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No. 959/MAS/1995

022135

Dated:30/01/2009

To

Ms. R. Vaigai
Advocate for The Tamil Nadu Networking People
with HIV/AIDS (TNNP+) and
The Indian Network for People living with HIV/AIDS (INP+)
No. 2, 1st Floor, S.M. Plaza
Armenian Street
Chennai – 600 001.

Sub: Pre-Grant Opposition; Decision reg. Ref: Patent Application No. 959/MAS/1995.

Gentlemen,

I am hereby directed to forward the decision of the hearing held on 21st January 2009 under section 25(1) and Rule 55(6) of the Patent (Amendment) Act, 2005 and the Patent (Amendment) Rules, 2006 in respect of the Patent Application No. 959/MAS/1995.

Yours faithfully,

(DR. S.P. SUBRAMANIYAN)
Assistant Controller of Patents & Designs.

Encl. : Copy of the Decision

THE PATENTS ACT, 1970

(39 of 1970) as amended by

THE PATENTS (AMENDMENT) ACT, 2005

(15 of 2005)

(with effect from 1-1-2005)

&

THE PATENTS RULES, 2003

as amended by

THE PATENTS (AMENDMENT) RULES, 2006

(with effect from 5-5-2006)

In the matter of Application for Patent bearing the number as 959/MAS/1995 filed on 27th April 1995 by M/s F.HOFFMANN-LA ROCHE AG a Swiss Company of 124 Grenzacherstrasse, CH-4002, Basel, Switzerland - Applicant And

In the matter of pre-grant opposition by way of Representation under Section 25(1) of the Patents (Amendment) Act, 2005 by The Tamil Nadu Networking People with HIV/AIDS, a community-based non-profit organization, Society Registration Number 14/2005, registered under the Societies Registration Act of 1989 in February 2005, and the Indian Network for People living with HIV/AIDS, a community-based non-profit organization, registered as a society under the Tamil Nadu Societies Registration Act in May 1997 – Opponents

HEARING HELD ON 21st January 2009

In the presence of

Mr. D.J.SOLMAN of M/s DEPENNING & DEPENNING of Chennai.

... Agents for the Applicant

Mr. ANAND GROVER of Mumbai.

... Counsel for the opponent

Dr. BINDHU JACOB

... Examiner of Patents & Designs

DECISION

M/s F.HOFFMANN-LA ROCHE AG a Swiss Company of 124 Grenzacherstrasse, CH-4002, Basel, Switzerland, hereinafter referred as applicant for patent, have filed an application for patent for their invention titled '2-(2-AMINO-1,6-DIHYDRO-6-OXO-PURIN-9-YL)METHOXY-1,3-PROPANEDIOL DERIVATIVE' on 27th day of July 1995 through their agent M/s Depenning and Depenning and it was numbered as 959/MAS/1995.

A request for examination of application for patent in the then specified Form – 19 was filed by their agent on 27th July 2004. The instant application was published under the provisions of Section 11(A) of the Patents Act (as amended) in the Patent Journal No. 06/2005 dated 25th February 2005.

Under the provisions of Section 12 of the Patents Act, 1970 the application was taken up for the examination and the First Examination Report (FER) was issued on 17th May 2006 wherein it is stated that the applicant has to comply with the office requirements within 12 months from the date of issue of FER i.e on or before 17th May 2007.

Section 25(1) of the Patents Act stipulates that where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the grounds provided there under. The Tamil Nadu Networking People with HIV/AIDS and the Indian Network for People living with HIV/AIDS, hereinafter referred as opponents in this decision, have filed a Pre-grant opposition by way of a representation on 12th July 2006 on the following grounds namely;

- i) 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 under section 25(1)(f);
- ii) That the applicant has failed to disclose to the Controller of Patents the information required by section 8 or has furnished the information which in any material particular was false to his knowledge under section 25(1) (h).

The opponents have filed their representation within the prescribed time limit and the written statements along with the evidences were taken on record. A notice with respect to the representation has been sent to the agent of the applicant along with the photocopies of the said representations on 15th November 2006 under rule 55 (3), requiring the applicant, if desired, to file their written statement and evidence, if any, in support of their application within THREE MONTHS from the date of notice according to the Rule 55(4) of the Patents (Amendment) Rules, 2006 came into force with effect from 5th May 2006.

The opponents along with written statement have filed FOUR EXHIBITs as evidences, namely;

- i) Copy of press release from Hoffmann-La Roche, 2nd April 2001
- ii) Copy of European Patent publication No. EP 0694547 A2 (hereinafter referred as '547 patent)
- iii) Copy of Online European Patent Register

iv) Copy of United States Patent No. 6083953 (hereinafter referred as '953 patent)

In reply to opponents' written statement and evidences, the applicant under the Patent Rule 55(4) has filed Reply Statements and Evidences on 30th November 2006. In the reply statement, the applicant "denied the opponents allegations that the entire application and all its claims were already in the public domain at the time of filing. Any invention belongs to public domain *only from the date of publication* and not from the day of the invention". Also stated that an annexure to Form 4 containing the filing particulars of all the corresponding foreign patent applications was filed at the Patent office with their letter no 1325 dated 8th June 1996. Subsequently, an updated annexure to Form 4 was filed with our letter number 7940 dated 23rd May 2006.

The then Controller of Patents has sent to the Counsel for the opponent on 12th November 2007 communicated that after considering the two grounds of opposition filed along with the written statement with evidences by way of opposition against the grant of patent and the reply statement filed by the applicant for the said written statement, found that the said issues have been met by the applicant and concluded to expedite the prosecution of application for patent".

On the direction of the Hon'ble High Court, Chennai the hearing was fixed initially on 20st January 2009, however the opponent requested for one day extension which is allowed and the hearing is refixed on 21st January 2009, both applicant's and opponent's representatives were present in the hearing.

Ground 1 of the pre-grant opposition u/s 25(1)(f)

Before the proceeding could be started the Counsel for the opponent submitted a rejoinder with additional documents before me and a copy to the applicant. It was vehemently opposed by the applicant for not to take any additional documents, and stated which will be seriously affect the interest of the applicant and referred the judgment and order dated 02nd December, 2008 in the Writ Petition No 24904 of 2008 and M.P.Nos 2

& 3 of 2008 of the HIGH COURT OF MADRAS has restricted the scope of hearing as under;

"We restrict the scope of consideration of pre-grant opposition with reference to the petitioner's representation only which came to be filed within the stipulated time limit as provided under Section 25(1) read along with Rule 55 of the Rules" (Kindly see para 66 of the order dated 2.12.2008)"

"The Counsel for the Applicant further argued that the Madras High Court order further records that the third respondent must hear only the petitioner and the fourth respondent on the petition's representation at the state of pre-grant opposition filed under Section 25(1) of the Act The third respondent need not consider any other pre-grant objection pursuant to this judgment. Such hearing should be completed by 31 January 2009".

"The order dated 2.12.2008 as passed by the Hon'ble High Court was challenged in the Supreme Court by the Applicant, and the same was modified vide order dated 18.12.2008, the Hon'ble Supreme Court while modifying the order dated 2.12.2008 was pleased to pass the following order:

The Assistant Controller of Patents, Designs and Trade Marks in the Intellectual Property Office shall decide the patent application no. 959/MAS/1995 on or before 31st January 2009, to the extent the impugned order is modified. We once again clarify that the matter shall be disposed of by 31st January 2009. Needless to add, while deciding the above Application, the Assistant Controller shall take into account the pre-grant opposition filed in this case (which is on record) by respondent nos. 1 & 2 herein".

"The third respondent (i.e Assistant Controller of Patent & Designs) need not consider any other pre-grant objection pursuant to this judgment"

The applicant also referred the judgment and order dated 18th December 2008 in Petition(s) for Special Leave to Appeal (Civil) No (s). 29857/2008 of the SUPREME COURT OF INDIA, "Needless to add, while deciding the above application, the

5

Assistant Controller shall take into account the pre-grant opposition filed in this case (which is on record)".

I unable to accept the contention of the opponent in view of the clear direction of the judgment and order dated 02nd December, 2008 in the Writ Petition No 24904 of 2008 and M.P.Nos 2 & 3 of 2008 of the Hon'ble High Court Of Madras in Indian Network for People Living with HIV/AIDS vs Union of India and Others wherein "The third respondent (i.e Assistant Controller of Patent & Designs) need not consider any other pre-grant objection pursuant to this judgment" and the judgment and order dated 18th December 2008 in Petition(s) for Special Leave to Appeal (Civil) No (s). 29857/2008 of the Hon'ble Supreme Court in F.Hoffmann-La Roche AG v., Indian Network for People Living with HIV/AIDS and Others directed "Needless to add, while deciding the above application, the Assistant Controller shall take into account the pre-grant opposition filed in this case (which is on record)". Hence the rejoinder filed on 19th January 2009 by the opponents has not been taken on record.

Learned Counsel for the opponents has however argued that section 25(1)(f) of the Patents Act, 1970 is an omnibus provision, which includes novelty, inventive step and inventions not patentable under the provisions of the Act and also said it is valid grounds to argue the issues of novelty and inventive step with the help of prior art documents which is already in the public domain. Further, the documents that have been appended to the rejoinder have all been referred to in the complete specifications:

- a) US Patent No. 5,043,339 (1991) [Exhibit A to the rejoinder] is referred to at page 6 of the complete specification;
- b) Beauchamp, et al, "Amino acid ester prodrugs of acyclovir" (1992) [Exhibit B to the rejoinder] is referred to at page 9 of the complete specification; and
- c) US Patent No. 4,957,924 (equivalent to EP 308065) [Exhibit C to the rejoinder] is disclosed at page 9 of the complete specification.

Further the opponent counsel argued, under the judgment of the Hon'ble Madras High Court in Novartis AG v. Union of India and others, (2007) 4 MLJ 1153, the burden is on the patent applicant to show that there is an increase in therapeutic efficacy of the

claimed substances over the known substances – i.e. valine ester of ganciclovir and / or its salts. The Patent Applicant has failed to discharge its burden with respect to increase in therapeutic efficacy over these known substances. Further, claim 9, being related to a pharmaceutical composition, fall under section 3(e).

The applicant denied that the opponent did not have any pleading in the Pre-grant Representation / Written Statement (which is on record) that

- a) the invention is not novel in view of any prior disclosure
- b) the invention is not inventive in view of any prior art teachings
- c) the invention is not patentable under Section 3(d) of the Patents Act, and
- d) the invention is not patentable under Section 3(e) of the Patents Act.

The above US patents 5,043,339 and 4,957,924 have been claimed to be submitted at the Patent Office only on 19 January 2009 with as Exhibit to the Rejoinder to the Reply Statement. These arguments travel beyond the pleadings and the Pre-grant Representation/written statement of the opponent and as such untenable. Even otherwise, these arguments appear to have been taken with the realization that the grounds raised in the written statement by the opponent do not hold any merit. However, the opponent in its Written Statement of Opposition choose to rely only on two ground namely 25(1)(f) and 25(1)(h). The fact that the opponent has not relied upon the ground of prior publication / anticipation (25(1)(b)), the ground of obviousness/lack of inventive step 25(1)(e), in its Written Statement of Opposition, is in itself is an admission on the part of the opponent that the claimed invention is novel and inventive. This is further in violation of the order dated 18.12.2008 as passed by the Hon'ble Supreme Court.

I agree with applicant's view that the opponent has not relied upon the ground of prior publication / anticipation (25(1)(b)), the ground of obviousness/lack of inventive step 25(1)(e), in the pre-grant opposition. The argument regarding novelty and inventive step by the opponents do not fall under the provisions of the 25(1)(f) of the Act which is taken as ground by the opponent in the pre-grant opposition. The provisions of section 25(1)(f) is reproduce below:-

"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."

It is cleat from the above; the provision is only related to section 3 and 4 of the Act.

Chapter II of the Act is reproduced below:-

CHAPTER II

INVENTIONS NOT PATENTABLE

Section 3. What are not inventions. The following <u>are not inventions</u> within the meaning of this Act,-

- a) an invention which is frivolous or which claims any thing obviously contrary to well established natural laws;
- b) an invention, the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
- c) the mere discovery of a scientific principle or the formulation of or discovery of any living thing or non living substance occurring in nature;
- d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least a new reactant.
 - Explanation. For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;
- e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substances;

- f) the mere arrangement or rearrangement or duplication of known devices each functioning independently of one another in a known way;
- g) --- omitted by Act 38 of 2002, s.4
- h) a method of agriculture and horticulture;
- i) any process for the medicinal, surgical, curative, prophylactic diagnostic therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products;
- j) plants and animals in whole or any part there of other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;
- k) a mathematical or business method or a computer programme per se or algorithms;
- a literary, dramatic musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;
- m) a mere scheme or rule or method of performing mental act or method playing game;
- n) a presentation of information;
- o) topography of integrated circuits;
- p) an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components;
- Section 4. Inventions relating to atomic energy not patentable. No patents shall be granted in respect of an invention relating to Atomic Energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962)
- Section 5. Omitted by the Patents (Amendment) Act, 2005

Now coming back to section 25(1)(f), the first part of the provision i.e., "that the subject of any claim of the complete specification is not an invention within the meaning of this Act," is clearly related to section 3(c) to section 3(o) of the Act, which are not inventions under provisions of the Act. Second part of section 25(1)(f), i.e., "is not patentable under this Act" is related to section 3(a), (b), (p) and section 4 of the Patents Act wherein the inventions related to section 3(a), (b), (p) and section 4 are inventions within the meaning of this Act, but those inventions are not patentable inventions under the provisions of this Act. Therefore the opponents argument regarding novelty and inventive step [section 2(1)(j) and section 2(1)(j)a] will not fall under the ground of opposition section 25(1)(f) taken by the opponent. Therefore, the ground taken by the opponent under section 25(1)(f) is not relevant for novelty and inventive step.

I agree with applicant's argument that the documents referred during the hearing with respect to novelty and inventive step were neither discussed nor submitted as evidence in the pre-grant opposition wherein the documents cited were very much available in the public domain at that point of time. The opponent have not mentioned or objected under therapeutic efficacy at the time of filing the opposition and there was no supporting document provided to that effect. The rejoinder was filed in the last movement that to one day before the hearing date. The documents filed with the rejoinder are in the public domain at the time filing the pre-grant opposition, but it is not mentioned in the representation. The opponents' fresh objection in written argument on the section 3(d) and 3(e) of the Act as follows:-

"the documents appended to the rejoinder have all been referred to in the complete specification"

It is only added to the written argument filed after the hearing, but not objected at the time of filing pre-grant opposition or during hearing. Therefore new documents filed along with the rejoinder on 19th January 2009 much after the direction of the Hon'ble High Court of Madras for hearing the case can not be taken on record as I was directed by the Hon'ble Court to hear the case <u>with the documents on record</u>. In view of the above the rejoinder filed can not be taken on record.

10

8

The opponent argued that the present patent application ought to be rejected as it claims priority from a pre-1995 convention country application. The Indian patent law does not contemplate product patent applications for pharmaceuticals that were invented prior to 1st January 1995. The Patents (Amendment) Ordinance, 1994, which allowed for mailbox filings and exclusive marketing rights, clearly shows that only those claims were permitted where the invention was made in India after 1st January 1995 or in a country other than India and before filing the claim in India, an application claiming the identical substance was filed in a convention country on or after 1st January 1995. Thus, product patent applications relating to pharmaceutical applications or agrochemicals in India either have to be first-time filings post-1st January 1995 or claim priority from an application filed in a convention country post-1st January 1995 under the provisions of the Patents (Amendment) Act, 1999. Therefore, the present application ought to be rejected, as it is a convention country application claiming priority from 1994 and not after 1st January 1995.

The applicant opposed the opponents' argument that any product relating to pharmaceutical and agricultural chemical invented prior to 1995 falls in the public domain. In the present case, the patent-under-dispute was filed for the first time on 28-07-1994 in USA while it was filed subsequently in India on 27-07-1995. Since it was filed within the India – specific stipulation 12 months, by virtue of the over-riding effect/primacy of Section 135 over Section 137(3), the Patent Applicant's Application cannot be held un-patentable on this ground of 'prior disclosure' / 'fallen into the public domain of knowledge. Therefore, the product invented prior to 1995 falls in the public domain is totally false and not supported neither by the Act nor the Rules. Thus, the opponent has completely failed to establish the grounds of opposition under Section 25(1)(f).

I unable to accept the above submission of the opponent's view on the subject matter of the invention of the present case in the **public domain** as the molecule invented before 1st January 1995. The question of **public domain** will only arise when the subject matter of the invention published or used prior to the filing date or priority date of the application. In the present case, the application was first filed in US patent application

number 08/281,893 dated 28th July 1994 and subsequently filed in India vide patent application number 959/MAS/1995 filed on 27th July 1995 and European Patent Office vide European patent Application No. 95111319.0 was filed on 19th July 1995, the said European Patent Office (EPO) application published by said EPO as publication number EP 0694547 A2 on 31st January 1996, which was filed along with the pre-grant representation as Exhibit-2. The copy of the Online European Patent Register dated 9th June 2006 filed as Exhibit-3, which is relevant to EPO publication referred above (Exhibit-2). The opponent also provided the United States Patent 6,083,953 (Exhibit-4 of the pre-grant opposition) published on 4 July, 2000. The opponent submitted a copy of the press release dated 2nd April 2001 as Exhibit-1 issued by Hoffmann-La Roche (the applicant for the patent) wherein they stated "Valganciclovir was discovered in 1994 in Palo Alto ----". Moreover the said EPO application and the said US Patent are claiming the priority of 1994 US application which is priority application for the instant application also. All the evidences as Exhibits 1-4 are published much after the date of filing of the instant application (27th July 1995). Therefore, it is clear from the above, the given documents submitted (Exhibits-1-4) by the opponent are not in public domain as on the filing date of the instant application. Therefore, the documents filed along with the pre-grant opposition as evidence along with the opposition are not relevant to this case.

Ground 2 of the pre-grant opposition u/s 25(1)(h)

As per records, the applicant filed the information as required under section 8(1) in Form 4 along with the application on 27th July 1995, later on additional information was filed on 10th June 1996, and subsequently the applicant filed additional and updated the already submitted information on 23rd May 2006.

The opponents counsel argued that section 8 casts a mandatory, positive obligation and mandatory on patent applicants to provide the information regarding foreign filings to the Patent Office within a specific time period. However, it is clear that section 25(1)(f) has to be read in conjunction with section 8, which prescribes the time period. Admittedly, the list provided on or about 6 June 1996 is delayed beyond the prescribed time period and is not accompanied by any petition for condonation of delay or extension of time. Secondly, the list submitted on or about 23 May 2006 also has been

filed after a long delay. The Patent Office has rejected the Patent Applicant's petition under rule 138 seeking extension of time. It appears that the 2006 list has been allowed under a petition under rule 137, which is impermissible under law. Any order of the Patent Controller in this behalf is null and void and cannot be given effect to. Thus, under the patent law, the lists provided by the Patent Applicant in 1996 and 2006 cannot be considered to be on record. Without prejudice to the above, the Opponents submit that even if the lists are considered, it clearly shows that information regarding foreign filings was not provided to the Patent Office within the prescribed time period.

The applicant replied that the statement and undertaking under section 8 (Form 4) have been filed on the day of filing this application (i.e. on 27 July 1995). The Form 4 contained the details of the US priority application no. 281893. annexure to Form 4 containing the filing particulars of about 35 corresponding foreign applications was filed on 8 July 1996. An updated annexure to Form 4 with details of about 83 corresponding foreign applications procedure (i.e. belated submission of details of foreign applications) was also filed with the prescribed fee. As per Rule 137, the Controller has power to correct any irregularity in procedure which in the opinion of the Controller may be obviated without detriment to the interest of any person. It is very important to note that all the particulars of the corresponding foreign applications were disclosed to the Controller well before the present pre-grant opposition was filed by the opponent on 12th July, 2006. A copy of granted European patent No. 694547B had submitted and intimated the granted US patent nos. 5840891, 5856481 and 60833953 on 23 May 2006 to the Controller of Patents. The cover page of the US patent clearly indicates that US application 08/281,893 and 08/453,223 had been abandoned. Copies of the above 3 US patents were submitted with the applicant reply statement itself.

The applicant further argued that the above ground has two issues.

- (i) The applicant has failed to disclose to the Controller the information required by Section 8, and
- (ii) The applicant has furnished the information which in any material particular was false to his knowledge.

The applicant further argued, Section 25(1)(h) does not give right to the opponent to challenge whether the information required by Section 8 has been disclosed within the prescribed time period, especially in the light of the fact that the Patent Applicant had already sought, and obtained, leave of the Ld. Controller for the condonation of delay under Rule 137 on 23rd May 2006, which was well before the filing of the Opponent's Written Statement.

From the filing of the instant application in 1995 and up to the last date of deciding the application i.e 17th May 2007, the procedure (Act and Rules) for filing information and taking extension for filing the said information with a petition to the Controller were changed number of times during the period 1995 to 2007 (around 12 years).

The relevant section and rules for filing the foreign particulars at the time of filing date of the application are reproduced below:

<u>Section 8</u>. (1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application-

- (a) a statement setting out detailed particulars of such application is being prosecuted, the serial number and date of filing of the application and such other particulars may be prescribed; and
- (b) an undertaking that, up to the date of the acceptance of his complete specification filed in India, he would keep the Controller informed in writing, from time to time, of details of the nature referred into clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

Rule 13 (1) Statement and undertaking regarding foreign applications.- (1). The statement and undertaking required to be filed by an applicant for a patent under sub-section (1) of section 8 shall be made in Form 4.

(2) The time within which the applicant for a patent shall keep the Controller informed of the details in respect of other applications filed in any country outside India in the undertaking to be given by him under clause (b) of sub-section (1) of section 8 shall be three months from the date of such filing.

Rule 123 Power of Controller generally.- Any document for the amendment which no special provision is made in the Act may be amended and irregularity in procedure which in the opinion of the Controller may be obviated without detriment to the interests of any person, may be corrected if the Controller thinks fit and upon such terms as he may direct.

Rule 124 Power to extend the time prescribed. The time prescribed by these rule for the doing of any act or the taking of any proceeding there under may be extended by the Controller, if he thinks fit and upon such terms as he may direct.

The relevant section and rules for filing the foreign particulars at the time of deciding the application are reproduced below:

Section 8 Information and undertaking regarding foreign applications.- (1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through along with his application ³¹[or subsequently ³²[within the prescribed period as the Controller may allow]]-³³

- (a) a statement setting out detailed particulars of such application; and]
- (b) an undertaking that, ³⁴[up to the date of grant of patent in India], he would keep the Controller informed in writing, from time to time, of ³⁵[detailed particulars as required under] clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

Rule 12 Statement and undertaking regarding foreign applications.—
(1) The statement and undertaking required to be filed by an applicant for a patent under sub-section (1) of section 8 shall be made in Form 3.

¹³[(1-A)The period within which the applicant shall file the statement and undertaking under sub-section (1) of section 8 shall be [six months] from the date of filing the application.

Explanation.- For the purpose of this rule, the period of [six months] in case of an application corresponding to an international application in which India is designated shall be reckoned from the actual date on which the corresponding application is filed in India]

Rule 137 Powers of Controller generally.- Any document for the amendment of which no special provision is made in the Act may be amended and any irregularity in procedure which in the opinion of the Controller may be obviated without detriment to the interests of any person, may be corrected if the controller thinks fit and upon such terms as he may direct.

Section 138 Power to extend time prescribed.- (1) Save as otherwise provided ⁷[in the rules 24B, sub-rule (4) of rule 55 and sub-rule (1-A) of rule 80], the time prescribed by these rules for doing of any act or the taking of any proceeding there under may be extended by the Controller for a period of one month, if he thinks it fit to do so and upon such terms as he may direct.

(2) Any request for extension of time made under these rules shall be made before the expiry of prescribed period.

The day on which the application was filed, time period for providing information relating to the application filed in other countries substantially same invention u/s 8 and u/r 13(2) of the Patent Act 1970 and Patent Rules 1972, was three months from the date of filing and the applicant can take extension at anytime till grant. The said provision for obtaining extension was prevailed till the Patents (Amendment) Act, 2002 and the Patents Rules, 2003. Under provisions of Section 8, rule 12 of the Patents (Amendment) Act, 2005 and Rules, 2006, time for providing said information is within six months from the date of filing. A request for extension of time is one month, which shall be made before expiry of prescribed period u/r 138. Even though the application was filed in 1995 under Black Box provision/WTO application (Prosecution of the applications filed under black box provision from 1st January 1995 was deferred up to 31st December 2004), the prosecution of the instant application was started in 2006 after the introduction of product patent regime introduced from 1st January 2005.

Yes, I agree with the applicant's arguments that the ground of opposition under section 25(1) (h) is only limited to (i) the applicant has failed to disclose to the Controller the information required by Section 8, and (ii) has furnished the information which in any material particular was false to his knowledge. The opponent have neither argued nor submitted any evidence regarding the applicant not disclosing the information and giving wrong information to the Controller, in the opposition ground taken under section 25(1)(h). The opponents argument are pertaining to the timeline (delay in filing and

taking the extension) for filing the information i.e., delay in filing the information to the Patent Office which is purely procedural aspect during prosecution of the application and not at all ground for opposition under section 25(1)(h). Under the provisions of the Act and Rules the Controller has the power to extent the time and condone the irregularity in the procedure, if the applicant prays for such an action with a relevant petition and fees. Hence the then Controller has taken the information on record after allowing the applicant's prayer with a petition. Therefore, the second ground of opposition above u/s 25(1)(h) is not maintainable.

In view of the discussion in the preceding paragraphs, considering the relevant arguments put forward by the Counsel for the opponents and Agent for applicant at the hearing, the **documents on record** and the relevant written submissions made by both the parties and all the circumstances of the case, the pre-grant opposition filed by the opponents under section 25(1) (f) and section 25(1) (h) of the Act is accordingly dismissed without any order as to costs.

Dated this 30th day of January, 2009.

(Dr. S.P.SUBRAMANIYAN)

Assistant Controller of Patents & Designs

Copy to:

1) Ms. R. Vaigai,

(Advocate for The Tamil Nadu Networking People with HIV/AIDS and Indian Network for People living with HIV/AIDS),

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2) Mr. D.J. Solomon, c/o M/s De Penning & De Penning 120, Velachery Main Road, Guindy, Chennai – 32.