BEFORE THE CONTROLLER OF PATENTS
THE PATENT OFFICE, DELHI

THE PATENTS ACT, 1970
The Patents Rules, 2003

(SECTION 25(1) and RULE 55)

In the matter of the Patent Application
No.963/DEL/2002 filed on 24th Sept, 2002

And

In the matter of opposition under section
25(1) to the grant of patent thereto by
Intermed Labs Pvt. Ltd,
77 KIADB Industrial Area, Jigani,
Bangalore, Karnataka (India).

GILEAD SECIENCE INC. USA..........................The Applicant

INTERMED LABS PVT. LTD. INDIA.......................The Opponent

Presents in the hearing:

Mr. G. Nataraj Agents for the Applicant
Mr. S. Majumdar Agent for the opponent
Dr. Rachna Nandwani Examiner of Patents and Designs

DECISION

Facts of the case:

1. M/S Gilead Science, Inc. a US company through their agent M/S
Remfry & Sagar filed an application for the grant of patent No
963/Del/2002 on 24th September 2002 for their invention entitled "Nucleotide Analogs Composition and method for the preparation thereof."

This application was filed as divisional application to the main application No.2174/Del/98 dated 24th July 98 which was claiming a priority date of 25th July 1997 on the basis of US parent applications No. 08/900752 and 60/053777. The main patent application (parent application) at the time of filing claimed a composition of formula as given below

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\begin{align*}
\text{B} & \text{ is adenine-9-yl and R independently is } \text{H or } \text{CH}_2\text{O-C(O)-O-CH(CH}_3)_2, \text{ but at least one R is } \text{CH}_2\text{O-C-(O)-O-CH(CH}_3)_2 \text{ including other dependent claims and method claims. The parent application was accepted on 30th September, 2002 and patent was granted to a process for preparation of fumarate salt of 9-[2-(R) \text{[[isopropoxycarbonyl]oxy]methoxy}\text{phosphinoyl}][\text{methoxy}]\text{propyl}][\text{adenine} \text{comprising reacting fumaric acid with 9-[2-(R)-[[isopropoxycarbonyl]oxy]methoxy]phosphinoyl]methoxy][\text{propyl}][\text{adenine} \text{optionally in the presence of a solvent of the kind such as herein described, wherein fumaric acid and 9-[2-(R)-[[isopropoxycarbonyl]oxy]methoxy]phosphinoyl]methoxy][\text{propyl}][\text{adenine}, \text{are preferably taken in molar ratio of 0.6:1 to 1.4:1.}}
\end{align*}
\]

2. This application was examined and First Examination Report (FER) was issued on 23rd January 2003. The applicants were required to put the application in order for acceptance within a period of 15 months i.e. by 23rd April 2004 which was further extendable for another 3 months under the provisions of law existing at that time. Since the applicants applied for extension of time for 3 months vide their request made on 26th March.
2004, the extension was allowed and accordingly the final date to put the application in order for acceptance was 23rd July 2004. The applicants resubmitted the documents along with their reply on 12th July 2004 and after further examination, the said application was put in order for acceptance on 23rd July 2004. M/S Subramanian, Nataraj & Associates replaced Remfry & Sagar as the applicant’s agent on 11th October 2004. However due to some administrative reasons the application could not proceed to grant of patent. The divisional application as originally filed contained same 29 claims as of main application including a claim for a composition of formula as given below

Wherein B is adenine-9-yl and R independently is –H or –CH₂-O-C(O)-O-CH(CH₃)₂, but at least one R is –CH₂-O-C-(O)-O-CH(CH₃)₂ and (2) the method of claim 12 wherein the lithium alkoxide is an alkoxide selected from the group consisting of methoxide, ethoxide, n-propoxide, i-propoxide, n-butoxide, i-butoxide, t-butoxide, neopentoxide, n-pentoxy, i-pentoxy or n-hexoxide, n-heptoxide, 2-heptoxide, n-octoxide, 2-octoxide, typically t-butoxide or i-propoxide. In addition to above, it also claimed various claims inter-alia for method comprising orally administering to a patient infected with virus or at risk to viral infection a therapeutically effective amount of composition of claim 1, a method comprising adjusting the pH of a solution, a method comprising mixing lithium alkoxide with a 9-(2-hydroxy propyl) adenine solution, a product produced by the process of preparing wet granules, a process for the preparation of fumarate salt of 9-[2-(R) [[bis[((isopropoxycarbonyl)oxy]
methoxy|phosphinoyl|methoxy|propyl|adenine etc. However the applicants during the examination finally amended and restricted their claim to following claims;

(1) A method of making lithium salt of (R)-9-(2-hydroxypropyl) adenine comprising the steps of mixing a lithium alkoxide of the kind such as herein described with (R)-9-(2-hydroxypropyl adenine.

(2) The method of claim 1 wherein the lithium alkoxide is an alkoxide selected from the group consisting of methoxide, ethoxide, n-propoxide, i-propoxide, n-butoxide, i-butoxide, neopentoxide, n-pentoxide, i-pentoxide, i-pentoxide or n-hexoxide, n-heptoxide, 2-heptoxide, n-octoxide, 2-octoxide, typically t-butoxide or i-propoxide.

(3) A method as claimed in claim 2, wherein the lithium alkoxide is lithium t-butoxide or lithium i-propoxide.

(4) A method for making a lithium salt of (R)-9-(2-hydroxypropyl adenine substantially as herein described with reference to the foregoing examples and the accompanying drawings.

3. M/S Intermed Labs Pvt. Ltd, an Indian company (herein after referred as opponent) filed the representation on 20.4.2007 to oppose the grant of patent u/s 25(1) on the grounds as mentioned in clause (b) to (h) of sub-section (1) of section 25 of the Patents Act 1970. This representation said to have been filed along with the evidence of Mr.Kankan Rajendra R. in support of representation on behalf of the opponent.

4. The applicant filed reply statement on 3rd August 2007 which has been supported by the evidence of Dr.Sundaramoorthi Swaminathan filed on 7th and 13th August 2007 on behalf of the applicant. Accordingly hearing was fixed on 10th OCTOBER 2008, which was attended by both parties along with their representatives. After hearing the opponents also submitted their written arguments vide their letter dated 11th February
Submissions/arguments of the opponents

5. The opponents, as prior art, have relied upon the documents namely US Patent No. 5476983 published on December 19, 1995 marked as Exhibit-1, US Patent No. 4808716 issued on February 28, 1989 marked as Exhibit-2 and US Patent No. 4003878 issued on January 18, 1977 marked as Exhibit-3 respectively. In their statement, the opponents have stated that the invention claimed in the impugned application is unpatentable on the ground of prior publication as disclosed in US Patent No. 5476938 (Exhibit-1) which is related to “Process for the preparation of nucleotides” filed on January 21, 1992 and published on December 19, 1995 but a continuation of US Application No. 566.200 dated August 10, 1990 which was abandoned. This document teaches a novel and economical process for the synthesis of hydroxyphosphonomethoxypropyl (HPMP)-substituted nucleotide antiviral compounds.

According to the opponents, as per the amended claims the alleged essential features of the invention lie in the method of making the lithium salt of (R)-9-(2-hydroxypropyl) adenine by mixing it with lithium alkoxide. However, the said essential features have been taught in the prior art as disclosed in Exhibit-1, particularly in lines 18-20, column 3, which are reproduced below:

“Purine or pyrimidine base” includes, but is not limited to adenine, guanine, thymine, uracil, cytosine…….” It is further stated in the statement that Exhibit 1 shows similar reaction of hydroxyalkylated purine or pyrimidine base (including adenine) with metal alkoxide e.g. potassium tert-butoxide, sodium methoxide and the like of the applicant’s alleged claims, particularly in lines 36-45, column which are reproduced below:
“In Scheme I, the first step involves the preparation of a compound of formula (IIIb). A purine or a pyrimidine base B, is first treated with a base in order to generate the corresponding anion. The base is not particularly restricted and may be selected from metal hydrides such as sodium and potassium hydrides, metal carbonates such as sodium and potassium carbonates, and metal alkoxides such as potassium t-butoxide, preferably the base is used in a catalytic amount.” It further states that the second step of the process involves the introduction of the methanephosphonate moiety to the secondary hydroxy group of a compound of formula (IIIb). Therefore according to the opponent, any person skilled in the relevant art after reading Exhibit-1 can reproduce the alleged invention using lithium alkoxide as metal alkoxide, which may lead to in-situ lithium salt formation. It is further stated that sodium, potassium and lithium are the members of group I of the periodic table also known as alkali metals. They can form strong bases capable of neutralizing acids as the number of electrons in their outer shell is one and therefore, they are ready to lose that one electron in ionic bonding with other elements. According to the opponents, lines 40 – 45, Column 4 of Exhibit-1 teach the examples of various metal alkoxide which can be used in the abovementioned reaction. The said lines are reproduced below:

Thus, a compound of formula (IIIb) is first treated with a base to generate the corresponding alkoxide anion. The base may be a metal hydride, for example sodium hydride, potassium hydride or lithium hydride; and metal alkoxide, for example, potassium t-butoxide or sodium methoxide and the like. The reaction mixture containing the alkoxide anion is then treated with the methanephosphonate \( \text{LCH}_2\text{P(O)(OR}_2\text{)}_2 \) (IV) wherein \( L \), is a leaving group and \( R^2 \) is an alkyl group containing 1-5 carbon atoms as previously defined to provide the protected HPMP nucleoside of formula (V). \( L \), is preferably selected from the group
consisting of p-toluenesulfonate (tosylate), methanesulfonate (mesylate), and trifluoromethanesulfonate (triflate); and \( R^2 \) is preferably an alkyl group having from 1-3 carbon atoms, e.g., methyl, ethyl, n-propyl, and isopropyl.

Therefore, according to the opponent the reaction of hydroxyalkylated purine or pyrimidine base (including adenine) with a metal alkoxide is known reaction and a person skilled in the art is aware that the reaction of a metal alkoxide with a purine base yields the metal salt of the purine base. If such a person skilled in art provided with the Exhibit-1 can easily make the lithium salt of hydroxypropyl adenine by the process claimed in the alleged invention. Hence, it does not involve any inventive step. Thus, the claims of impugned application are bad in law and should be rejected.

6. The opponents further stated that US Patent No.4808716 (Exhibit-2) entitled as “9-(phosphonytmethoxyalkyl) adenines, the method of preparation and utilization thereof” filed on April 25, 1985 and granted patent on February 28, 1989 clearly teaches preparation of alkali metal salts of 9-(phosphonytmethoxyalkyl adenines. To name a few, it specifically teaches the preparation of lithium salt of 9-(2-benzyloxy-3-phosphonylmethoxypropyl) adenine, 9-(3-phosphonytmethoxy-2-tetrahydro pyranyloxypropyl)adenine, 9-(3-phosphonytmethoxy-2-(1-ethoxyethyl) oxypropyl_ adenine and the like in particular the lines 54-55, Column 3 which specifically teaches the lithium salts as one of the alkali metal salts to have advantages over other. The said lines are reproduced below:

“The advantage of the last-mentioned salts (sodium and lithium salts) is their good solubility in water.”

The opponent further stated the applicant in its impugned specification had earlier claimed inter alia a composition of PMPA, a
composition comprising lithium alkoxide and 9-(2-hydroxypropyl) adenine and later amended and restricted to method of preparation of lithium salt of 9-(2-hydroxypropyl) adenine. Thus, if the lithium salt of PMPA is taught in Exhibit-2, then any person skilled in the field of chemistry would be motivated to prepare the lithium salts of the intermediate used in the preparation of final product i.e. PMPA whose lithium salt is taught in prior art (Exhibit-2). It is therefore obvious for a skilled person to try the salts of the intermediate when looking for alternative processes to the compounds known from the disclosure of prior art. In other words, it is obvious to a person skilled in the relevant art that lithium salt of the dephosphorylated analogs of PMPA can be prepared. Therefore, the essential feature alleged by the applicant of the method of preparation of lithium salts of 9-(2-hydroxypropyl) adenine of the alleged invention which is a conventional method of salt formation does not involve any technical advance as compared to existing knowledge thereby making the invention obvious to a person skilled in art. Therefore, lithium salt of (R)-9-(2-hydroxypropyl) adenine, which is the product of the process claimed by the applicant in its impugned specification is obvious in view of the prior art. Hence, it is stated that the claims amended by the applicant do not involve any inventive step and thus said claims are bad in law and should be rejected.

7. The opponent further stated that US Patent No.4003979 (Exhibit-3) entitled as “Method of preparing an alkali-metal salt of an alkoxysolfonated benzoic acid glycol ester” filed on March 26, 1973 and granted patent on January 18, 1977 teaches similar method of forming alkali metal salt using metal alkoxide as that of the applicant’s alleged claims where the reaction of the hydroxy group with alkali metal alkoxide
to form the corresponding alkali metal salt is disclosed particularly in lines 51-53, Column 1. The said lines are reproduced below:

“the alkali-metal alkoxides are the sodium potassium and lithium methoxides ethoxides, propoxide and butoxides.”

The opponents stated that the amended claims of impugned specification also claim lithium alkoxides selected from the group consisting of methoxide, ethoxide, n-propoxide, i-propoxide, n-butoxide, i-butoxide, neopentoxide, n-pentoxide or i-pentoxide or n-hexoxide, n-heptoxide, 2-heptoxide, n-octoxide, 2-octoxide typically t-butoxide or i-propoxide. Therefore, the process for the preparation of lithium salt of (R)-9-(2-hydroxypropyl) adenine, as alleged by the applicant in its specification is a known process of salt formation and does not involve any inventive step.

Accordingly, the claims of impugned application are bad in law and should be rejected being devoid of an inventive step having regard to the aforesaid publications viz. Exhibit 1 to Exhibit 3 which clearly indicates and makes it obvious to any person skilled in the art to arrive at the claimed method of preparation of lithium salt of (R)-9-(2-hydroxypropyl) adenine using lithium alkoxide and this knowledge is available in the prior art on the date of the application under opposition.

8. The opponent further stated that the cited documents viz. Exhibit 1 to Exhibit-3 have been in public domain much prior to the date of the application under opposition and therefore forms the subject matter of prior public knowledge. The opponent states that the process of the alleged invention has been used in India and elsewhere and therefore the ground of prior public use/prior public knowledge is established beyond doubt.
9. The opponent further stated that the claimed falls under the mischief of Section 2(1)(ja) being devoid of inventive step as according to definition of inventive step, the invention should be an a technical advancement over the prior art or it should show economical significance or both and should not be obvious to a person skilled in the art. The Opponent state that Applicant’s invention is neither a technical advancement nor it is giving any economic significance.

10. The opponent further stated that the claimed invention falls under the mischief of Section 2(1)(l) being devoid of new invention as according to the definition “new invention” means 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 states of art. Opponent stated that the invention claimed by the applicant is not a new invention as it is anticipated by the Exhibit 1 to 3.

11. The opponent further stated that the claimed invention is not patentable as it falls within the mischief of Section 3(d) of the Indian Patent Act as mere use of a known process to form a salt by using a metal alkoxide giving a salt of a known intermediate is not patentable. The process also has not resulted in any new product but just a salt of the well-known intermediate. The opposed application is liable to be refused under this ground alone. The section 3(d) is stated below:

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 opponents unless such known process results in a new product or employes 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, combination and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The opponent further stated that the Manual of Indian Patent Act further states that "Mere use of a known process is not patentable unless such known process results in a new product or employes at least one new reactant." The opponent further stated that it was held by the Courts to be obvious to merely use an old process for even a new but analogous purpose.

12. The opponent further stated that the complete specification of the alleged invention does not sufficiently and clearly describe the invention or the method by which it is to be performed. It was further that the alleged invention claimed by the applicant in the opposed application is insufficient at least because of the following reasons:

(a) The text of the opposed application does not teach or illustrate the product of the process of the alleged invention throughout the specification.

(b) The text of the opposed application does not even disclose the characteristics of the product of the process purported to be their alleged invention.

(c) The claimed invention does not even disclose the isolation and purity of the product obtained by their process.
The opposed application is therefore liable to be rejected on the ground of insufficiency.

13. The opponents further stated that the applicants were required to provide all the information regarding the prosecution of their equivalent applications till the grant of patent to Indian application to the Controller in writing from time to time and also within the prescribed time under section 8 of the Act, which the applicant have failed to do. Thus the opponent demands rejection of the application on this ground also.

**Submissions/arguments of the applicants:**

14. While replying to the representation filed by the opponents, the applicants stated that the representation is frivolous and vexatious and has no merit. The applicants further stated that the representation has been filed for the sole purpose of delaying grant of patent on their application. It was further submitted that the opposition is based on grounds which are not available to the Representers under section 25(1) of the Patents Act, 1970 and therefore is liable to be dismissed in toto on the following grounds

(a) The Representers have not demonstrated any real or substantial interest, whether manufacturing/trading/research, in the area of technology in question with any supporting evidence. There is no evidence on record on the Representers having ever made or sold or done any research in the field of nucleotide analogs.

(b) The Representers have made collusive action with CIPLA Ltd. of Mumbai, India with sole intention to delay grant of patent. This is a substantive abuse/misuse of the Patents Act, 1970. The evidence of such collusion is clearly established by the facts of the so called ‘expert evidence’ submitted by the opponents of the same person
who submitted the evidence on behalf of CIPLA Limited who is also an employee of CIPLA Ltd as can be seen from paragraph 1.4 of his evidence which clearly stated that “I am informed that the opponent has again opposed the amended application” (emphasis added). He admitted on oath that his evidence is based on his personal knowledge that the “opponent has again opposed the amended application”. This shows that the present Representation is at the instigation of CIPLA Ltd. who realizing that their chances of success are weak, if not non-existent on the two separate Representations that they have already initiated under section 25(1). The evidence of the collusion between CIPLA Ltd. and Intermed Labs is also evident by the fact that the cause title of the expert evidence clearly states that the evidence is on behalf of CIPLA Ltd. although he has made the evidence on behalf of Intermed Labs. Such a collusive act is a clear violation of the spirit and scope of the Patents Act and gross contempt of the Hon’ble Tribunal and therefore liable to pay punitive cost due to their attempts to defraud the patent office and abuse of the procedure under the law.

(c) The opponents are estopped from opposing the claims on the file on the ground of specific self-admitted disclaimer of action in view of the collusive nature of the opposition. It was submitted that CIPLA Ltd has already in its two earlier representations stated that their representation was directed only to the product claims as well as claims relating to process for preparation of fumarate salt on this application and they were unaware that the claims allowed on this application actually related to a process for preparation of lithium salt. Thus, it is a clear disclaimer of any right of action against any of the claims that have been allowed. The claims
allowed on this application are all method claims for preparation of lithium salt. This representation comprises an afterthought or rearguard action by CIPLA Ltd. through its intermediary Intermed Labs Pvt. Ltd. to ensure delay in grant of patent, and in view of the fact that their earlier representations are rendered infructuous due to their own statements. Therefore the opponents are now estopped from extending any intent to oppose to any of the claims allowed on this application.

15. The applicants have stated in the reply statement that although the opponents have listed in the representation the grounds mentioned in clause (b) to (h) of section 25(1) namely, (a) prior publication, (b) prior claiming, (c) prior public knowledge/use in India, (d) lack of inventive step, (e) absence of invention, (f) insufficient description and (g) non compliance with section 8, the written representation relied only on the grounds of (a) lack of inventive step (b) prior public knowledge/use in India, (c) absence of invention (d) insufficient description and (e) non compliance with section 8 and therefore have voluntarily withdrawn the grounds namely (a) wrongful obtaining, (b) prior publication and (c) prior claiming. Therefore the above-mentioned non-contested grounds may be treated, as withdrawn and implicit admission on the part of the opponents is that the invention as claimed in the instant application is novel.

16. The applicants have denied all the contents of the written statement and stated that US Patent 5,476,938 is immaterial and irrelevant to the invention covered by the claims allowed on the present application. It was stated that Exhibit-1 of the Representers does not teach specifically, or guide towards the use of lithium alkoxides to obtain a lithium salt of
(R)-9-(2-hydroxypropyl) adenine. It is not denied that the term ‘purine or pyrimidine bases’ would include within itself adenine. In fact, Exhibit-1 does not teach reaction of hydroxyalkylated purine or pyrimidine base with metal alkoxides but the preparation of HPMP type nucleoside analogues involving, inter alia the treatment of a purine or pyrimidine base with a metal alkoxide selected from sodium or potassium alkoxides to obtain the corresponding anion. However, the role played by the metal alkoxide is that of a catalyst in formation of an anion and not as a reactant to form a salt.

Further, in the prior art disclosed in the Exhibit -1, the starting material is a purine or pyrimidine base and not (R)-9-(2-hydroxypropyl) adenine. There is no teaching/guidance that (R)-9-(2-hydroxypropyl) adenine is considered equivalent to phosphonomethoxy nucleoside analogues or to their precursor purine or pyrimidine bases disclosed therein. The anion obtained as disclosed in Exhibit-1 is reacted with glycidol to generate 2, 3-dihydroxynucleoside, followed by introduction of methanephosphonate moiety. This is in direct contrast to the process of the instant invention, which comprises reacting a lithium alkoxide with (R) -9-(2-hydroxypropyl) adenine to obtain a lithium salt thereof. In Exhibit – 1, even where the glycidol reactant comprises a primary alcohol protected glycidol, the compound of formula IIIb obtained is not reacted with the base as alleged. It is only treated with the base.

It was further stated that a clear reading of Column 4 of the Exhibit-1 (comprising the portion relied on by the Representers) makes it clear that if the metal used is lithium, only lithium hydride base can be used. In the case of alkoxides, only sodium and potassium are used. Thus, it is clear that while sodium, potassium and lithium may all belong to one Group in the Periodic Table, they are not equivalents in terms of their activity in reactions involving nucleoside analogues. Therefore it
would be incorrect to equate lithium alkoxide being used for salt formation with (R)-9-(2-hydroxypropyl) adenine with sodium or potassium alkoxides, which are being used as bases and function as catalysts in the prior art. It was further stated that the entire Representation only reveals the gross ignorance of both law and chemistry on the part of the Representers as it comprises a selective and out of context reading of the Exhibit. The instant invention avoids the problem of use of NaH (which results in the formation of a product with an improved byproduct profile. The cited document further teaches the hydride-based treatment prior to reaction with glycidol and therefore, the instant application is inventive over Exhibit-1.

17. The applicants have further stated that Exhibit-2 (US Patent 4,808,716) teaches a method for preparing compounds of a given general formula I [(9-(phosphonylmethoxyalkyl) adenines] wherein compounds of formula II [9 hydroxyalkyladenines] are reacted with sodium hydride whereas the instant invention relates to a method for making a lithium salt of 9-(2-hydroxypropyl) adenine. The applicant submitted that compounds of formula II of the citation are structurally different from 9-(2-hydroxypropyl) adenine as in formula II of the citation, either of R3 and R4 is a benzoyl group, or both R3 and R4 together are dimethylaminomethylene group. These groups are protective groups and are required to protect the amino group in the reaction of compound of formula II with sodium hydride. Therefore the present invention differs from the cited document in that the present invention teaches a method of making a lithium salt of (R)-9-(2-hydroxypropyl) adenine, whereas, the citation teaches a composition of sodium hydride and a protected adenine compound. The citation is silent and contains no disclosure of a method for making a lithium salt of (R)-9-(2-hydroxypropyl) adenine. The citation
also provides no guidance or motivation to a person of even ordinary skill in the art to a method for making a lithium salt of \((r)-9-(2\text{-hydroxypropyl})\) adenine.

It is further stated that the averment of the Representers is incorrect and has no bass, either in law or in chemistry that because a lithium salt of the parent compound PMPA is known, it would be obvious to make lithium salt of an intermediate. In fact citation clearly teaches that a lithium salt of PMPA is formed simply because of certain advantages in storage and because of their easy solubility in water. There is no teaching that the salt forming lithium compound is a lithium alkoxide. Secondly, there is no guidance or teaching that it is necessary to obtain the same properties/advantages of a parent compound in the precursor compounds as well. Thus, there is no teaching or guidance that it would be advantageous to prepare lithium salts of \((R)-9-(2\text{-hydroxypropyl})\) adenine in the citation, which are soluble in water. The instant invention uses lithium alkoxides as reactants to obtain a salt of \((R)-9-(2\text{-hydroxypropyl})\) adenine in order to obtain a product with an improved byproduct profile compared to that obtained by using NaH. The exhibit on the other hand specifically teaches the use of only NaH.

The applicant further stated that instant invention avoids the problem of use of NaH (which results in the formation of hydrogen gas leading to difficulty in process control) and results in the formation of a product with an improved byproduct profile. The cited document equates lithium and sodium salts only with respect to the final product phosphonomethoxy nucleoside analogues and not the precursor compounds.

18. The applicants have further stated that the Exhibit -3 (US Patent 4,003,878) is completely irrelevant and immaterial to the present
proceedings as it neither even relate to the field of technology to which the present invention relates nor to the field of technology of Exhibit-1 and Exhibit-2 since international patent classification of the Exhibit -3 is different than the present invention and Exhibit-1 and Exhibit-2. It is further stated that the document of Exhibit-3 teaches preparation of an alkoxy sulphonated benzoic acid glycol ester by reaction of hydroxy substituted benzoic acid with an alkali metal and a solvent reactant comprising alkylene glycol and such there is no teaching of nucleoside analogs let alone hydroxyalkyl adenine or its reaction with lithium alkoxide and therefore the ground of lack of inventive step raised by the opponent is liable to rejection.

19. The applicants have further stated that the submissions of the Representers are contradictory. On one hand, the Representers have voluntarily waived the ground of anticipation by prior publication and have therefore admitted that the invention covered by the claims of the present application is novel. On the other hand, they allege that Exhibit-1 to 3 relied on by them under the ground of lack of inventive step comprise anticipatory prior use and prior knowledge in India. It is further stated that this averment of the Representers establishes the absolute ignorance of patent law on the part of the Representers. Therefore if a document is not anticipatory prior publication, it can neither be anticipatory prior use nor can be prior public knowledge in India. Further the Representers have not demonstrated which parts of the document constitute the alleged anticipated prior use or knowledge against claims relating to formation of a lithium salt of (R)-9-(2-hydroxypropyl) adenine. The applicants submitted that the Representers are now estopped from relying on the ground of anticipation by prior publication since such ground has been specifically waived by them in their representation. It is
therefore submitted by the applicants that the ground of prior public use/prior public knowledge in India also has not been established.

20. The applicants have denied the contention of the opponents that the invention is devoid of inventive step and lacks economic significance and technical advancement and stated that the opponents have not provided any submission or evidence in this regard. However they have submitted that use of lithium alkoxide to from a salt with (R)-9-(2-hydroxypropyl) adenine results in a product with an improved byproduct profile, which is adequately described in the specification. The avoidance of formation of hydrogen gas which occurs in the conventional prior art processes using metal hydride is sufficient technical advancement. Therefore this ground be dismissed being baseless and not established.

21. The applicants have denied the contention of the opponents that the invention claimed in the claims of the instant application is not an invention within the provisions of the Act. The applicants further stated that none of the cited documents under the ground of lack of inventive step teach or disclose or guide towards a process of reacting (R)-9-(2-hydroxypropyl) adenine which lithium alkoxide to form a lithium salt resulting in a product with an improved byproduct profile. In any event, the submissions of the Representers are contradictory. On one hand, the Representers have voluntarily waived the ground of anticipation by prior publication, and have therefore admitted that the invention covered by the claims of the present application is novel. On the other hand, they now allege that Exhibits – 1 to 3 relied on by them under the ground of lack of inventive step comprise anticipation. It has been submitted that this averment of the Representers establishes the absolute ignorance of the patent law on the part of Representers. Since the ground of
anticipation by prior publication is available under Section 25(1)(a) but has specifically not been relied on by the Representers and therefore, there is a clear waiver of action.

Accordingly, it has been submitted by the applicant that the failure to take the ground of anticipation by prior publication as provided under Section 25(1) constitutes an estoppels against reliance on anticipation under any other ground. Further, the Representers have not demonstrated which parts of the document constitute the alleged anticipation against claims relating to formation of a lithium salt of (R)-9-(2-hydroxypropyl)adenine and therefore the Representers are now estopped from relying on the ground of anticipation by prior publication since such ground has been specifically waived by then in their representation. It is therefore submitted by the applicants that the ground of lack of invention based on anticipation also has not been established.

22. The applicants have further stated that Section 3(d) is completely inapplicable in the case of the present invention. The present invention does not reside in a mere use of a known process but actually employs a new reactant for formation of lithium salt of (R)-9-(2-hydroxypropyl)adenine, providing a product with improved by product profile and avoids the formation of hydrogen gas. It is therefore submitted by the applicants that the ground of not a patentable invention due to Section 3(d) has not been established.

23. The applicants have denied the ground of insufficient disclosure and further stated that the Representers have clearly either failed to read the written description or are unaware of how a patent specification is to be read or construed. The specific method for formation of lithium salt of (R)-
9-(2-hydroxypropyl) adenine by reaction with lithium alkoxide is sufficiently described in the complete specification with clear guidance to any person of even ordinary skill in the art. The method of working the invention is therefore clearly described and enabled.

24. The applicants have denied the ground of non compliance with provisions of section 8 in submitting the information about corresponding foreign applications and further stated that the applicants have regularly kept the Patent Office informed of the status of all corresponding foreign applications including their prosecution histories and are continuing to do so. It has been further submitted that a mere perusal of the records of this application would show that information required under Section 8 has been regularly submitted to the Patent Office, therefore this ground has also not been established by the Representers and accordingly the entire representation is liable to rejection.

**Consideration of preliminary issues:**

25. Before looking into each ground in the representation for opposition relied upon and evidence filed by the representers or opponents, reply statement and evidence filed by the applicants and the submissions made during hearing by both arties, let me consider the issues raised by the applicant in preliminary objections in their reply statement. The issues, are mainly (a) whether the representers need to prove their interest to file representation for opposition? (In other words, **locus standii**) , (b) whether the act of representers by filing representation for opposition alongwith the evidence of Mr. Kankan Rajendra.R. In their support, who happens to be working for CIPLA Ltd on that day is a collusion? , And (c) whether the evidence of Mr. Kankan Rajendra.R., be taken on record in view of the statement in cause title of expert evidence of the expert evidence
Although this issue was not raised by the applicant in their reply statement).

As regards locus standii or interest of the opponent is concerned, it is made clear that the scheme of opposition proceeding so laid down in the provisions of section 25 of the Act is such that any person may file a representation by way of opposition under section 25(1) on the grounds mentioned therein after publication of the application but before the grant of patent with only exception that patent can not be granted before expiry of six months period from the date of publication of the application(rule 55(1A)) and in case of an opposition under section 25(2), the notice of opposition may be filed by any person interested within a period of one year from the date of publication of the grant of patent. Therefore, it is very clear from the provisions of the law as stated above that in order to qualify to file an opposition under section 25(2), the opponent is required to establish his interest whereas to file an opposition under section 25(1) the opponent need not establish or demonstrate his interest as the law permit any person to file such an opposition. Accordingly I hold that the opponents need not to demonstrate or establish his interest in filing this opposition.

As regards second issue relating to collusive act of the opponent with CIPLA Ltd by filing the evidence of a person who was working for CIPLA Ltd, I think evidence from any independent person who has worked or has been working in the same or similar field of technology (not working for the opponent) should always be appreciated. Although, the deponent is working for CIPLA LTD, what is important is whether the deponent is competent to depose the evidence or not. After considering his Academic qualifications, experience and Professional contribution and achievements I am fully satisfied that deponent is quite competent to
Depose the expert evidence. As the present opponent might have also
touched the same person to depose the evidence, it is quite possible
for him to say in his evidence that the opponent has again opposed the
amended application (paragraph 1.4 of the evidence) particularly when
same application is being opposed again. Since the representation for
opposition was filed within the prescribed time limit as provided in the
statute and not filed one after disposal of other, the act of opponent can
not be held to be collusive in nature to delay the grant of patent.

As regards third issues, whether the evidence deposed by Mr.
Kankan Rajendra.R., be taken on record or not in view of the statement in
cause title of expert evidence, it is observed that the statement of the
cause title clearly says that the evidence is filed in the matter of
opposition by CIPLA Ltd and not for the opposition filed by Intermed
Labs. However in today's world of computer, where things are being done
by copy past method, it is quite possible for such mistakes to occur
particularly when the deponent like him had already given evidence in
same case. In spite that I hold that the expert evidences filed by Mr.
Kankan Rajendra.R., are refused to be considered for this opposition as
they are not filed on behalf of Intermed Labs.

**Consideration of grounds/submissions/Arguments of both parties**

26. Now I shall consider each of the grounds as mentioned below, which
have been relied upon by the opponent in the light of the arguments in
the hearing, written submissions submitted by both parties and facts of
the case including their replies and evidences barring the evidence of Mr.
Kankan Rajendra.R.

**(a) Prior publication:** Although the opponents in their
representation relied upon three US Patents as mentioned elsewhere
where the invention is alleged to have been published but in the hearing, the opponents had categorically mentioned to drop this ground. This has also been pointed out and clarified by the applicants not only in their reply statement but also during hearing and therefore this ground is considered to have been dropped, accordingly need no consideration.

(b) Prior claiming: This ground was also relied upon in the representation but dropped during hearing as well as no document was submitted in support of it and therefore needs no consideration.

(c) Lack of inventiveness or inventive step: In support of this ground, the opponents have relied upon three documents namely US Patent No. 5476983 published on December 19, 1995 marked as Exhibit-1, US Patent No. 4808716 issued on February 28, 1989 marked as Exhibit-2 and US Patent No. 4003878 issued on January 18, 1977 marked as Exhibit-3. In view of the disclosure therein the invention was alleged to have been lacking in the inventive step. During hearing the opponents placed their reliance on several case laws on the issue of obviousness, for instance **PFIZER, INC vs. APOTEX** (United States Court of Appeals for the Federal Circuits), T-0253/92T-0133/01, T-0197/86, T-0253/92, T-0561/94, T-0513/90, T-0659/00 of Boards of Appeals of EPO etc. On the other hand, the applicants in their reply statement have denied and stated that the ground is baseless as none of the documents disclose the use of lithium alkoxide in the reaction with (R) -9-(2-hydroxypropyl) adenine to obtain a lithium salt thereof as claimed in the instant application and therefore the invention is inventive over the prior art documents. According to the evidence of Dr. S.Swaminathan submitted in the support of the applicant, Exhibit-I (US Patent 5,476,938) contains no guidance or specific teachings towards the use of lithium alkoxide. On the contrary, it discloses the preparation of HPMP nucleoside analogues by treating purine or pyrimidine base, which
includes adenine with metal hydride such as sodium hydride, potassium hydride or lithium hydride and alkoxide such as sodium or potassium alkoxide to obtain the corresponding anon. Moreover the role played by the metal alkoxide is that of a catalyst in the formation of an anion and not as a reactant to form a salt.

It was admittedly stated by the applicant that it is true that lithium, sodium and potassium are generally in the same class of elements in the periodic table but it would be incorrect to state that the three are equivalent in all area of technology and therefore lithium alkoxide cannot be equated with sodium or potassium alkoxide, which are being used as bases and function as catalysts. It has been further stated by Dr. S. Swaminathan in the evidence that present invention avoids the problem of use of NaH which results of in the formation of the hydrogen gas leading to difficulty in process control. The same arguments were made by the applicant during the hearing.

The "term inventive step" has been defined in section 2(1)(ja) of the Patents Act, 1970 "as a feature of the invention that involves technical advance as compared to the existing knowledge or having economical significance or both and that makes the invention not obvious to a person skilled in the art". Therefore for proper investigation as to whether the alleged invention involves the inventive step or not is to find out (a) the closest prior art or existing knowledge on the date of priority of the alleged invention (b) Is there any technical advancement or economic significance or both made by the alleged invention as compared to the existing knowledge or prior art and (c) whether such technical advancement or economical significance is obvious to a person skilled in the art. If the answer is affirmative, in that situation the invention is obvious and if the answer is negative, the invention is non-obvious and involving the inventive step.
After perusing the description in the specification of the instant application, it is observed (page No 16) that the use of a highly reactive base such as NaH, results in an exothermic reaction that generates hydrogen gas in the reaction that is difficult to control. Further, the use of NaH requires more labour and care than the use of lithium alkoxide. However on the same page the applicants have also admittedly disclosed that the use of lithium alkoxide is also mildly exothermic. The only point is that this does not generate hydrogen gas in the reaction mixture, which is difficult to control and requires more labour and care. But what about the reaction with sodium or potassium alkoxides which are disclosed in the prior art.? The applicants have kept silence on this issue even in their evidence. It has been admitted by the applicants in their reply statement (page-7 lines 2-4) that the citation clearly teaches use of only sodium hydride or potassium hydride or lithium hydride reaction with the hydroxyalkyl adenine and same has been admitted in the expert evidence in page 8 and 9. They have also admitted that only alkoxides used in the prior art are sodium or potassium except that they have refused to equate them with lithium alkoxide.

I have no doubt in my mind that adenine is nothing but a purine base, as all general chemists know. This is also disclosed in para- 3, lines 18 and 19 of Exhibit-I. Similarly the same exhibit discloses in para-4, lines 40-45 that a compound of formula (IIIb) is treated with a base to generate the corresponding alkoxide anion. The base may be a metal hydride, for example sodium hydride, potassium hydride or lithium hydride; and metal alkoxide, for example, potassium t-butoxide or sodium methoxide and the like (emphasized). That means it would be obvious for any person skilled in the art to try to use lithium alkoxide as well particularly where sodium, potassium and lithium hydride are used in case of hydride with reasonable expectation of success. This
expectation of success need only be reasonable not absolute. Therefore it would be impossible for any chemist not to try to use lithium alkoxide where alkoxides of potassium or sodium have been disclosed to have been used to derive reasonable success as only hydrides generate the hydrogen gas when reacted with hydroxy alkyl adenine but not metal alkoxide and this takes care of exothermic nature of reaction with NaH.

In order to avoid the issue of obviousness or lack of inventive step the applicant must show the unexpected results as compared with closest prior art. Therefore, what was expected from the applicant was to compare the results of use of sodium or potassium alkoxide, which is closest prior art, with the results of lithium alkoxide (of alleged invention) but certainly not with NaH. Moreover, the applicants, although stated in the reply statement as well as in the expert evidence about obtaining of a product with improved byproduct profile and greater purity in the final product, failed to provide any comparison of such results in the specification. I also have doubt about the synthesis of lithium salt of (R)-9-(2-hydroxypropyl) as an independent product since no evidence is given in the description either as an example or as reaction scheme as shown on page 14. In fact what is described in page 18-20 of the specification is the process of synthesis of (R)-9-[2-(Diethylphosphonomethoy) propyl] adenine wherein 9-(2-hydroxypropyl) adenine and lithium alkoxide contacted with p-tolunesulfonyloxymethylphosphonate in tetrahydrofuran and dimethylformamide as organic solvent during which a slurry of lithium salt of 9-(2-hydroxypropyl) adenine might have been formed in situ reaction process which in my opinion is also alkoxide anion of corresponding hydroxyl group where lithium as cation (similar to alkoxide anion obtained in the prior art with sodium or potassium alkoxides) and therefore overcoming the issue of generation of hydrogen gas and handling of it due to exothermic nature of the reaction. In view of
above discussion, I am of the opinion that the alleged invention as claimed in claims is lacking inventive step or in other words is obvious to a person skilled in the art as the alleged invention has neither disclosed any technical advancement nor any economic significance as compared to the existing knowledge as disclosed in exhibit-I.

As regards Exhibit-II, I agree with the applicant that it does not teach the formation of lithium salt of 9-(2-hydroxypropyl) adenine but definitely teaches the synthesis of 9-[Phosphonylethoxalkyl] adenine (which appears to be one of the intermediate compound prepared in step -4 of the alleged invention) wherein sodium or lithium salts are prepared by using hydrides of respective metals and not alkoxides. Similarly I also agree with the applicant that exhibit-III teach a very general method of preparation of alkali metal alkoxides of alkoxisulphonated aromatic carboxylic acids but does not teach anything about the preparation of lithium salt of 9-(2-hydroxypropyl) adenine. In view of this, I am of the opinion that Exhibit-II and Exhibit-III although, are not relevant for the purpose of closest prior art, but may motivate the skilled person to prepare the lithium salt of hydroxy alkyl adenine.

Another point, which I would like to make here, is that same process of preparation of lithium salt of 9-(2-hydroxypropyl) adenine has been disclosed in specification filed in respect of another Indian patent application No.2076/DEL/1997 which is claiming the priority date of 26th July 1996 of US Application but filed by same applicant for "Antiviral phosphonomethoxy Nucleotide Analogous prodrug (page No....), which is claimed to have been invented by altogether different inventors namely MURTHY N. ARIMILLI, KENNETH C.CUNDY, JOSHEPH P.DOUGHERTHY, CHOUNG U.KI, REZA OLIYAL and VELENTINO J.STELLA. Interestingly none of them is named as inventor in this application. Since the above-mentioned application was filed (not
published) before the filing date of this application, it cannot be used as prior art. But point which I am trying to derive out is that, the inventors of this invention (of course the applicant is same) in fact, would have made no inventiveness in the step of converting of 9-(2-hydroxypropyl) adenine into its lithium salt as same has been disclosed in the earlier application of the applicants having earlier priority date and altogether different invention (No.2076/DEL/1997) and therefore the claimed step is being a general step in the preparation of such intermediates which in turn can be used in obtaining the final product which might have therapeutic effect.

(d) Prior public use or prior public knowledge: I have gone through the contentions of the opponents and also the reply of the applicant including the evidence of Dr. Swaminathan in support of the applicant and submissions made during the hearing. I fully agree with the applicant that if a document is not anticipatory prior publication, it can neither be anticipatory prior use nor can be prior public knowledge in India. Further the opponent have completely failed to have demonstrated by any evidence that the alleged invention been publicly used in India or any person has any prior knowledge on the date of priority of the application. Therefore, this ground has not been established by the opponents.

(e) Not an invention under section 2(1) (ja) of the Act: At the outset I do not agree with contention of the applicant that this ground is not available for opposition under section 25(1) as stated in the reply statement of the applicant due to the fact that provisions of section 25(1)(f) clearly provides for it on the ground that the subject matter of any claim in the specification is not an invention. Needless to say that applicants as well as opponents clearly know that term "invention' encompasses novelty, inventive step and industrial application within its
definition. However, the opponents are relying only upon one of its components such as lack of inventive step due to lack of technical advancement and economic significance. Although the applicants stated in the reply statement as well as in the expert evidence that they are avoiding the formation of hydrogen which makes the process difficult to control due to its exothermic reaction and also the process leads to a product with improved byproduct profile and greater purity in the final product, failed to give the comparative data in the specification in this regard particularly comparison with sodium or potassium alkoxides which are disclosed in the prior art to prove clearly that nothing but lithium alkoxide avoids the problem faced in the prior art. As discussed earlier, due to non availability of such information in the specification, the alleged invention lacks inventive step and therefore I hold that the opponents have partially succeeded on this ground.

(6) Not an invention under section 2(1)(l) of the Act: The term "new invention" has been defined in the Act "as 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 states of art". Since the opponent, have dropped the ground of prior publication due to lack of any evidence on their part, this ground must fail automatically. After considering the submissions/arguments of the applicant, I hold that the opponents could not establish this ground beyond doubt.

(6) Not a patentable invention under section 3(d) of the Act: The opponents have relied upon the fact that alleged invention is nothing but a mere use of a known process to form a salt by using a metal alkoxide giving a salt of a known intermediate. Moreover, the process also has not resulted in any new product but just a salt of the well-known
intermediate. I don’t agree with contention of the opponents to the extent that they have not been able to put forward their point as to whether the alleged invention is a 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 is it a mere discovery of any new property or new use for a known substance or whether it is a 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. I also do not agree with the contention of the applicant that alleged invention does not reside in a mere use of a known process but actually employs a new reactant for formation of lithium salt of (R)-9-(2-hydroxypropyl) adenine, providing a product with improved by product profile and avoids the formation of hydrogen gas. Since use of metal alkoxide such as sodium and potassium is already disclosed in the prior art, the use of lithium alkoxide is quite obvious for the formation of lithium salt for a person skilled in the art. Therefore in order to be successful on this ground the opponent has to prove beyond doubt that the alleged invention is either a mere discovery of any new property or new use for a known substance or it is a 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 it is a 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. Since the opponents have proved neither clearly nor explicitly, this ground fails.

(g) Insufficient disclosure: The opponents argued that the opposed application does not teach or illustrate the product of the claimed process of the alleged invention throughout the specification. It was further argued that it did not even disclose the characteristics of the product of the claimed process. They further argued that the claimed
invention does not even disclose the isolation and purity of the product obtained by their process. On the other hand the applicants denied the contentions of the opponents and stated that all the essential information including sufficient illustrations relating to preparation of lithium salt of (R)-9-(2-hydroxypropyl) adenine is provided in the specification. In order to satisfy the requirement of sufficiency of description, the applicant for patent is required to satisfy at least following three conditions, namely (a) the complete specification must describe an embodiment of the invention claimed in each of the claims, (b) the description must be sufficient to enable those in the industry concerned to carry it into effect without making further invention or experiments and (c) the description must be fair i.e. it must not be unnecessarily difficult to follow [Patent law by P. Narayanan, fourth Edition 2006, para 16-175 and page 463]. Since the sufficient disclosure of the invention to the public through the specification is the basis of the patent grant, the controller [being the custodian of the public rights] has to consider the rights of the public so that the public can exploit the invention commercially [without doing further experiments] after the expiry of the term of patent. Therefore he has to ensure that the description is not ambiguous to understand by the ordinary skilled person.

On pursuing the specification, I do not agree with this contention of the applicant for the following reasons, namely (a) the specification fails to describe as to what is the objective of the invention in preparing the lithium salt of (R)-9-(2-hydroxypropyl) adenine, or what benefits are derived by converting (R)-9-(2-hydroxypropyl) adenine into its lithium salt (b) what difficulties were being faced in the prior art and how are they obviated by converting (R)-9-(2-hydroxypropyl) adenine into lithium salt (c) how is the final product is isolated and purified from the reaction mixture (d) there has been no schematic illustration of reaction of the
claimed process,(e) there has been no independent example as to the lithium salt of (R)-9-(2-hydroxypropyl) adenine preparation in the specification and finally(f) how does lithium salt help in the process of preparation of the final product that is "(bis(POC)PMPA fumarate" or "BPPF". Therefore, what was expected from the applicants was to compare the results of use of sodium or potassium alkoxide, which is closest prior, art, with the results of lithium alkoxide (of alleged invention) but certainly not with NaH and come out clearly with difficulties faced by them. Thereafter the applicants were expected to detail out the benefits of final product such as lithium salt to the trade or society or role played by the lithium salt in the preparation of final product that is "(bis (POC) PMPA fumarate" or "BPPF", in the absence of which it would be very difficult for any chemical intermediate to be patentable. For this conclusion I relied upon Justice Ayyangar Report, on the revision of the patent law in India where at para 22,page 11, he mentioned that “the consideration justifying the grant of monopoly for a new invention is not only the disclosure to the public the information which they can use when the period of monopoly expires but the benefit to the trade by the new invention being brought into the commercial use during that period” .The similar principles are well applicable in United States jurisprudence, for instance in Brenner v. Manson, where Supreme Court held that "the basic quid pro quo......for granting a patent monopoly is the benefit derived from an invention with substantial utility.... and unless and until a process is refined or developed to this point-where specific benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field"

The applicants further failed to give the information regarding the product having so called improved byproduct profile and greater purity in the final product by comparing of such results in the specification. The
improved product or byproduct profile that is given in the specification is that of "(bis (POC) PMPA fumarate" or “BPPF” but not of lithium salt of (R)-9-(2-hydroxypropyl) adenine. I have neither found an independent example of the synthesis of lithium salt of (R)-9-(2-hydroxypropyl) as a product in the given description nor any reaction scheme as given on page 14. In fact what is described in page 18-20 of the specification is the process of synthesis of (R)-9-[2-(Diethylphosphononomethoy) propyl] adenine wherein 9-(2-hydroxypropyl) adenine and lithium alkoxide contacted with p-tolunesulfonoyloxymethylphosphonate in tetrahydrofuran and dimethylformamide as organic solvent during which a slurry of lithium salt of 9-(2-hydroxypropyl) adenine might have been formed in situ reaction process. Even on these pages there has been no description in clear terms as to how the end product of the claimed process would be isolated or separated from the reaction mixture. In fact what I found is that the end product would be produced as slurry (page 19) which has never been separated from the reaction mixture, rather further reacted with p-toluenesulfonoyloxymethylphosphonate to obtain the intermediate which would ultimately lead to produce fumarate salt of 9-[2-(R)[[bis [[(isopropoxycarbonyl) oxy] methoxy] phosphinoyl] methoxy] propyl]-adenine "(bis (POC) PMPA fumarate" or "BPPF" which was what the applicant's alleged invention.

According to the process described in the stage-IV of the process, it only leads to a compound such as (R)-9-[2-(Diethylphosphononomethoy) propyl] adenine as an intermediate which cannot be separated and isolated from the reaction mixture. Therefore the lithium salt of 9-(2-hydroxypropyl) adenine does not even qualify for being as intermediate for the purpose of preparation of a drug such as fumarate salt of 9-[2-(R)[[bis [[(isopropoxycarbonyl) oxy] methoxy] phosphinoyl] methoxy] propyl]-adenine"(bis (POC) PMPA fumarate" or "BPPF" as same can not be
separated and therefore can not be independently commercially transacted in the channels of commerce and trade. Therefore, any process in order to be patentable must result in some effects which have some commercial value or applicability or if such process resulting in the product, such product must be separable so that they can be commercially transacted in the channels of commerce and trade. This becomes more important for the controller while granting patent monopoly to ensure that such benefits are reflected in the specification so that public at large can take benefits or advantage of them after the expiry of patent monopoly. In view of the above discussion and circumstances, I hold that the description of the alleged invention in the specification is insufficient or in other words the applicants have failed to describe the alleged invention sufficiently, clearly and fully.

(h) Failure to furnish information under section 8: Lastly the opponents have relied upon the ground that applicants have failed to provide all the information regarding the prosecution and other details of their corresponding foreign applications till the grant of patent to the Controller in writing from time to time and also within the prescribed time under section 8 of the Act, which the applicants have denied. They also submitted in the hearing that applicants have regularly kept the Patent Office informed of the status of all corresponding foreign applications including their prosecution histories and are continuing to do so. This can be seen from mere perusal of the records of this application submitted to the Patent Office. I fully agree with the submissions of the applicants that the opponents have not brought any information to the notice of the controller even until the date of hearing or even till date which the applicants might have concealed and not furnished. I therefore hold that the opponents failed to prove this ground in the absence of any evidence.
After having considered all the circumstance of this case, representation for opposition, reply of the applicants, expert evidence in support of the applicant, written submissions and arguments in the hearing made by both parties and also my discussion and findings as mention above, I am of the opinion that the alleged invention as claimed in the claims is not only obvious to person skilled in the art and lacking in inventive step but also insufficient and ambiguous as described in the specification. In view of the above, I refuse this application to proceed further for the grant of patent thereon.

Dated this 9th day of MARCH 2009

(Dr. K.S. Kardam)
Deputy Controller of Patents & Designs.

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