

The Patents Act, 1970 (As Amended in 2005)
(Section 15)

In the matter of Application no. 1135/del/2007 filed in India on 29/05/2007 for Grant of Patent;
Divided out of application no 896/del/2002 filed on 04/09/2002 (refused for grant on 30/07/2009)
which further divided out of main application no 2174/del/1998 filed on 24/07/1998
Patent No. 190780 accepted on 30.09.2002, Date of Sealing 15.03.2004
Claiming Priority Date 25/07/1997 Of USA from basic application no 2174/del/1998;

Applicants:- M/S Gilead Sciences, Inc., US

Applicants Attorneys: M/S Subramaniam, Natraj and Associates, New Delhi

ATTORNEY'S PRESENT FOR ARGUMENT: Mr. Subramaniam H., Ms. Gaytri Bhasin

EXAMINER: DR. Sunil Gautam, Examiner PATENT OFFICE, NEW DELHI, INDIA

Date of Hearing: 03/12/2012

DECISION

[A] The present application came up for hearing U/S 14 of the Patent Act due to the following unresolved objections of the Examination reports sent to them in accordance with the provisions of the Patents act:

1 Subject matter of revised claims 1-3 does not constitute an invention as it lack in inventive step under section 2(1)j of the Patent Act 1970 as amended in view of documents;

D1- Bischogberger et. Al., Bis (POC) PMPA an orally bio available pro drug of the anti retroviral agent PMPA, Conf, Retroviruses opportunistic infect 1997, Jan. 22-26, 4TH 104 (Abstract no. 214), published on 22-26/01/1998. Document D1 discloses the active agent Bis (POC) PMPA. Document D1 further discloses that Bis(POC) PMPA itself is chemically stable in solution over a broad pH range.

D2- Gould et. Al., Salt selection or basic drug, International journal for pharmaceutics, 33 (1986), 201-217. Document D2 discloses a rationale to salt selection for basic Drugs. D2 at Page 2 provides a table 'FDA SALT FORMS' which list "Fumarate" as a possible salt form used in 0.25% of the basic Drug marketed till 1974. The document D2 also discloses the reason for selection of various salts including Fumarate salts. These salts preparations of pharmaceutically active compounds develop the improved properties such as improved Bioavailability and the enhanced stability.

D3-Berge et. Al., Material safety data sheets for citric acid and fumaric acid. Document D3 discloses that the solubility of fumaric acid in water is 0.61%w/w at 25 degree C, whereas the solubility of citric acid is 162g/100ml.

D4-Pharmaceutical salts, Journal of pharmaceutical sciences, Jan. 1997, vol. 66 Number 1. Document D4 on page 2, first col. teaches that a salts hydrophobicity and high crystal lattice energy can effect the dissolution rate and bioavailability of basic drug.

D5-CA2126601 discloses phosphonate nucleotide ester derivatives or pharmaceutically acceptable salts thereof which can be orally administered as antiviral agents.

D6-US5498419 discloses that the Fumarate salt of 4-(diethyl 1-3 (1-methyloctyl-7, 8, 9, 10-tetrahydro-6, 9, 9 trimethyl 6H dibenzo [b, d] pyran-1-ol, 4, dimethyl aminobutyric acid ester is found surprisingly stable, nonhydroscopic, crystalline, stable over prolonged periods of storage at RT. This document indicates that Fumarate salts are more appropriate to use as pharmaceutical agent unlike other known salts.

D7-US5994387 relates to fumarate salt of (R)-5-(methylaminosulphonylmethyl)-3-(N-methylpyrrolidin-2-ylmethyl)-1H-indole. In view of prior art documents, the solution proposed in instant invention is the result of obvious measures which the skilled person would arrive at within routine experimentation and without having to apply inventive activity.

2 Revised claims 1-3 fall u/s 3(d) of the Patents (Amended) Act, 2005 as the said claims defines new form/new use of the known compound (as cited by the prior art documents as described in para 1 of the report) which does not result in the enhancement of the known efficacy of that substance.

Revised claim 3 falls u/s 3(e) of the Patents (Amended) Act, 2005 as the said claim defines a mere admixture resulting only in the aggregation of the properties of the components thereof. It is not clear if the combined agents act together to provide a technical effect that is greater than just the sum of the two or more agents alone, or whether the combination is in fact a mere juxtaposition with no interaction of the agents.

3 The claims of the instant application are not sustainable u/s 16 of the Patents (Amendment) Act, 2005 because of the following reasons-

1. According to section 16, a divisional application can only be made out of a main independent application, which is not the case here. The instant application has been carved out of 896/DEL/2002, which is itself a dependent divisional application out of 2174/DEL/1998. The instant application should have been made out of 2174/DEL/1998 instead of 896/DEL/2002. The divisional out of a divisional application is not allowable u/s 16.

2. Further, the disclosure and claims of 2174/DEL/1998 has come into the public domain for free use and, therefore allowing reclaiming of claims in the form of a divisional application shall be against the public interest as patentee of such divisional application shall be entitled to file infringement suit against the user of that already published and granted patent document.

3. Section 16(1) of the Patent Act clearly stipulates that the applicant may file a divisional application if "the claims of the complete specification relate to more than one invention," The claims of the Parent application no 2174/DEL/1998 conflicts with the claims of the instant application.

4 The assignment filed by you should be attested by competent authority or attached with a original stamp paper (Please note that photocopy of the attestation shall not be allowable).

5 Power of authority should be attached with a original stamp paper in accordance with Indian Stamps Act, 1899 (2 of 1899).

6 Priority documents should be filed in prescribed manner.

[B] The claims of the application no. 2174/del/1998 as accepted are as follows:

1. A process for preparation of fumarate salt of 9-[2-(R)-[[bis[[[(isopropoxycarbonyl)oxy]methoxy]phosphinoyl]methoxy]propyl]-adenine comprising reacting fumaric acid with 9-[2-(R)-[[bis[[[(isopropoxycarbonyl)oxy]methoxy]phosphinoyl]methoxy]propyl]-adenine optionally in the presence of a solvent of the kind such as herein described, wherein fumaric acid and 9-[2-(R)-[[bis[[[(isopropoxycarbonyl)oxy]methoxy]phosphinoyl]methoxy]propyl]-adenine are preferably taken in molar ratio of 0.6:1 to 1.4:1.

2. A process as claimed in claim 1, wherein fumaric acid and 9-[2-(R)-[[bis[[[(isopropoxy carbonyl)oxy]methoxy]phosphinoyl]methoxy]propyl]-adenine are more preferably taken in molar ratio of 0.9:1.1.

3. A process as claimed in claim 1. wherein fumaric and 9-[2-(R)-[[bis[[[(isopropoxycarbonyl)oxymethoxy]phosphinoyl]methoxy]propyl]-adenine are more preferably taken in molar ratio of 1:1.

4. A process as claimed in any of the preceding claims, wherein said solvent is selected from a group consisting of alkyl acetate, 1-methyl-2-pyrrolidinone, a trialkylamine, a C1-6 alkanol, pyridine, dimethylformamide, dimethylsulfoxide, acetone, dichloromethane (CH₂Cl₂), tetrahydrofuran, acetonitrile, toluene, a xylene, methyl ethyl ketone, 1,2-dichloroethane or chloroform (CHCl₃).

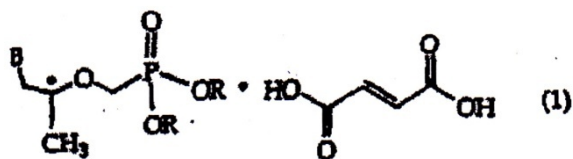
5. A process as claimed in claim 4, wherein said a C1-6 alkanol is selected from a group consisting of n-hexanol, n-pentanol, n-butanol, isopropanol, n-propanol, ethanol or methanol.

6. A process as claimed in any of the preceding claims, wherein said solvent is 2-propanol.

7. A process for preparation of fumarate salt of 9-[2-(R)-[[bis[[[(isopropoxycarbonyl)oxy]methoxy]phosphinoyl]methoxy]propyl]-adenine substantially such as hereindescribed with reference to the forgoing examples.

[C] The claims of application no 896/del/2002 Divisional of 2174/del/1998 is as follows:

1. A nucleotide analog of formula (1).

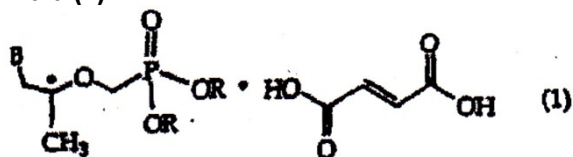


Wherein B is adenine-9-yl and R independently is $-H$ or $-CH_2-O-C(O)-O-CH(CH_3)_2$, but at least one R is $-CH_2-O-C(O)-O-CH(CH_3)_2$.

2. The compound as claimed in claim 1 wherein both R are $-CH_2-O-C(O)-O-CH(CH_3)_2$.
3. The compound as claimed in claim 1 wherein the compound is a crystalline solid.
4. The compound as claimed in Claim 1 wherein the compound is attached or resolved at the carbon atom chiral center (*).
5. The compound as claimed in claim 1 having an X-ray powder spectrum peak using Cu- α radiation, expressed in degrees 2 θ at about 25.0.
6. A method for the preparation of compound of formula 1 comprising contacting 9-[2-(R)-[[bis (isopropoxycarbonyloxy) methoxy] phosphinoyl] methoxy] propyl] - adenine with fumaric acid in a manner such as herein described.
7. The method as claimed in claim 6 wherein said fumaric acid is dissolved in 2-propanol.
8. A composition comprising an (R,S)-PMPA solution at a pH of 2.7-3.5 wherein the solution has less than 0.1 g/ml (R,S)- PMPA and wherein 90-94% of the PMPA is the (R) configuration.
9. A Composition comprising a lithium alkoxide and 9-(2-hydroxypropyl) adenine solution for the preparation of PMPA such as herein described.

[D]The claims of application no 1135/del/2007 are as follows:

1. A compound of formula (1)



wherein "B" is adenine-9-yl, both R are $-CH_2-O-C(O)-O-CH(CH_3)_2$, wherein said compound is enriched or resolved at the carbon atom chiral center (*), and said compound is a crystalline solid.

2. The compound as claimed in claim 1 having an X-ray powder diffraction spectrum peak using Cu-K α radiation, expressed in degrees 2 θ at about 25.0.

[E] The applicant's agent was heard in detail on 03/12/12

[F] Pre grant opposition:- A pregrant opposition U/S 25(1) has been filed by M/S S. Majumdar & Co, Mumbai on behalf of Intermed Pvt Ltd, Bangalore against the grant of Patent on this application on the following Grounds:

- (a) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after the priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than the applicant's claim;
- (b) that the invention so far as claimed in any claim 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) of Section 25(1) or having regard to what was used in India before the priority date of the applicant's claim;
- (c) That the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act;
- (d) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
- (e) That the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge.

The proceeding on Pregrant opposition is under process and hearing is yet to be taken.

[G] In view of the already filed opposition and pending Decision on claimed Parent application no 896/Del/2002 in the Hon'ble IPAB against the refusal order of the Controller dated 30/7/2009, the decision on objection no A/1, A/2, A/4, A/5 and A/6 as mentioned herein above will be taken while deciding Pregrant opposition filed against the Grant of this application.

[H] Hence the decision hereinafter will deal with the objection no 3 of the communication for hearing which relates to the validity of this application U/S 16 of the Patent Act, 1970.

[I] The section 16 of the Patents Act recites as follows:-

16(1) A person who has made an application for a patent under this Act may, at any time before the grant of the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.

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

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

"Explanation-For the purposes of this Act, the further application and the complete specification accompanying it shall be deemed to have been filed on the date on which the first mentioned application had been filed, and the further application shall be proceeded with as a substantive application and be examined when the request for examination is filed within the prescribed period".

Thus following are the requirement which should coexist for filing patent application u/s 16;

(1)The applicant should have already made an application known as first application (parent application).

(2) Further application (Divisional Application)may be filed at any time before the grant of patent to the first mentioned application.

(3)First mentioned application should have claims relating to more than one invention.

(4) Further application has been filed either on (i) Applicant's own desire to avoid distinctness of claims or (ii) with a view to remedy the objection of the controller on distinctness of claims.

(5)Further application should be accompanied with complete specification only.

(6) Further application can not include any matter not in substance disclosed in the complete specification of first mentioned application.

(7)Claims of further application and first mentioned application should not conflict with each other.

Further application accords the date of filing of first mentioned application and proceeded with as substantive application.

[J] Argument of the Applicant on the Objections:

(J-1) Objection no 3.1 and 3.2 as mentioned hereinabove:- Applicant arguments is that the Divisional out of Divisional or Second generation divisional application is permissible for the following reasons:

(a) Section 16 (3) explanation states that the further application (viz. a divisional application) shall be proceeded with as a substantive application and be examined if the Request for Examination is filed. Thus, once a divisional is filed, and is accorded the priority date, it proceeds as substantive application. Thus, there is no difference between such substantive application and any other application. If such divisional, when examined as a substantive application, evokes objection on the ground of "distinct invention", the Applicant will again have a right to file a divisional under Section 16. In other words, every divisional, unlike patent of addition, is a separate substantive application.

(b) As per Section 16(3), the Controller can require the amendments of the divisional application to ensure that it does not include a claim for any matter claimed in the parent

application. In this regard it is submitted that the claims on record on the present application have not been granted in any of the parent application. It is further submitted that the claims have been amended and restricted to crystalline BPPF.

- (c) The present application was filed before the grant of the parent application 896/DEL/2002 and there was an objection regarding distinct invention in 896/DEL/2002.

The applicants further argued that:-

- (d) "Divisional out of divisional have been granted by the Patent Office in the past. In this connection, we rely on the decision issued on 264/DEL/2002 u/S 15 of the Patents Act."

It is submitted that in stated decision for application no 264/Del/2002 it is clear that Divisional out of Divisional application no 294/Del/1996 (Parent application) was granted a Patent on 23/9/2000. First generation Divisional application no 937/Del/1999 was granted a Patent on 11/7/2005 and second generation divisional application 863/Del/2003 filed on 01/07/2003 has been granted a Patent on 01/09/2006. Thus the second generation divisional filed after grant of Parent Application has been granted in the past.

- (e) The applicant also submitted a decision of EP TECHNICAL BOARD OF APPEAL (T 1158/01-3.4.2) which applies to second generation divisional applications. "Page 5, paragraph 3.2 of said decision while interpreting the substantive conditions to be met by a divisional application states that a divisional application is deemed to have been filed on the date of filing of the earlier application and has the benefit of any right to priority. "If the divisional application itself is a second-generation divisional, there is in principle no difficulty in applying Article 76 EPC mutatis mutandis, since the earlier application out of which the second-generation divisional was divided is then the first-generation divisional. If the first-generation divisional itself is a valid divisional of the parent application, it inherits the latter's date of filing, which then under Article 76(1) EPC also applies to the second-generation divisional".

[H] Decision:-

(H-1) Decision on objection no 3.1 & 3.2 as mentioned hereinabove in the light of Attorney's Arguments: To deal with the objection no. 3.1 and 3.2 mentioned herein above it is necessary to decide first that which is the parent application (first mentioned application) for the instant application no. 1135/del/2007. According to Sec.16 (1) the first application filed for the invention claimed is the parent application and rest of the applications are further (divisional) applications. According to Sec. 16(1) the divisional application should have been filed before the grant date (i.e 15/3/2004) of the parent application. For the instant case the parent application is 2174/del/1998 and rest 896/del/2002 and 1135/del/2007 are the divisional

applications. 896/Del/2002 has been filed before 15/03/2004 is a valid divisional application whereas 1135/del/2007 filed on 29/05/2007 is not a valid divisional application.

The applicant's argument in this regard does not appear convincing for the following reasons:-

(i) The statute mentioned valid further application (divisional application) as substantive application for examination procedure. The further application remains in force with all the priorities if parent application loses its existence. It does not mean to disregard the timeline of "filing of further application before the grant of main (parent) application". Since all the priorities of divisional application comes from the very first application and in divisional application subject matter claimed cannot go beyond the disclosure of very first application, the very first application is the parent /main application out of which all the divisional applications may flow out and remains valid if filed before the grant of parent application in this case on or before 15.3.2004. However, since 1135/del/2007 has been filed on 29.05.2007 i.e. quite a big gap after grant of 2174/del/1998 (i.e. 15/3/2004) is not a valid divisional application.

(ii) The intention of statute is very clear in Sec. 16 that it limits the applicant to claim the monopoly only up to time of grant of the patent on main application in a divisional application and rest applicant does not wish to claim and is free in public domain.

(iii) In application no. 2174/del/1998, objection of distinctness were raised for the claims of 1135/del/2007 at the time of FER so as to file divisional claims. This mean divisional application for claims of 1135/del/2007 should have been filed before the expiry of time limit i.e. 15/3/2004 which the applicant failed to do. Therefore none of the arguments of applicants is acceptable and the application no. 1135/del/2007 is a time barred divisional application and is not a valid divisional application.

The applicant's argument regarding allowance of divisional out of divisional in the past does not appear convincing for the following reason:-

In the present practice there are so many applications where divisional out of divisional filed after grant of main application are not allowed, for example 264/Del/2005 refused U/S 16 on 31/03/2010. As per the requirement of the statute the divisional out of divisional may be allowed only in the condition when filed before the grant of main (very first) application and claims filed in divisional out of divisional are truly distinct from main application and not coming under single inventive concept. All the presented cases have been filed in 1996 to 2003 etc.

Honourable Supreme Court in 1995(1) SCC745 has held that "because the authority has passed an illegal order in the past does not entitle the honourable high court to compel the authority

that illegality over again and again". "It is also said that illegal orders can not constitute the basis of legitimate complain of discrimination". Accordingly an order for allowance of divisional application filed after the grant of the main application is contrary to Law. So if there are prior orders they are contrary to Law and cannot be allowed.

Regarding the decision of EP Technical Board the argument of the applicant does not appear convincing for the following reason:

This decision does not apply for the instant case as article 76(1) of EPC does not define any time limit for filing of divisional application whereas Indian Law limits filing of divisional application only to the date of or prior to the date of patent grant of the first application. Also EPC art. 76 does not impose any requirement on applicant to file divisional application only for the invention not coming under the single inventive concept whereas Indian Law does specifically requires the same. In absence of such limits in EPC the Law position of India regarding requirement of filing of divisional application is different and hence the judgement provided to support arguments does not serve any purpose.

(H-2) Decision on objection no 3.3 in the light of the Attorney's Argument:-

Sec.16(i) requires that the divisional application may be filed only for the claims which relate to more than one invention and not for the claims relating to single inventive concept or to the conflicting claims. The claims of the main Parent application no. 2174/del/1998 and 896/del/2002 did have conflict of the claims with claims of 1135/del/2007. The claims of 1135/del/2007, 2174/del/1998 and 896/Del/2002 comes under unity of invention. However at that point of time (in 1998)the product claims were not allowed under the law therefore such claims appear to have been shifted to application no. 896/Del/2002 and 1135/del/2007. Claims of 1135/del/2007 conflicts with all related applications 896/del/2002 and 2174/Del/1998.

Applicant's argument that the division can be done on desire of the applicant and therefore product claims were claimed at the time of after 2005 is not convincing as Sec. 16 does not afford this facility to the applicant and division can be done only when claims relate to invention distinct from the rest. Therefore claims of 1135/del/2007 conflicts with parent application no 2174/del/1998 and 896/Del/2002 as these claims fall under the unity of the invention.

Applicants' agent failed to prove that claims of 2174/Del/1998, 896/Del/2002 and 1135/del/2007 relate to the plural invention.

Reliance is placed on Honourable IPAB decision no. 30/2013 where it has been held in para 4 "once divisional application has been held to be identical to the parent application, it deserves

to be dismissed in limine and the applicant can not seek any indulgence with regard to the application which is impermissible in law” and in para 5 “an order or grant for a divisional application without a plurality of invention is contrary to Law. So if there are prior orders they are contrary to Law and can not be followed”, and in para 7 page 4 the Hon’ble IPAB stated that “At no point did the learned counsel submit that the parent application contains more than one invention and the divisional application related to one of the inventions for which the separate application has been made. The fact that in the First Examination Report, there is mention of plurality of the invention" may be a point in their favour. But still before us they have to show the existence of more than one invention and what each of those inventions related to. The learned counsel did not do that but on the other hand it was submitted again and again that the invention sought to be patented earlier was not patentable under the earlier Act. But now with the change in the Act, this application must be received and examined. Therefore, the learned counsel is not really advancing the case of a divisional application but of a fresh application. If we treat this as a fresh application it would require to be tested as such on the grounds of prior use, prior knowledge etc. But obviously the appellant does not want that.”. Therefore the Claim of 1135/Del/2007 conflicts with the claims of 2174/Del/1998 and 896/Del/2002.

[I] In the light of the above discussion it is clear that the divisional application no 1135/del/2007 has not been filed validly in accordance with the provisions of sec 16(1) of the Patent Act as it is time barred and the claims of the 1135/DEL/2007 conflicts with the parent application no. 2174/DEL/1998 and 896/DEL/2002 as all these claims fall under the single inventive concept. Therefore I refuse to proceed with the instant application further. Opposition U/S 25(1) is pending on this application and if the proceeding on this application is restored the opposition filed must be disposed of before the final disposal of this application.

DATED: 26/06/2013

(HARDEV KARAR)
DEPUTY CONTROLLER OF PATENTS & DESIGNS
PATENT OFFICE, NEW DELHI