

**THE PATENTS ACT, 1970.  
SECTION 25 (2)**

In the matter of the  
Patents (amendment) Act, 2005  
and  
In the matter of the  
Patents (amendment) Rules, 2006.  
and  
In the matter of the Patent Application  
No. (863/MUMNP/2003)  
and  
In the matter of the Patent No. 204091  
and  
In the matter of opposition u/s 25(2) on  
the grant of Patent thereon.

**PFIZER PRODUCTS INC. ... Patentee**  
**DR. REDDY'S LABORATORIES LIMITED ... Opponent**

**HEARING HELD ON 02<sup>nd</sup> November, 2010**

**BEFORE**

**DR. AMARENDRA SAMAL  
ASSISTANT CONTROLLER OF PATENTS & DESIGNS**

**Present:**

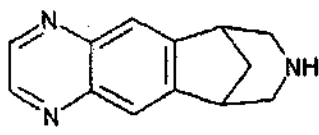
1. Mr. S. Majumdar & Ms. M. Venkatesh                      Opponent's Attorneys
2. Mr. Jitesh Kumar & Ms. Payal Kalra                      Patentee's Agent
3. Dr. Sharana Gouda                                              Examiner of Patents & Designs

**DECISION**

This is a post-grant opposition under section 25(2) of Patents (amendment) Act, 2005 and the corresponding Rules 55-A to 62 of Patents (amendment) Rules, 2006, by Dr. Reddy's Laboratories Limited, India (herein after referred to as opponent) after grant of a patent to Pfizer Products Inc. of Eastern Point Road, Groton, Connecticut 06340,

USA (herein after referred to as patentee) on their patent IN 204091 (Application No. 863/MUMNP/2003) for an invention relating to "COMPOUND OF 5,8,14-TRIAZATRACYCLO[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>]-HEXADECA-2(11),3,5,7,9-PENTAENE". The said patent application was filed as a PCT national phase application on 12<sup>th</sup> September, 2003 and was published on 21<sup>st</sup> October, 2005 under section 11-A of Patents (amendment) Act, 2005. As a matter of prosecution of the patent application under the provisions of the Act, as well as in view of applicant's request for examination, the said application was examined under section 12 and 13 of the Act and later on was granted a patent (IN 204091). Notification of such grant was published on 25<sup>th</sup> May, 2007 under Section 43(2) of the Act. The claims of the granted patent which is exclusively for protection of a product are as follows:

1. The compound of 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene.



2. A compound as claimed in claim 1 wherein the said compound is anhydrous L-tartrate salt.
3. A compound as claimed in claim 1 wherein said compound having at least one of the following powder x-ray diffraction pattern peaks expressed in terms of 2θ as measured with copper radiation chosen from: 6.1, 16.8 and 21.9.
4. A compound as claimed in claim 1 wherein said compound having the following principal powder x-ray diffraction peaks expressed in terms of 2 θ and d-spacings as measured with copper radiation:

Angle	d-value (Å)
6.1	14.5
12.2	7.2
13.0	6.8
14.7	6.0
16.8	5.3
19.4	4.6
21.9	4.1
24.6	3.6

5. A compound as claimed in claim 2 wherein said compound having solid state<sup>13</sup>c NMR resonance peaks at 178.4, 145.1, and 122.9 ppm.

6. A compound as claimed in claim 1 wherein said compound having at least one powder x-ray diffraction pattern peaks in terms of  $2\theta$  measured with copper radiation chosen from: 5.9 and 21.8.
7. A compound as claimed in claim 1 wherein said compound having the principal powder x-ray diffraction pattern peaks in terms of  $2\theta$  and d-spacings measured with copper radiation.

Angle $2\theta$	d-value (Å)
5.9	15.0
12.8	6.9
14.4	6.1
15.3	5.8
16.9	5.2
17.2	5.2
21.8	4.1
23.8	3.7
25.1	3.5

8. A compound as claimed in claim 5 wherein said compound having the solid state  $^{13}\text{C}$  NMR principal resonance peaks at: 179.2, 178.0, 144.4, 124.8 and 122.5 ppm.
9. A compound as claimed in claim 1 wherein said compound is a hydrate of L-tartrate salt and a hydrate.
10. A compound as claimed in claim 8 wherein said compound having at least one of the powder x-ray diffraction pattern peaks in terms of  $2\theta$  as measured with copper radiation chosen from: 11.8, 16.5, 23.1 and 26.5.
11. A compound as claimed in claim 8 wherein said compound having the principal powder x-ray diffraction pattern peaks in terms of  $2\theta$  and d-spacings as measured with copper radiation.

Angle $2\theta$	d-value (Å)
0.2)	0.2)
5.9	15.1
11.8	7.5
16.5	5.4
21.2	4.2
23.1	3.8
23.8	3.7
23.8	3.7
26.5	3.4

12. A compound as claimed in claim 11 wherein said compound having solid state  $^{13}\text{C}$  NMR principal resonance peaks: 179.0, 176.1, 147.5 and 144.5 ppm.

An opposition under section 25(2) of Patents Act, and corresponding Rule 55-A of Patents Rule was filed on 26<sup>th</sup> May, 2008 by the opponent, accompanied by full written statement with the annexure relying upon various grounds of opposition. The patentee also filed reply statement under Rule 58 of Patents Rule on 29<sup>th</sup> July, 2008 along with affidavit of Dr. George J. Quallich as expert. The opponent then filed evidence-in-reply along with expert evidence by K. Sumesh Reddy on 29<sup>th</sup> September, 2008 as required under Rule 59 of Patents Rule and served a copy to the patentee. The opposition board constituted u/r 56 of Patents Rule submitted their report and joint recommendation on 09<sup>th</sup> June, 2009.

**Various grounds of opposition as relied upon by the opponent are as follows:**

- (a) Under Section 25 (2)(b), i.e anticipation by prior publication;
- (b) Under Section 25 (2)(c), i.e. prior claiming;
- (c) Under Section 25 (2)(e), i.e. obviousness and lack of inventive step;
- (d) Under Section 25 (2)(f), i.e. not an invention or patentable invention;
- (e) Under Section 25 (2)(g), i.e. lack of clarity and insufficiency of description;
- (f) Under Section 25(2)(h), i.e. failure to disclose details of corresponding foreign applications;

Hearing under Rule 62 of Patents Rule, 2003 (as amended), was fixed on 2<sup>nd</sup> November, 2010, at 11.00 A.M. vide office letter dated 28<sup>th</sup> September, 2010 and both the opponent and patentee were intimated to attend the hearing and address their pleadings already on record.

As per the above schedule, hearing was conducted and the opponent initiated the arguments by first analyzing the claims of the impugned patent and put forth the points for invalidation of all the claims. However, the opponent was advised to discuss the said issue while arguing on the specific ground of opposition they have relied.

The patentee also argued that the affidavit of Mr. K. Sumesh Reddy submitted by the opponent is not in compliance with Rule 59 as it is not strictly confined to the matters in

the patentee's evidence. The said affidavit additionally discusses the case "Pfizer, Inc. v Apotex Inc" which was not a matter in the patentee's evidence. However, I put forth my opinion that the said landmark case which is frequently referred is an instance wherein the whole public including the patentee and the opponent learn from it. Referring the said case in opposition proceedings under Rule 59 does not mean that the evidence filed by the opponent contains some additional document and the patentee is not aware of the said case. So, I do not admit the patentee's contention to dismiss the alleged evidence but allows it to take on record for discussion in appropriate juncture.

The patentee with regard to the granted claims further argued that the 'tartrate salt' were replaced in claim 1 with the word 'compound' during the prosecution only because the Examiner had raised an objection at the time of issuance of First Examination Report which should be actually read as tartrate. The opponent resisted the patentee's contention and expressed that such an act by the patentee was to get rid of the objections under Section 3(d) of Patents Act. However, my observations under such a circumstance are as follows: After the opposition is filed and also during hearing under Rule 62 of Patents Rule, 2003 (as amended), the patentee is aware of the fact that the granted claims suffer from erroneous presentation. However, they have failed to propose any amendment during hearing but seeking only Controller's direction to carry out amendment is surprising. The intention of the patentee for not proposing amendment on claims to clarify the error is not clear.

The opponent has relied on the following prior art documents for the shake of argument which are as follows: The nomenclatures like D1, D2, D3 ---- etc. which appears below will adhere to the rest of the proceedings.

- (a) **D1**: 598/DEL/2001 granted as IN 193961 which claims the priority of US provisional application 60/207,629 dated 26<sup>th</sup> May, 2000, before the claimed priority date of the impugned patent;
- (b) **D2**: EP 1078637, which was published on 28<sup>th</sup> February, 2001;
- (c) **D3**: WO/1999/35131, which is published on 15<sup>th</sup> July, 1999;

- (d) **D4**: Salt selection for basic drugs, International Journal for pharmaceutics, 33 (1986), 201-217, Gould et.al.; and
- (e) **D5**: Pharmaceutical Salts, Journal of Pharmaceutical Sciences, January 1977, volume 66, Number 1, Berge et.al.

Now I would like to make a complete view on the arguments and submissions by both the parties in the hearing taking into account separately various grounds of opposition and various documents relied upon by them.

**1. Invention claimed in any of the claims of the patentee's invention is not novel in view of prior publication under section 25(2)(b) of the Act.**

The opponent argued that D3 page 4, line 13 defines R10 and R17 as a group having the formula (C<sub>0</sub>-C<sub>6</sub>)-alkoxy-(C<sub>0</sub>-C<sub>6</sub>)-alkyl and when R10 and R17 are independently selected such that the number of carbon atoms is zero, the resulting compound is a compound which is otherwise known as 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene, the free base compound claimed in the impugned patent. D3 teaches the pharmaceutically acceptable acid addition salt such as tartaric acid (line 16, page 10) of formula I. Again D2 teaches 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene as one of the preferred compound as seen in lines 30 and 31 at column 6 and further lines 13 and 14 at column 7 teaches that the compounds in their pharmaceutically acceptable forms and optical isomers are included. The opponent states that the publication date of D2 (i.e. 28/02/2001) is prior to the priority date of the impugned patent (i.e. 14/05/2001).

However, the patentee argued that their invention discloses a selection invention claiming the specific tartarate salt of 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene, which has improved capabilities in terms of low hygroscopicity. The prior art as cited by the opponent D3 and D2 (indirectly since D3 takes reference of D2) has been referred in the subject patent. The patentee further argues that the tartrate salt possess unexpected and significant superior properties when compared with the closest prior art admitted by the opponent wherein the comparison of the hygroscopicity

of the tartrate salt and hydrochloride salt has been provided in the affidavit of Dr. Quallich. The L-tartrate salt form B (anhydrous) and L-tartrate salt form C (monohydrate), both picked up less than 0.5% of water content by weight under conditions of 90% humidity whereas the hydrochloride salt gained 64% of water by weight. Such a difference in hygroscopicity is important in the development of pharmaceutical products for several reasons including its impact on the *in vivo* activity of the drug and the ability to stably maintain the drug under typical manufacturing and storage conditions.

- 2. 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 that of applicant's claim Sec. 25(2)(c);**

The opponent submitted that D1 discloses the tartrate salt form of the compound in claim 16 which being a dependent claim, would evade the application of multiple claim dates. The opponent further contended that as per Section 11(5) of Patents Act, where any claim would have two or more priority dates, the priority date shall be the earlier or earliest of those dates. Accordingly, the impugned patent has a priority date 14<sup>th</sup> May, 2001 which is later than the priority date 26<sup>th</sup> May, 2000 of D1, thereby allowing its application as a document depicting a prior claim. Since the claim as claimed in claim 2 is same as claim 16 of D1, which although published later has a priority date and therefore it clearly falls under the mischief of section 25(2)(c) and ought to be revoked.

The patentee however argued that D1 claims priority from an application filed in United States on 26<sup>th</sup> May, 2000 and the reference to varenicline was added to the specification/claims for the convention filing in 2001 in Cuba and separately in Trinidad/Tobago. Thus, the priority date for the information regarding varenicline, including Example 5, is 15<sup>th</sup> May, 2001 which is after the priority date of the subject application.

**3. Invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step under section 25(2)(e) of the Act.**

The opponent argued to establish that invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step. The opponent furthered the submission by ascertaining that since a ground of obviousness can't be applied to an invention that is admittedly not novel, the contentions and discussions surrounding the ground of obviousness without prejudice to the ground of anticipation.

They say that D2 and D3 provide substantial motivation and direction to an individual attempting to prepare a salt form of the base compound. They further argue that when experimenting for salt forms, an individual would refrain from trying different, unknown and untested salts at random and refer to the document D5 wherein in Table I on page 2 indicate that as per universal logic, the most frequent of these salts would be used for experimentation and tartrate was present in top ten most frequently used FDA approved salts, and is the fifth most used salt having a frequency percentage of 3.35%. Therefore the present invention claimed in the impugned patent is wholly devoid of an inventive step in view of D2 and D5. The opponent also relied on lots of cases like, US CAFC decision in the matter of Pfizer Inc. vs. Apotex Inc, 2006-1261; T – 0442/02-3.3.1; etc. to say that the claimed invention in the impugned patent lack inventive step and is obvious to a person skilled in the art.

The patentee strongly denied such contention of the opponent and states that apart from the disclosure of D2 and D3 as discussed under Section 25(2)(b), D4 and D5 discuss salts in general and do not discuss the claimed tartrate salt of 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene. The patentee further argued that, these documents do not provide any hint that tartrate salt of 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene will possess unexpected and significant superior properties. The subject patent is a selection invention that discloses and claims the specific tartrate salt of 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene which has improved capabilities. The difference in hygroscopicity is important in the development of pharmaceutical products for several

reasons, including its impact on the *in vivo* activity of the drug and the ability to stably maintain the drug under typical manufacturing and storage conditions. The unexpected and surprising decrease in hygroscopicity of the granted tartrate salts is non-obvious to the worker skilled in the art.

**4. 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(2)(f) of patents Act.**

The opponent has relied upon Section 3(d) of patents Act and stated that 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 and the L-form of the tartaric acid addition salt of varenicline is not patentable as it is a new form of a known substance which does not have any enhanced efficacy over the known form i.e., varenicline thereby not significantly differing in therapeutic efficacy over the known prior art compound. The opponent has relied on some of the judgments/decisions on this specific issue (e.g. (i) Novartis AG & Anr. Vs. Union of India & Others., (2007) 4 MLJ 1153; (ii) Patent application nos. 1354/DEL/98; 1440/MAS/1998; 729/DEL/1998 etc.) wherein it is stated that increase in stability/physical properties does not correspond to enhance efficacy of a compound. They also state that unless properties like stability, anhygroscopicity, solubility etc. can be correlated to an enhanced efficacy, the compounds fail to satisfy the criterion of Section 3(d) and hence ought to be revoked.

The patentee's attorneys strongly resisted the opponent's contention that the said compound is a novel compound and are not a new form of known substance and accordingly, the granted patent does not come within the mischief of Section 3(d) of the Act. It is submitted that the claimed tartrate salt has unexpected and surprising lower hygroscopicity as compared to the hydrochloride salt. The L-tartrate salt form B (anhydrous) and L-tartrate salt form C (monohydrate), both picked up less than 0.5% of water content by weight under conditions of 90% humidity whereas the hydrochloride salt gained 64% of water by weight. Such a difference in hygroscopicity is important in the development of pharmaceutical products for several reasons including its impact on the *in vivo* activity of the drug and the ability to stably maintain the drug under typical manufacturing and storage conditions.

**5. The complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed under section 25(2)(g) of patents Act.**

The opponent contended that the specification and description provided by the Patentee was not substantial or detailed enough to allow a person skilled in the art to successfully work the invention. The data provided by the patentee lacked merit due to dearth of accurate data, as well as discrepancy in the claims with regard to the sufficiently and clearly describing the invention. The patentee failed to provide data in the specification supporting the lower hygroscopicity of tartrate salt over other salt forms.

The patentee in their defense expressed that over 50 patents have been granted on corresponding applications filed in various countries where the complete specification fulfilled the test of describing the invention sufficiently and best mode of carrying out the invention.

**6. The applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information in which any material particular was false to his knowledge;**

The opponent contends that the patentee has failed to comply with the requirements of Section 8 of the Act. They state that they adopts the statements made in full written statement which says that the patentee has failed to comply with the requirements of Section 8 of the Act and therefore liable to be rejected on this ground.

Contrary to the Opponent's allegation, the patentee says that they have complied with the requirement of Section 8 of Patents Act during the prosecution of Patent application as evident from the Form 3 filed in Patent office.

*After hearing the opponent and the patentee, their arguments, the documents they have relied upon, and the report and joint recommendation of the Opposition Board, I am drawing the following conclusions parawise on each and every grounds of opposition.*

At the outset I find that the patentee's submission at each and every stage of opposition as well as argument is based on as if the claims are amended to avoid the errors they have made before. Apart from the argument on the originally granted claims,

the opponent has also argued on the outcome of the claims as if amended. In absence of any proposal for amendment to the claims, I will be deciding the case based on the originally granted claims on record.

**A. Referring to the ground of opposition u/s 25(2)(b), that the Patentee's invention is not novel,** I find that D3 page 4, line 13 defines R10 and R17 as a group having the formula (C<sub>0</sub>-C<sub>6</sub>)-alkoxy-(C<sub>0</sub>-C<sub>6</sub>)-alkyl and when R10 and R17 are independently selected such that the number of carbon atoms is zero, the resulting compound is a compound which is 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene, the free base compound claimed in the impugned patent in claim 1. D3 teaches the pharmaceutically acceptable acid addition salt such as tartaric acid (line 16, page 10) of formula I which anticipates the invention claimed in claim 2 and its dependent claims also. D2 teaches 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene as one of the preferred compound as seen in lines 30 and 31 at column 6 whose publication date is 28/02/2001, prior to the priority date of the impugned patent 14/05/2001.

*I conclude that the invention claimed in claims 1 and 2 and its dependent claims by the patentee is not novel and the opponent's ground of opposition is validly established.*

**B. Referring to the ground of opposition u/s 25(2)(c), on prior claimed invention,** I agree with the opponent's contention that that D1 discloses the tartrate salt form of the compound in claim 16 whose priority date is 26<sup>th</sup> May, 2000 earlier than the priority date of the impugned patent 14<sup>th</sup> May, 2001. However, incorporation of such a provision as a ground of opposition is to avoid double patenting on the same invention. The valid and granted claims of D1 is exclusively for a process patent whose scope of protection is to be adjudged by the provision contained under Section 48 of Patents Act, before commencement of Product patent regime in India prior to 01<sup>st</sup> January, 2005. The said section which is repealed by amendment of Patents Act after 01<sup>st</sup> January, 2005, pronounces that "where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using,

offering for sale, selling or importing for those purposes the product obtained directly by that process in India: **Provided that the product obtained is not a product in respect of which no patent shall be granted under this Act**". Publication of Acceptance of D1 dates back to 04<sup>th</sup> September, 2004, who's granted process claims can't cover the scope of protection to the extent of product obtained by the process. So I differ with the view of the opponent that the product claims granted in the impugned patent is same as the granted process claim of D1. I infer that the provision of Section 11(5) of Indian Patents Act, as argued by the opponent can't stand valid.

*Hence, the opponent's ground of opposition is not validly established.*

- C. Referring to the ground of opposition u/s 25(2)(e), on obviousness,** I have stated before that invention claimed in claim 1 and consequently its dependent claims are anticipated by D3 and claims 2 and its dependent claims are anticipated by D2. This view leaves no choice to further evaluate the inventiveness of the claimed invention in the impugned patent and I would not appreciate to further discuss on such a ground of opposition.

*I conclude that the patentee's claimed invention is not novel and hence not inventive as well.*

- D. Referring to the grounds of opposition u/s 25(2)(f), not an invention within the meaning of this Act, or is not patentable under this Act;** I am of the opinion that such a ground of opposition is worth to discuss as the patentee has not proposed any amendment to the granted claims to rectify the error happened during prosecution, but the opponent has argued expecting such an amendment in advance. I find that the patentee has not provided any data to substantiate enhancement of efficacy of the claimed invention. What the patentee has submitted is that the said compound is a novel compound and is not a new form of known substance and accordingly, the granted patent does not come within the mischief of Section 3(d) of the Act. It is submitted that the claimed tartrate salt has unexpected and surprising lower hygroscopicity as compared to the hydrochloride

salt. The L-tartrate salt form B (anhydrous) and L-tartrate salt form C (monohydrate), both picked up less than 0.5% of water content by weight under conditions of 90% humidity whereas the hydrochloride salt gained 64% of water by weight. Such a difference in hygroscopicity is important in the development of pharmaceutical products for several reasons including its impact on the *in vivo* activity of the drug and the ability to stably maintain the drug under typical manufacturing and storage conditions.

While analyzing the claims of the impugned granted patent, I would certainly like to draw the content of section Section 3(d) of the Patents (amendment) Act, 2005 is described as below:

*“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 the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant.”*

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

As per the provision of the above section certainly the L-tartrate salt of the known substance 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene which the applicant claims should show an enhanced efficacy over the known compound. On the interpretation of Section 3(d) and the explanation there under by Madras High Court in the matter of Novartis AG & Anr. Vs. Union of India & Others, (2007) 4 MLJ 1153, the Court held that *“Therefore it is clear from the amended section and the explanation that in the pharmacology field, if a discovery is made from a known substance, a duty is cast upon the patent applicant to show that the discovery had resulted in the enhancement of a known efficacy of that substance and in deciding whether to grant a Patent or not on such new discovery, the Explanation creates a deeming fiction that all derivatives of a known substance would be deemed to be the same substance unless it*

*differ significantly in properties with regard to efficacy. In our opinion, the amended section and Explanation give importance to efficacy. We have already referred to the meaning of "efficacy" as given in Dorland's Medical Dictionary. Scientifically it is possible to show with certainty what are the properties of a "substance". Therefore when the Explanation to the amended section says that any derivatives must differ significantly in properties with regard to efficacy, it only means that the derivatives should contain such properties which are significantly different with regard to efficacy to the substance from which the derivative is made. Therefore in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the Patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy."*

Taking into consideration the results provided, the arguments offered during hearing, the submission made by the opponent as well as the patentee and the findings from judgment of Madras High Court as made in the above para, I do not find any substantial data that the L-tartrate salt of the known substance 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene which the applicant claims shows an enhanced efficacy over the known compound 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene. The patentee has failed to provide any data in support of the granted claims especially with reference to the requirement under Section 3(d) of Patents Act. In absence of substantial data that would be supporting that the L-tartrate salt of the known substance is possessing enhanced efficacy. I am not convinced that the claims possessing the L-tartrate salt of 5,8,14-triazatracyclo[10.3.1.0<sup>2.11</sup>.0<sup>4.9</sup>] hexadeca-2(11),3,5,7,9-pentaene, would be a patentable invention.

*I conclude that such a ground of opposition is validly established by the opponent.*

**E. Referring to the ground of opposition u/s 25(2)(g), on insufficiency, I see that the disclosure in the granted patent is clear and sufficiently describe the invention as**

claimed and the method by which it is to be performed. From the disclosure of the invention a person skilled in the art would be able to perform the invention without any ambiguity.

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

**F. Referring to the ground of opposition u/s 25(2)(h), failure to disclose details of corresponding foreign applications;** I find that the patentee has provided the statement and undertaking in Form 3 in details. The opponent has not brought to the notice of the Controller their findings in respect of which the patentee has not provided the details corresponding foreign applications filed.

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

Considering the post-grant opposition, report and recommendation of Opposition Board, pleadings of both parties and in view of my above findings, I hereby order **revocation** of the patent IN 204091 granted on Patent Application No. 863/MUMNP/2003. **There is no award of costs to either party.**

Dated this 23<sup>rd</sup> Day of May, 2011.

**(DR. AMARENDRA SAMAL)**

**Asst. Controller of Patents & Designs**

**Copy to :**

1. Mr. S. Majumdar of S. Majumdar & Co., 5, Harish Mukherjee Road, Calcutta – 700 025, State of West Bengal.
2. Mr. Jitesh Kumar of Remfry & Sagar, Remfry House at Millennium Plaza, Sector 27, Gurgaon – 122 002., New Delhi National Capital Region, India.
3. The concerned post grant opposition file and register of Patent.