfillment 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, "person skilled in the art” is a person conversant in researching and developing antiviral drugs or prodrugs used in the treatment of hepatitis C (HCV).**

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

D1 discloses the compound of formula 1 (Free base in table 7, compound 5-2 as given below) for the treatment of a host infected with a HCV virus via administration of an effective amount of the compound or its pharmaceutically acceptable salt.D1 also discloses compound 5-2 (Table 7) .D1 disclsoes that in certain pharmaceutical dosage forms, the prodrug form of the compounds, especially including acylated (acetylated or other), and ether (alkyl and related) derivatives, phosphate esters, thiophosphoramidates, phosphoramidates, and various salt forms of the present compounds, are preferred. One of ordinary skill in the art will recognize how to readily modify the present compounds

to prodrug forms to facilitate delivery of active compounds to a targeted site within the host organism or patient. The routineer also will take advantage of favorable pharmacokinetic parameters of the prodrug forms, where applicable, in delivering the present compounds to a targeted site within the host organism or patient to maximize the intended effect of the compound.D1 discloses examples of pharmaceutically acceptable salts are organic acid addition salts formed with acids, which form a physiological acceptable anion, for example, tosylate, methanesulfonate, acetate, citrate, malonate, tartrate, succinate, benzoate, ascorbate, a-ketoglutarate, and a-glycerophosphate. Suitable inorganic salts may also be formed, including sulfate, nitrate, bicarbonate, and carbonate salts. Pharmaceutically acceptable salts may be obtained using standard procedures well known in the art, for example by reacting a sufficiently basic compound such as an amine with a suitable acid affording a physiologically acceptable anion. Alkali metal (for example, sodium, potassium, or lithium) or alkaline earth metal (for example calcium) salts of carboxylic acids can also be made. D1 also discloses 5-2 show no cytotoxicity against bone marrow stem cells in vitro and no cytotoxicity against iPS cardiomyocytes in vitro.

D2: **G. Steffen Paulekuhn et al** discloses the concepts and importance of salt selection of active pharmaceutical ingredient. Salt formation is a well-known technique to modify and optimize the physical chemical properties of an ionisable research or development compound. Properties such as solubility, dissolution rate, hygroscopicity, stability, impurity profiles, and crystal habit can be influenced by using a variety of pharmaceutically acceptable counter ions. The modification of physical chemical properties, mainly solubility and dissolution rate, may also lead to changes in biological effects such as pharmacodynamics and pharmacokinetics, including bioavailability and toxicity profile. G. Steffen Paulekuhn et al further discloses that there are only two anions with an average incidence of more than 5% over the whole period. These are the chlorides and **sulfates**. The anion encountered with highest frequency after chloride is sulfate. The table 2 in the said document further discloses the distribution of anions used in active pharmaceutical ingredients of category I, where chloride possesses 53.4% and sulphate 7.5%. For oral delivery two most common anions are chloride and **sulphate**.

D3: **Herve Rebiere et al** discloses general list of various antiviral drugs, **the sulfate salt** is one of the common salt for antiviral drugs.

D4 **US'773** disclose the Tenofovir alafenamide hemifumarate which is an antiviral drug which has improved thermal stability as compared with the monofumarate form.

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

The invention lies in the hemisuifate salt of Compound 1, which is provided as Compound 2, exhibits therapeutic properties against hepatitis C **(**HCV), including enhanced bioavailability and target organ

selectivity, over its free base (Compound 1). Compound 2 is referred to as the hemi -sulfate salt of isopropyl((S)-(((2R,3R,4R,5R)-5-(2-amino-6-(methylamino)-9.Hpurin-9-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2- yl)methoxy)(phenoxy)phosphoryl)-Z-alaninate and its pharmaceutical composition for the of treatment of a hepatitis C infection.

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):

D1 discloses examples of pharmaceutically acceptable salts are organic acid addition salts formed with acids, which form a physiological acceptable anion, for example, tosylate, methanesulfonate, acetate, citrate, malonate, tartrate, succinate, benzoate, ascorbate, a-ketoglutarate, and a-glycerophosphate. Suitable inorganic salts may also be formed, including sulfate, nitrate, bicarbonate, and carbonate salts. Pharmaceutically acceptable salts may be obtained using standard procedures well known in the art, for example by reacting a sufficiently basic compound such as an amine with a suitable acid affording a physiologically acceptable anion. Alkali metal (for example, sodium, potassium, or lithium) or alkaline earth metal (for example calcium) salts of carboxylic acids can also be made. D1 also discloses 5-2 show no cytotoxicity against bone marrow stem cells in vitro and no cytotoxicity against iPS cardiomyocytes in vitro. The difference lies in the present invention and D1 is that **D1 does not disclose particular hemi sulfate salt of compound 1**.

D2 is general state of art which provides the concepts and importance of salt selection of active pharmaceutical ingredient. These are the chlorides and **sulfates**. The anion encountered with highest frequency after chloride is sulfate. The table 2 in the said document further discloses the distribution of anions used in active pharmaceutical ingredients of category I, where chloride possesses 53.4% and sulphate 7.5%. For oral delivery two most common anions are chloride and **sulphate**. **D2 does not talk about hemi sulfate salts**.

D3 discloses general list of various antiviral drugs, **the sulfate salt** is one of the common salt for antiviral drugs however D3 also does not discloses the **hemi sulfate salt form** of antiviral drugs.

D4 discloses the Tenofovir alafenamide hemifumarate which is an antiviral drug which has improved thermal stability as compared with the monofumarate form however **D4 does not discloses the semi sulfate form.**

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?

In view of above paragraphs & reply submission filed by applicant's agent as well as by the opponent's submissions it is clear that the invention lies in hemisuifate salt of Compound 1, which is provided as Compound 2, exhibits therapeutic properties against hepatitis C **(**HCV), including enhanced bioavailability and target organ selectivity, over its free base (Compound 1). Compound 2 is referred to as the hemi -sulfate salt of isopropyl((S)-(((2R,3R,4R,5R)-5-(2-amino-6-(methylamino)-9.Hpurin-9-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2- yl)methoxy)(phenoxy)phosphoryl)-Z-alaninate and its pharmaceutical composition for the of treatment of a hepatitis C infection. Application also relates to the compound 2 and a pharmaceutical composition comprising said compound 2.

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;

D1 is considered closest prior art which already discloses the compound of formula 1 (Free base in table 7, compound 5-2 as given below) for the treatment of a host infected with a HCV virus via administration of an effective amount of the compound or its pharmaceutically acceptable salt.D1 also discloses compound 5-2 (Table 7) Likewise, the activity of the parent nucleoside P-D-2'-deoxy-2'-a-fluoro-2'-P-methyl-N^6- dimethyl-2,6-diaminopurine in a replicon assay (EC50 = 10.7 micromolar, "μM") indicates that it is also not suitable for use as a human drug due to insufficient activity, however, the stabilized racemic phosphate prodrug (phosphoramidate) exhibits an EC50 = 12 nM, in a replicon assay, which is more than a 890 fold increase in activity .

D2 is general state of art which provides the concepts and importance of sulfate salt selection of active pharmaceutical ingredient.

D3 discloses the discloses **the sulfate salt** is one of the common salt for antiviral drugs & D4 discloses the hemifumarate form of Tenofovir alafenamide.

It is clear that only Document 1 is discloses the compound of formula 1 and its antiviral activity. None of the documents D1-D4 suggest the hemisulfate form of the compound of formula 1.

Applicant has provided that the Hemi-sulfate salt Compound 2 surprisingly concentrates in the liver over the heart (shown below; refer Example 18 and FIG. 16A on page 74). Therefore, it is a surprising benefit that the hemisulfate salt concentrates in the diseased target organ. Heart and liver tissue levels of the active triphosphate of Compound 2 of the present application were measured 4 hours after oral

doses of Compound 2. Tissue samples were harvested, flash frozen, homogenized and then analyzed by LC-MS. Compound levels were measured in rat, dog and monkey as shown in the figure below. In all animals, the compound 2 concentrates in the liver over the heart;

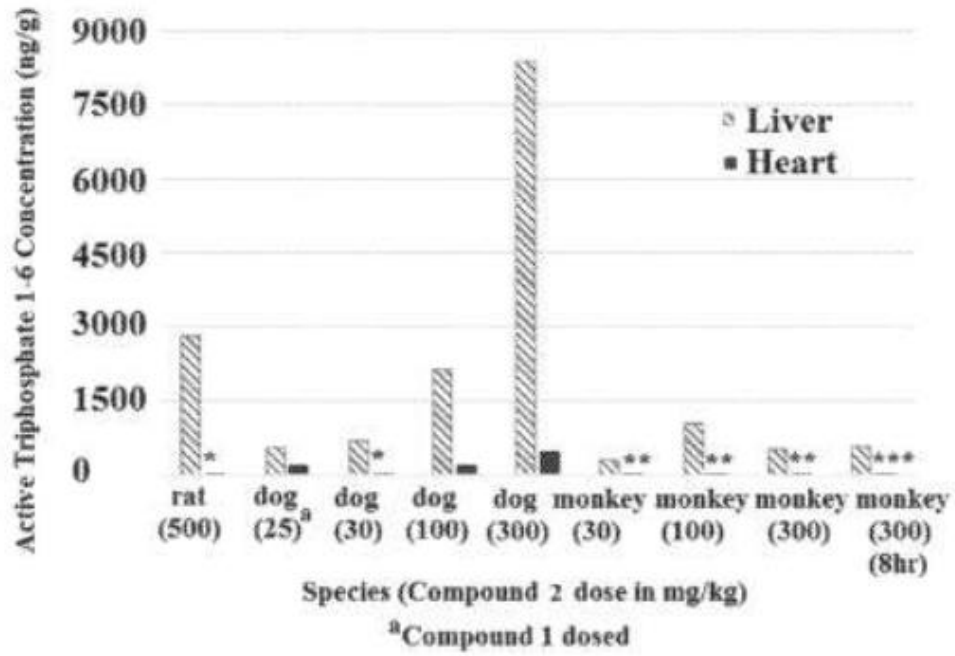


FIG. 16A

This data was measured in the heart and liver of dogs (n=2) taken 4 hours after a single oral dose of Compound 1 or Compound 2 of the present invention. Table 29 of the complete specification is tabulated data from FIG. 16B, which clearly shows that claimed Compound 2 has a surprising 20:1 selectivity for the liver over the heart whereas Compound 1 concentrates only 3.1:1.

Dosed Compound	Mean Dose-normalized AUC(0-4hr) (μM*hr) for:		
	Liver	Heart	Liver/Heart
Compound 2	565	28	20
Compound 1	537	174	3.1

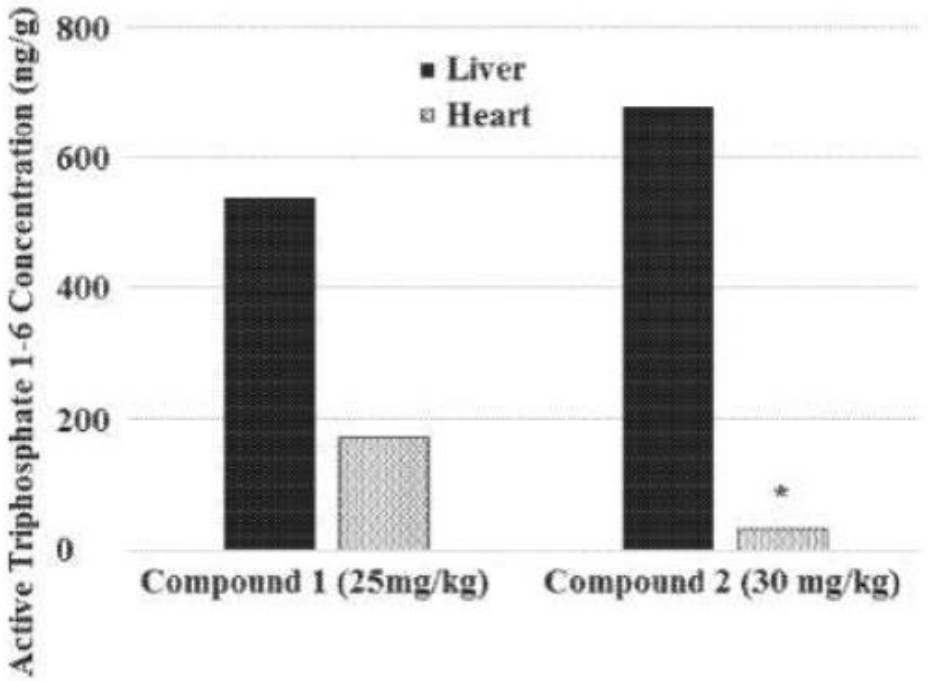


FIG. 16B

Further, applicant has provided that Compound 2 results in over twice the plasma concentration of Metabolite 1-7 than Compound 1 (Table below). This data was measured in a head-to-head comparison study of dogs. The compounds were dosed (Compound 1: 25 mg/kg, Compound 2: 30 mg/kg, results for both compounds normalized to 25 mg/kg).

Dosed Compound	Mean Dose-normalized AUC(0-4hr) (μM*hr) for:		
	Compound 1	Metabolite 1-7	Compound 1+ Metabolites 1-7
Compound 1	0.2	1.9	2.1
Compound 2	1.0	4.1	5.1

The high liver concentration seen when animals are dosed with the hemisulfate salt causes decreased cardiotoxicity and enhanced bioavailability which has shown in above table. Applicant has also compared that the sulfuric acid salt of the claimed compound which was extremely hygroscopic and chemically unstable and the hemi sulfate salt of compound 1 is extremely stable as shown in below table;

	Day 0		Day 7		Day 14	
Salt	**HPLC Purity**	**Observation**	**HPLC Purity**	**Observation**	**HPLC Purity**	**Observation**
Sulfate	98.4	White Solid	55.7	Sticky White Solid	–	Sticky Gum
Hemisulfate	98.7	White Solid	98.1	White Solid	96.4	White Solid

As none of the documents D1-D4 discloses hemisulfate form of the compound 1 and it is non-obvious to a person skilled in the art as the present application shows its technical advancement in terms of physical & chemical stability, purity, enhanced bioavailability, and target liver selectivity over the free base over the free base. Therefore, inventive step can be acknowledged for the amended claims 1-3 under section 2(1)(ja) of the Patents Act.

I conclude that such a ground of opposition is not validly established by the Opponent.

17. GROUND UNDER SECTION 25(1) (f) i.e SECTION 3(d)

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) of the Act**.**

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) 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, and other derivatives of known

substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

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."*

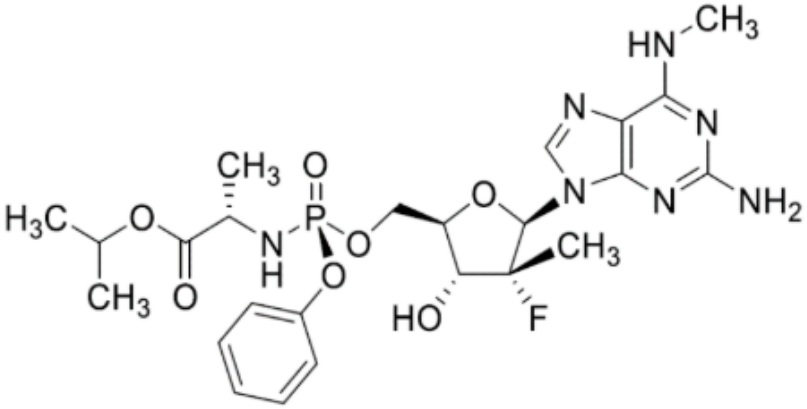
Further, I would like to rely on the judgment by High Court of Delhi *FAO(OS) (COMM) 178/2021 and CM Nos.46299/2021, 46300/2021, 46301/2021, 46302/2021, 19118/2022, 19119/2022 and 30850/2022 in the matter of NATCO PHARMA vs NOVARTIS AG AND ANR*., In this case, the Court observed that;

Section 3(d) of the Act, in effect, sets a supra standard to qualify as an invention. This is in addition to being a new product and involving an inventive step. As held in Novartis v. UOI 1 , Section 3(d) of the Act sets a higher threshold to qualify as an invention in respect of medicinal products and chemical substances. ***In view of Section 3(d) of the Act as amended, the inventive step as defined is, in effect, further narrowed in respect of pharmaceutical products and chemicals. Thus, a pharmaceutical product/chemical may satisfy the criteria involving technical advancement over existing knowledge and not being obvious to a person skilled in the art, and yet be excluded from being considered as an invention if it is a new form (as specified in the Explanation to Section 3(d) of the Act) of a known substance.*** *The said Explanation excludes certain forms of known substance (salts, esters, ethers, polymorphs, metabolites, pure form, particle size, other forms etc.) as expressly set out.* ***The clear objective of specifically excluding such forms of pharmaceutical substances/chemicals is to posit a higher threshold for a claim to be eligible for grant of patent by excluding claims on the basis of known and usual qualities attributed to the specified forms****. However, to retain room for incremental inventions, the Explanation admits exceptions to the given forms if their properties in respect efficacy (therapeutic efficacy in pharmaceutical/chemical products) differ significantly from those of the known substance. In the context of the present case, ELT-O being a pharmaceutical salt of the known substance (ELT) would not qualify as an invention notwithstanding that (i) it may involve technical advancement (as compared to the existing knowledge); (ii) it has economic significance; and (iii) it is not obvious to a person skilled in the art, if its properties are not significantly different in regard to the therapeutic efficacy of the known substance (ELT).*

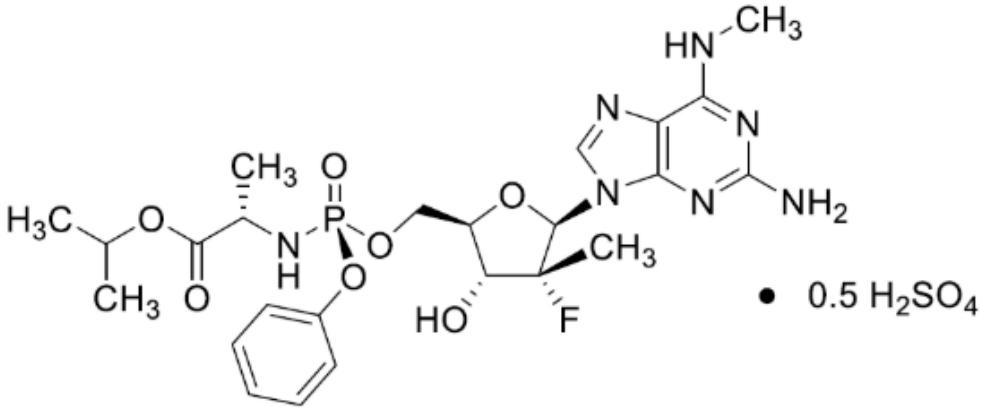
In the present application, the applicant sought protection of hemisuifate salt of Compound 1 i.e compound 2 & its pharmaceutical composition which has better solubility and bioavailability than the base compound i.e. Compound 1 and that the hemi sulphate salt (Compound 2) accumulates more in

the liver and less in the heart because of which it has decreased cardiotoxicity than the base compound i.e. Compound 1.

D1 discloses compound 1 and its pharmaceutical dosage forms. The antiviral prodrug compound is known as AT-511 (Compound 1 of D1) and the salt form of AT-511 which has been claimed in the present application is known as AT-527. AT-527 is the hemi-sulphate salt of AT-511(compound 2). **Compound 2 of the instant Application (compound of Document D1) is referred as Compound 1.** The structures of AT-511 and At-527 are shown below:



AT-511 (also known as Compound 1 in the impugned application and also known as Compound 5-2 in the prior art document WO 2016144918)



AT-527 (also known as Compound 2 in the impugned application)

AT-527 is the hemi-sulfate salt of the prodrug AT-511, this salt form in itself also acts as a prodrug. Thwe claimed compound AT-527 hemi-sulfate salt form of prodrug AT-511 is also a prodrug. Therefore, it is proved from above paragraphs that **compound 1 or prodrug AT-511 or free base is known substance u/s 3(d)** with respect to the present invention.

Example 30 of D1 discloses that the compound 5-2 was tested on cardiac cells and it was found that the compound 5-2 has no cardiotoxicity.

Example 30. iPS Cardiomyocyte Assay

iPS Cardiomyocytes (Cellular Dynamics) were seeded in microliter plates at 1.5 x 10^4 cells per well. After 48-hr incubation, cells were washed and maintenance medium containing serially diluted TA was added in triplicate. After incubating for an additional 3 days, cell viability was measured by staining with XTT and CC_{50} values were calculated.

Compounds 25, 27 and 5-2 show no cytotoxicity against iPS cardiomyocytes in vitro.

Similarly, Example 31 of D1 also discloses that the Compound 5-2 was found to be safe in bone marrow cells as well as it does not inhibit the human DNA polymerase in cells. Tables 4 and 5 of D1 disclose that Compound 5-2 gets accumulated in high amounts in hepatocytes i.e. in liver cells.

D1 also discloses that the amount of compound included within therapeutically active formulations according to the present invention is an effective amount for treating the HCV infection, reducing the likelihood of a HCV infection or the inhibition, reduction, and/or abolition of HCV or its secondary effects, including disease states, conditions, and/or complications which occur secondary to HCV. In general, a therapeutically effective amount of the present compound in pharmaceutical dosage form usually ranges from about 0.001 mg/kg to about 100 mg/kg per day or more, more often, slightly less than about 0.1 mg/kg to more than about 25 mg/kg per day of the patient or considerably more, depending upon the compound used, the condition or infection treated and the route of administration. The active nucleoside compound according to the present invention is often administered in amounts ranging from about 0.1 mg/kg to about 15 mg/kg per day of the patient, depending upon the pharmacokinetics of the agent in the patient. This dosage range generally produces effective blood level concentrations of active compound which may range from about 0.001 to about 100, about 0.05 to about 100 micrograms/cc of blood in the patient.

Applicant's agent provided in the affidavit from Mr. STEVEN S. GOOD which stated that "*Figures 23A-F of the IN'812 specification show human clinical trial data confirming that plasma levels of Metabolite 1-7 above the EC95 result in virologic response, as measured by HCV RNA levels (Example 24). After dosing Compound 2, the plasma levels of Metabolite 1-7 rapidly raise, indicating high levels of the active triphosphate (Metabolite 1-6) is being made in the cells. As the levels of active triphosphate increase, the level of HCV RNA (the metric of virologic response) precipitously decreases. Below I provide an annotated version of FIG. 23A for reference*."

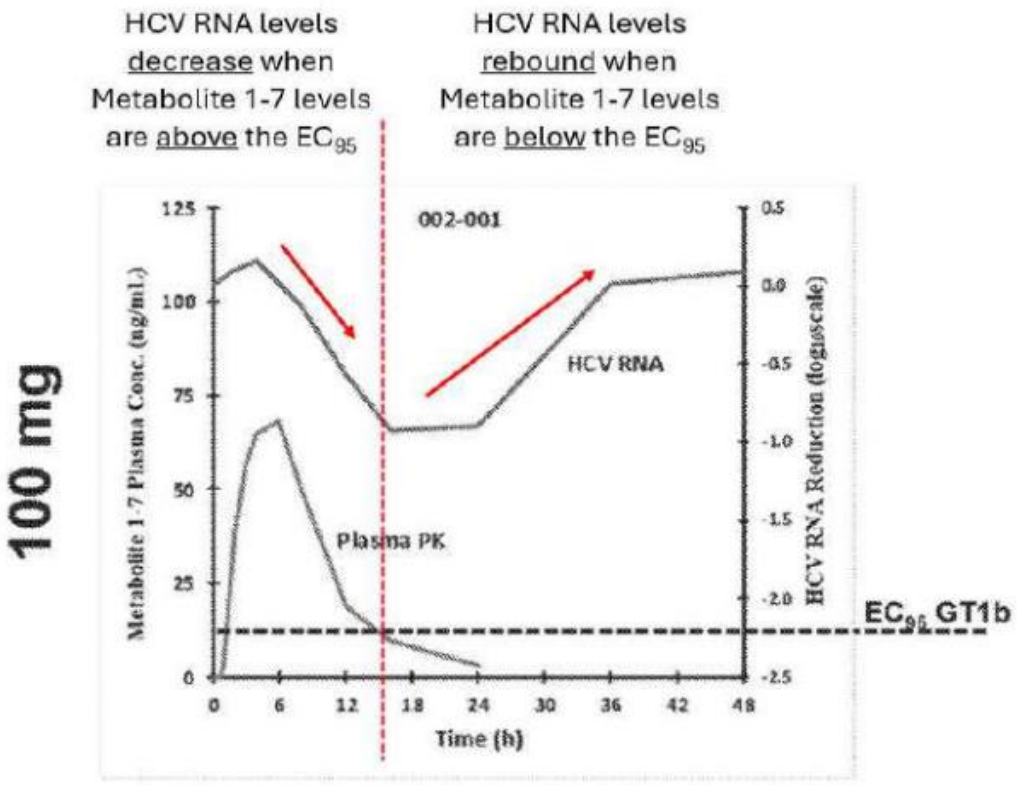


FIG. 23A

Further, affidavit from Mr. STEVEN S. GOOD stated that "*In a head-to-head study in dogs, plasma concentrations of Metabolite 1-7 measured 4 hours post-dose were higher after administration of Compound 2 compared to Compound 1. In dogs, the concentration of Metabolite 1-7 was 3.7-fold higher after administering Compound 2 compared to Compound 1*."

Page 7 line 26-29 of the CS discloses that FIG. 23A-F *(Example 24) provides the Individual pharmacokinetic/pharmacodynamic analyses of patients dosed with Compound 2 showed that* ***the viral response correlated with plasma exposure of metabolite 1-7 of Compound 2*** *(Example 24, FIGS. 23A-23F),* ***indicating that profound vial responses are achievable with robust doses of Compound 2.***

Now I would like drawn my attention on Example 24 of the present application as ;

"measurements *of HCV R A quantitation were performed before, during, and after administration of Compound 2. Plasma HCV RNA determinations were performed through the use of a validated commercial assay. Baseline was defined as the mean of Day -1 and Day 1 (pre-dose).* ***A single 300 mg dose of Compound 2 (equivalent to 270 mg of Compound 1) resulted in significant antiviral activity in GTlb-HCV infected subjects. The mean maximum HCV RNA reduction 24 hours post-dose following a single 300 mg dose was 1.7 logio lU/mL and this compares to a -2 log 10 IU/mL reduction after 1 day of 400 mg of sofosbuvir monotherapy in GTl a HCV-infected subjects****. The*

mean maximum HCV RNA reduction 24 hours post-dose following a single 100 mg dose was 0.8 logio IU/mL. The mean maximum HCV RNA reduction was 2.2 logio IU/mL following a single 400 mg dose. Individual pharmacokinetic/pharmacodynamic analyses for the individual subjects from Part B of the study are shown in FIGS. 23A-23F. Metabolite 1-7 concentration is plotted against HCV RNA reduction concentration, and as shown in FIGS. 23A-23F, plasma HCV RNA reduction correlates with plasma metabolite 1-7 exposure. Viral response is sustained with metabolite 1-7 plasma concentrations that are greater than the EC95 value against GTlb. The correlation between plasma concentration and HCV RNA reduction levels indicates that a more profound response will be achievable with higher doses of Compound 2"

Further**, I focus on the [page 8, para 2] of the complete specification which state that ;**

FIG. 24 and Example 25 highlight the striking invention provided by Compound 2 for the treatment of hepatitis C. As shown in FIG. 24, the steady-state trough plasma levels (C_{24},ss) of metabolite 1-7 following Compound 2 dosing in humans (600 mg QD (550 mg free base equivalent) and 450 mg QD (400 mg free base equivalent)) was predicted and compared to the EC95 of Compound 1 in vitro across a range of HCV clinical isolates to determine if the steady state plasma concentration is consistently higher than the EC95, which would result in high efficacy against multiple clinical isolates in vivo. ***The EC95 for Compound 1 is the same as the EC95 of Compound 2.*** *For Compound 2 to be effective, the steady-state trough plasma level of metabolite 1-7 should exceed the EC95.*

The data comparing the efficacy and pharmacokinetic steady state parameters in FIG. 24 clearly demonstrates the unexpected therapeutic importance of Compound 2 for the treatment of hepatitis C. In fact, the predicted steady-state (C : : ..} plasma level after administration of Compound 2 is predicted to be at least 2-fold higher than the EC95 for all genotypes tested, and is 3- to 5-fold more potent against GT2. This data indicates that Compound 2 has potent pan- genotypic antiviral activity in humans. As shown in FIG. 24, the EC95 of sofosbuvir against GT I, GT3, and GT4 is greater than 100 ng/mL. Thus ***surprisingly, Compound 2 is active against HCV at a dosage form that delivers a lower steady-state trough concentration (40-50 ng mL) than the steady-state tough concentration (approximately 100 ng/mL) achieved by the equivalent dosage form of sofosbuvir.***

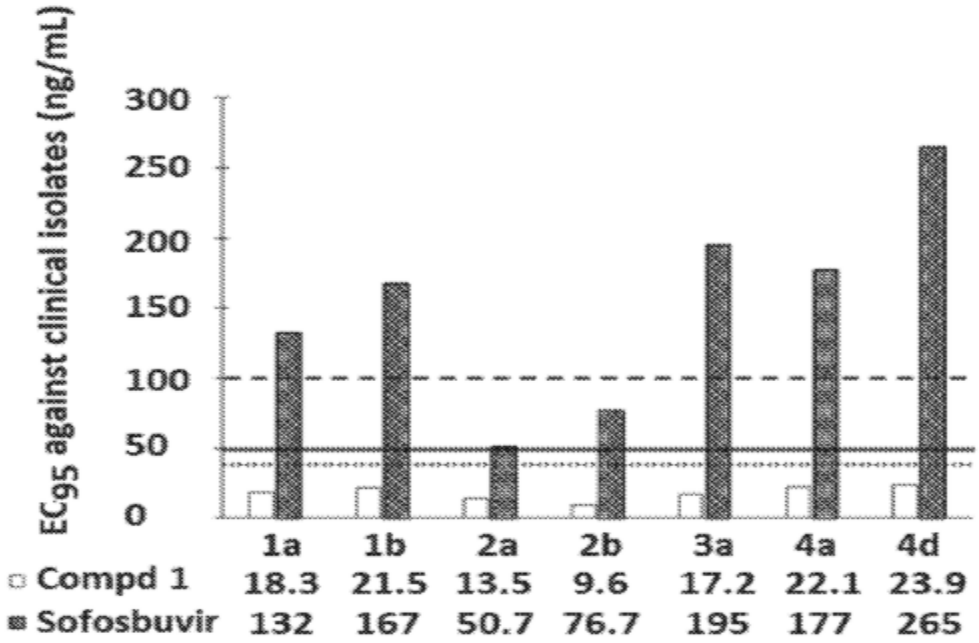


FIG. 24

In example 22 of the complete specification discloses the EC50 values for Compound 1 were 6-11 times lower than sofosbuvir against laboratory strains of HCV Genotypes 1-5 (FIG. 19).

Further table 33 of the CS provides dose escalation up to 600 mg in HCV-infected patient as given below;

Table 33. Dosing Regimen for Compound 2 in Part B of Study

Cohort	Population	N (active)	Compound 2 (Compound 1)*
1b	GT1 HCV-Infected	3	100 (90) mg x 1 day
2b	GT1 HCV-Infected	3	300 (270) mg x 1 day
3b	GT1 HCV-Infected	3	400 (360) mg x 1 day
4b	GT1 HCV-Infected	3	600 (540) mg x 1 day

*Clinical doses are expressed in terms of Compound **2**, with the approximate Compound 1 base equivalent in parenthesis.

Patients infected with HCV were treatment-naive, non-cirrhotic GT1-infected subjects with a viral load of ≥ 5 $\log_{10}$ IU/mL.

After a meticulous examination of the present application, it is observed that Fig 24 provide comparative evidence related to the **EC95 of sofosbuvir** against GTI, GT3, and GT4 is greater than 100 ng/mL**. Compound 2(compound 1 is mentioned in Fig 24) is active against HCV at a dosage form that delivers a lower steady-state trough concentration (40-50 ng mL) than the steady-state tough concentration (approximately 100 ng/mL) achieved by the equivalent dosage form of sofosbuvir. It is crucial to note that compound 1 is the known substance in connection with the**

present invention and sofosbuvir is not a relevant or known substance in connection with the compound 2.

Further, the FIG. 23A-F (Example 24) provides that **a single 300 mg dose of Compound 2 (equivalent to 270 mg of Compound 1)** resulted in significant antiviral activity in GTlb-HCV infected subjects. The mean maximum HCV RNA reduction 24 hours post-dose following a single 300 mg dose was 1.7 logio lU/mL and this compares to a -2 log 10 IU/mL reduction after 1 day of 400 mg of sofosbuvir monotherapy in GTl a HCV-infected subjects.

The above paragraph and data provided in the complete specification clearly indicate that the EC95 of Compound 1 is the same as the EC95 of Compound 2, reflecting that the efficacy of Compound 1 is the same as that of Compound 2**. All results provided in example 24 & Figure 24 of the complete specification relates to Compound 1 or 2 (same) which is compared with sofosbuvir.** HCV RNA reduction by the **single 300 mg dose of** Compound 2 (**equivalent to 270 mg of Compound 1**) were also **compared with sofosbuvir only**. **Therefore, the applicant has admitted in the complete specification that the EC95 of Compound 1 is the same as the EC95 of Compound 2 or** HCV RNA reduction by the dose of compound 1 and 2 are same, **indicating that there is no improved efficacy of Compound 2 over Compound 1.**

The AT-527 is the hemi-sulfate salt of the prodrug AT-511 to be patentable should be showing enhanced efficacy and that to unexpected enhanced therapeutic efficacy for treatment of treating HCV. The comparative data, which has been placed on record, relates to enhanced physical & chemical stability, enhanced bioavailability and target liver selectivity over the free base over the free base which facilitates the accumulation of the compound to the liver over the heart which would eliminate the side effects can't be correlated with the enhanced therapeutic effect unless data relating to the improved efficacy of AT-527 which is the hemi-sulfate salt of the prodrug AT-511. Physical & chemical stability, enhanced bioavailability and target liver selectivity aspect does not lead to establishment of any therapeutic efficacy. It is argued by applicant's agent that reduced toxicity and target liver selectivity should also be taken into consideration to judge enhanced therapeutic efficacy of a claimed hemi sulphate form of compound 1 in terms of section 3(d). **However, enhanced bioavailability, target liver selectivity and plasma concentrations of Metabolite 1-7 measured 4 hours post-dose were higher after administration of Compound 2 compared to Compound 1 as submitted by the applicant indicate the fraction extent to which a dose of drug reaches its site of action or liver or a biological fluid from which the drug has access to its site of action or the degree to which a drug or other substance becomes available to the target tissue after administration. A demonstration of increase in bioavailability or plasma concentrations is not a demonstration of improved or enhanced efficacy unless results** relating to the improved efficacy of AT-527 which is the hemi-sulfate salt of the prodrug AT-511 is **provided. It is proved from the above analysis that EC95 of Compound 1 is the same as the EC95 of Compound 2, indicating**

that there is no improved efficacy of Compound 2 over Compound 1.There is no direct comparative data provided with respect to the EC95 of Compound 2 with compound 1. In the absence of any such credible evidence regarding enhanced therapeutic effect of the claimed compound 2 or hemi-sulfate salt of the prodrug AT-511 or AT-527 is considered salt form or hemi sulfate form of known compound 1 or prodrug AT-511. Therefore, the claimed compound 2 or hemi-sulfate salt of the prodrug AT-511 or AT-527 claimed in claim 1(as objected in hearing notice) or amended claims 1-3 i.e compound 2 or hemi-sulfate salt of the prodrug AT-511 or AT-527 & its pharmaceutical composition (as objected by the opponent) are 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), no valid merit was provided by the opponent & hemi-sulfate salt of the prodrug AT-511 or AT-527 or API is claimed so, as per my opinion 3(e) is not applicable.

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

18. After considering hearing submissions, other formal and technical objections u/s 10 (4) ((in view of deletion of claims) raised in hearing notice are met.

19. The instant application does not meet the requirement of sections 3(d) 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 No. 201917029812 entitled "NUCLEOTIDE HEMI-SULFATE SALT FOR THE TREATMENT OF HEPATITIS C VIRUS" has been refused to proceed further under section 15 of the Act and simultaneously, I dispose of the pre-grant opposition as per the provision under Section 25(1) of the Act and corresponding Rules made thereunder.

Dated: 03/06/2024

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