BEFORE CONTROLLER OF PATENTS THE PATENT OFFICE, MUMBAI

In the matter of section 25(2) of The Patents Act,1970 as amended by The Patents (Amendment) Act, 2005

And

In the matter of The Patents Rules, 2003 as amended by The Patents (Amendment) Rules, 2006

And

In the matter of Patent No.231479 (Application No: 96/MUM/2005)

APPLICANT: **TROIKAA PHARMACEUTICALS LTD.**, TROIKAA PHARMACEUTICALS LTD, COMMERCE HOUSE 1, SATYAMARG, BODAKDEV, AHMEDABAD 380 054

OPPONENT: **LINCOLN PHARMACEUTICALS LTD.,** NIRAV COMPLEX, OPP. NAVRANG HIGH SCHOOL, NARANPURA, AHMEDABAD- 380014, GUJARAT, INDIA,

Hearings held on: 03/12/2018, 03/01/2019, and 13/12/2019.

Present in hearing:

1) **Agents representing the Applicant: Dr.Prabuddha Ganguli, Mr. Himanshu Kane and others**
2) **Agents representing the Opponent: Dr. Gopakumar Nair, Mrs. Aruna Sree and others**
3) **Dr.Ajay Thakur, Asstt Controller of Patents & Designs & Chairman of Opposition Board**
4) **Dr.Latika Dawara, Asstt Controller of Patents & Designs & Member of Opposition Board**

DECISION

The Post-grant opposition proceedings in subject Patent Application bearing No. 96/MUM/2005 and Granted Patent No. 231479 is disposed under Section 25(2) of the Patents Act read with corresponding Rule 55 of The Patents Rule, 2003 (as amended).

A. Back Ground of the Application:

1. An application for a patent bearing number 96/MUM/2005 was filed in Patent Office, Mumbai on 01st February, 2005 entitled "Injectable preparations of Diclofenac and its pharmaceutically acceptable salts. A Request for Examination under Section 11-B was filed on 30th October, 2006 and was assigned a Request No. 2294/RQ-MUM/2006. As per the provision under Section 11-A of Patents Act, the said application was published on 10th August, 2007.

2. The said application was examined in accordance with the provisions of the Patents Act, 1970 and the First Examination report was issued on 14.01.2008 and the reply to First Examination submitted on 22.02.2008. Upon reply to first examination report (hereinafter called FER) FER, further examination carried out on 14.07.2008 reply to which was submitted on 30.07.2008 amending the specification and claims thereof on 30.07.2008. A Pre-grant opposition filed on 31.10.2007, by Neon Labs Ltd. The said pre-grant oppositions were prosecuted and heard by the then Learned Controller Dr. B.K. Singh. The application was recommended for Grant of the Patent on 04.03.2009. The grant was published on 27.03.2009 in the official journal of the Patent office.

3. Prosecution history of the case,

Consequently, a writ petition (No. 211 of 2010) in the Bombay High Court was filed by Neon against the grant of the patent on the grounds that fair hearing and Natural Justice was denied on opposition to the amended claims. As per the judgment dated 26.11.2010 of the Bombay High Court, while setting aside the grant of the patent, the Patent Office was directed to give personal hearing to Neon and the Patentee. Hence, the hearing was fixed on 19.01.2011.

On 18.02.2011, the Patentee replied to Opponent's response (dated 07.10.2008) to amended claims along with Affidavit. Subsequently, the hearings continued from 23.02.2011 and were concluded on 28.02.2011.

In the meantime, on 23.12.2008, pre-grant Opposition was filed by Mr. Hiren Patel and on 11.02.2009 Pre-grant Opposition was filed by Lincoln Pharma. The Patentee filed their reply to Pre-grant Opposition on 13.02.2009. On 26.02.2009 hearing between Lincoln (Opponent) and Troikaa (Patentee) was held at the Patent Office.

Thereafter, all the three pre-grant oppositions were rejected by Patent office, Mumbai and the patent was granted on 15.04.2011. On 13.05.2011, the grant of the patent was published as *"earlier date of grant of patent 04/03/2009 has been changed to 15/04/2011"*.

5. Subsequent to the publication, the Opponent (M/s. Lincoln Pharma Pvt Ltd) filed a Post - grant opposition under Section 25(2) of the Patents Act, 1970 on 19th March, 2012 along with Form-7 and written statement of opposition for the revocation of the said Patent.

6. Accordingly, agent for Patentee has filed petition under Rule 138 of Patents Rules 2003 as amended by the Patents (Amendment) Rules, 2006 on 28th March, 2013 for extending the period for submission of the reply statement/evidence u/r 58 by one month to 08th May, 2013 and submitted the reply statement and evidence on 08th May, 2013. The Agent for opponent filed petition u/r 138 for the extension of time of one month for filing reply evidence under rule 59 on 10th June, 2013. The agent for the opponent filed reply evidence under Rule 59, along with permission to file further evidence under Rule 60 on 09th July**,** 2013.

7. upon completion of procedural part, the Opposition Board under S*ection 25(3), and* U/r. 56 of The Patents Act was constituted consisting of three technical experts, subsequently the joint findings of the Board and the recommendation of the Opposition Board was submitted under Rule, 56 of the Patent Act, on 12.12.2013.

8. A notice of hearing along with board recommendations were forwarded to both the parties on 11th November, 2014 and the final hearing was concluded on 13.12.2019. After hearing both the parties submitted their written submissions.

9. Before getting into the details of this opposition and the grounds mentioned vis-à-vis a cited prior art documents. Before going to decide technical grounds, I will first decide the Preliminary objection on the ground of "res-judicata" raised by the agent of the applicant.

B. Preliminary objection on the ground of Res Judicata:

1. The Patentee contented that the post-grant opposition is barred by the principles analogous to "res-judicata" as contained in Section 11 of the Code of Civil Procedure, 1908

because the very same Opponent had filed pre-grant opposition to the Patentees Patent Application No.96/MUM/ 2005 corresponding to its Patent No.231479 inter alia on the same grounds as contained in the present post-grant opposition. The Opponent also argued and presented their side. After considering the arguments of both the parties and hearing submissions, it is my considered view that the concept of "res-judicata" is applied to avoid repetitive litigations in an irksome manner. After going through the arguments of both the parties and from the decisions cited by the learned agent of the Opponent, it is clear that the Supreme Court, High Court of Delhi and IPAB are of the opinion that the post-grant opposition is the only remedy for a 'person interested', after his failure at pre-grant stage. The agent of the opponent also argued that there are additional documents under analysis are different at pre-grant and post-grant stages. I am of the opinion that the ground of res-judicata does not apply in this application.

2. To arrive at this , I herein refer to the landmark decision of Delhi High Court in the cases - UCB Farchim SA v Cipla Limited and ors; Colorcon Inc v Ideal Cures Pvt Ltd & Ors; Colorcon Inc v Ideal Cures Pvt Ltd & Ors; Yeda Research & Development Co. Ltd vs Natco Pharma Limited; Eli Lilly & Co. v Ajanta Pharma Limited. Ors; Eli Lilly & Co v Ranbaxy Laboratories Ltd & Ors, wherein the High Court considering the situation - Where the pre-grant opposition is rejected and patent is granted. The Delhi High Court in this case clearly pointed out differences between the pre and post grant oppositions, on para 13 : *"13.In the first instance a distinction has to be drawn between a pre-grant opposition and a post-grant opposition. While a pre-grant opposition can be filed under Section 25 (1) of the Patents Act at any time after the publication of the patent application but before the grant of a patent, a post-grant opposition under Section 25(2) of the Patents Act has to be filed before the expiry of one year from the date of the publication of the grant of patent. A second significant difference, after the amendment of 2005, is that a pre-grant opposition can be filed by "any person" whereas a post-grant opposition under Section 25(2) can be filed only by "any person interested". It may be noticed that the application for revocation of a patent in terms of Section 64 of the Patents Act can also to be filed only by "any person interested". In other words, the post-grant opposition and the application for revocation cannot be filed by just about any person who is not shown to be a person who is "interested". A third significant difference is that the representation at the stage of pre-grant is considered by the Controller himself. Rule 55 of the Patents Rules requires the Controller to consider the statement and evidence filed by the applicant and thereafter either refuse to grant the patent or require the*

complete specification to be amended to his satisfaction. Of course, in that event notice will be given to the applicant for grant of patent who can file his reply and evidence. This Court finds merit in the contention that the pre-grant opposition is in fact "in aid of the examination of the patent application" by the Controller. The procedure is however different aspect as far as the post-grant opposition is concerned. There in terms of Section 25(3), the Controller has to constitute an Opposition Board consisting of such officers as he may determine and refer to such Opposition Board the notice of opposition along with other documents for its examination and recommendations. After receiving the recommendations of the Opposition Board, the Controller gives the patentee and the opponent an opportunity of being heard. The Controller then takes a decision to maintain, amend or revoke the patent. The fourth major difference between the pre-grant and the post-grant opposition is that while in terms of Section 117 A an appeal to the IPAB is maintainable against the order of the Controller in a post-grant opposition under Section 25(4) of the Patents Act, an appeal has not been expressly been made available against an order made under Section 25(1) of the Patents Act".

3. The Delhi High Court also in the same case has observed at paragraphs 15-16, 18 - where the pre-grant opposition is rejected and the person who has filed that opposition happens to be a person interested has in fact two remedies a) the remedy of either filing a post-grant opposition u/s 25(2) or b) an application before the IPAB under Section 64 of the Patents Act for revocation of the patent. The relevant paragraphs 15, 16 and 18 of this decision are reproduced as below: *"15. In the eventuality, where the pre-grant opposition is rejected, it is apparent from the decision in J. Mitra and from a reading of Section 25 with section 117A that as long as the person who has filed that opposition happens to be a person interested, he would, after 1st January 2005 [the date with effect from which section 25(2) came into force although the provision was introduced only on 4th April 2005] have the remedy of filing a post-grant opposition. He can, after 2nd April 2007, also file an application before the IPAB under Section 64 of the Patents Act for revocation of the patent. In other words, as explained by the Supreme Court in J.Mitra & co. as long as that person is able to show that he is a 'person interested', he is not without a remedy after his pre-grant opposition is rejected. He in fact has two remedies. Even if his post-grant opposition is rejected, he can thereafter file an appeal to the (PAR under Section 117A. Against the decision of the IPAB in either event he will have the remedy of seeking judicial review in accordance with law by filing a petition in the High Court. At this juncture it may be noticed*

that in an order dated 2nd March 2009 in SLP (C) No. 3522 of 2009 (Indian Network for People with HI V/AIDS v. F. Hoffman-La Roche) the Supreme Court permitted the unsuccessful pre-grant opposer, who had challenged the rejection of his opposition by the Controller, to participate in the post-grant stage.".

4. 16. The law is well settled that notwithstanding that a High Court has the power and the jurisdiction under Article 226 of the Constitution to interfere with the orders of any statutory authority which is of a quasi-judicial nature; it will decline to exercise such jurisdiction where there is an efficacious alternative statutory remedy available to the aggrieved person. See for e.g., Special Director v. Mohd. Ghulam Ghouse (2004) 3 5CC 440 [para 5 at page 443] Uttaranchal Forest Development Corp. v. Jabar Singh (2007) 2 SCC 112 [paras 43-45 at page 137], U. P. State Spinning Company Ltd. v. R.S.Pandey (2005) 8 SCC 264 [paras 11-24 at pages 270-275], Titaghur Paper Mills Company Ltd. v. State of Orissa (1983) 2 5CC 433 [para 6 at pages 437-438; paras 8 & 9 at page 439; para U at page 441], Karnatalca Chemical Industries v. Union of India (2000) 1OSCC 13 [para 2 at page 14] Assistant Collector of Central Excise v. Jainson Hosiery Industries (1979) 4 SCC 22 [para I at page 23] and U.P. Slate Bridge Ltd. v. U.P. Rajya Setu Nigam S. Karamchari Sangh (2004) 4 5CC 268 [para ii at pages 275-276; para 17 at page 278]."

5. "18. To summarise this part of the discussion, as regards persons who have not succeeded in the pre-grant opposition stage to prevent the grant of a patent, and are persons 'interested' within the meaning of Section 25(2) and Section 64 of the Patents Act, their remedy against the rejection of their pre-grant opposition is to file a post-grant opposition under Section 25(2) and await the decision of the Controller. If they are still aggrieved by that decision under Section 25(4) of the Patents Act, they can file an appeal before the IPAB in terms of Section 1 17A of the Patents Act."

Thus the Delhi High Court, has clearly identified, three important distinguishing features between pre-and post-grant procedures: a) The first distinguishing feature, a pre-grant opposition under Section 25 (1) is before the grant of a patent whereas a post-grant opposition under Section 25(2) of the Patents Act has to be filed before the expiry of one year from the date of the publication of the grant of patent. b) The second, a pre-grant opposition can be filed by "any person" whereas a post-grant opposition can be filed only by "any person interested". c) The third significant difference is that "the representation at the stage of

pre-grant is considered by the Controller himself", therefore, pre-grant opposition is in fact "in aid of the examination" of the patent application by the Controller, whereas in post-grant opposition, in terms of Section 25 (3), the Controller has to constitute an Opposition Board and after receiving the recommendations of the Opposition Board, the Controller gives the patentee and the opponent an opportunity of being heard. The Controller then takes a decision to maintain, amend or revoke the patent. Also from the combined reading of the paragraph 13 with that of paragraphs 15 to 18 of the cited decision of the Delhi High Court it is clear that the procedures and the manner of analysis are totally different. Hon'ble Court has clearly expressed its view that where the litigant is the "person interested", he can reappear in the post-grant proceedings. The contention of the learned agent of Patentee that the same proceedings was already held doesn't hold good as it was a proceeding under pre-grant and thus stands separate from the post-grant procedures. Therefore, the principle of Res Judicata is not applicable to this case.

6. Having dealt with the Preliminary objection that the ground of "res-judicata" raised by the agent of the applicant.

I further proceed on the grounds on which the actual opposition is based.

C. the Claims upon which the Patent is granted:

1) Injectable preparations of viscosity ranging from about 1.5 to 3.50 CPS and pH of ~8-9 containing 75-100mglml of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac in a solvent system comprising combinations of at least two or more co-solvents/solubilisers selected from differing classes, wherein the monohydric alcohol(s) is upto~15% v/v, preferably 4-8% polyhydric alcohol(s) is upto~25% v/v, preferably upto 15%, tetrahydrofurfuryl alcohol, propylene glycol ether (glycofurol) up to ~25 % v/v of preferably upto~15%; with water as principal solvent, such that the total amount of co-solvent/solubilisers does not exceed 35%v/v of the composition.

2) Injectable preparations of viscosity ranging from about 1.50 to 4.7 CPS and pH of -8-9, containing 75 mg/ml of diclofenac

sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, comprising,

cosolvents /solubilisers such as a monohydric alcohol ~ 4 % to 25% % v/v, or a polyhydric alcohol ~ 27 % to 45 %v/v, or tetrahydrofurfuryl alcohol propylene glycol ether (glycofurol)~18 % to 35"% v/v, in combination with water as principle solvent.

3) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-2, wherein the said diclofenac salt is selected from alkali metal salts, diethyl ammonium salts.

4)Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-3, wherein the co-solvents/ solubilisers are selected from differing classes of monohydric alcohols such as benzyl alcohol, ethyl alcohol, polyhydric alcohols such as propylene glycol, polyethylene glycols with molecular weight 300 to 600 Dalton, glycerin and 1, 3-butylene glycol.

5) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-4, wherein the polyhydric alcohol is polyethylene glycol 300, polyethylene glycol 400, and polyethylene glycol 600.

6) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-5, wherein benzyl alcohol as the sole co-solvent /solubiliser for 75mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, is incorporated at ~4% to 25% v/v.

7) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-6, wherein benzyl alcohol as co-solvent I co-solubiliser in combination with other co-solvents, for the 75mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, as well as for the 100 mg/ml concentration of diclofenac sodium or its

therapeutically equivalent amounts of water-soluble salts of diclofenac, the amount of benzyl alcohol used is up to about 15 %v/v preferably reduced to about 4-8% v/v.

8) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-7, wherein polyhydric alcohol such as propylene glycol as sole co-solvent/solubiliser for 75 mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, is in the range of ~27 % v/v to ~45 % v/v.

9) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-7, wherein polyhydric alcohol is polyethylene glycol 400.

10) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-8, wherein polyhydric alcohol ,such as propylene glycol, polyethylene glycol 400 as co-solvent/ solubiliser in combination with other co-solvents/ solubilisers, for 75mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac as well as for the 100mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, the amount is up to~ 25 v/v% v/V, preferably ~15% v/v.

11) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-7, wherein tetrahydrofurfuryl propylene glycol (glycofurol) as sole co-solvent/solubiliser, for 75 mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, is in the range of ~18-35 % v/v.

12) Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-7, and 11 wherein tetrahydrofurfuryl propylene glycol (glycofurol) as a co-solvent /

solubiliser with other co-solvents/solubilisers, for 75mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac as well as for the 100 mg/ml concentration of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, the amount is upto about 25 v/v % , preferably up to15 % v/v.

13) A process for the preparation of-1 ml injectable preparations containing 75 mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac as claimed in claim 1, wherein the water soluble diclofenac salt is suspended in a solvent system comprising a combination of requisite quantities of solvents chosen from at least two or three different classes of co-solvents/solubilisers selected from monohydric alcohol/s and/or polyhydric alcohol/s, and I or tetrahydrofurfuryl alcohol propylene glycol ether (glycofurol), under inert conditions to which sterile water for injection is added with stirring maintaining inert conditions, followed by addition of buffer and antioxidant, adjusting the pH between 8 - 9 using alkali, followed by diluting with sterile water for injection to achieve the concentration of ~75 mg in 1 ml.

14) A process- for the preparation of ~1 ml injectable preparations containing 100mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac as claimed in claim 1, wherein the water soluble diclofenac salt is suspended in a solvent system comprising a combination of requisite quantities of solvents chosen from at least two or three different classes of co-solvents/solubilisers selected from monohydric alcohol/s and or polyhydric alcohol/s, and I or tetrahydrofurfuryl alcohol propylene glycol ether (glycofurol), under constant nitrogen bubbling to which sterile water for injection is added with stirring and nitrogen bubbling, followed by addition of buffer and antioxidant, adjusting the pH between 8 -9 using alkali, then diluting with sterile water for injection to achieve concentration of -100 mg in 1 ml.

15)A process for the preparation of ~1 ml injectable preparations containing 75 mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac as claimed in claim 2, wherein the water-soluble diclofenac salt is suspended in requisite quantities of either monohydric alcohol or polyhydric alcohol, or tetrahydrofurfuryl alcohol propylene glycol ether (glycofurol), under inert conditions, to which sterile water for injection is added with stirring maintaining inert conditions, followed by addition of buffer and anti-oxidant, adjusting the pH between 8-9 using alkali, then diluting with sterile water for injection to achieve concentration of -75 main 1 ml.

16) A process for the preparation of injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-15, wherein the antioxidant is selected sodium salts such as sodium bisulphite, sodium metabisulphate, the alkali is selected from hydroxides such as sodium hydroxide, potassium hydroxide, and the buffer system is a phosphate buffer, bicarbonate buffer.

D. GROUNDS OF OPPOSITION:

The opponent relied on the following grounds of opposition U/S 25(2):

1. U/S25(2)(b): that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim

(i) In any specification filed in pursuance of an application for a patent made in

India on or after the 1st day of January, 1912; or

(ii) In India or elsewhere, in any other document;

2. U/S25 (2) (c): 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 claim of the patentee 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 the claim of the patentee;

3. U/S25(2)(d): that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim;

4. U/S25(2)(e): 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 section 25 (2) (b)or having regard to what was used in India before the priority date of the Patentee's claim;

5. U/S 25 (2) (f): 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;

6. U/s. 25 (2) (g): that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;

E) Documents relied (cited prior arts documents) in support of Grounds of opposition

The opponent has relied upon the cited following prior arts documents in support of the opposition**.**

1) INDIAN PHARMACOPOEIA (IP) 1996 (ANNEXURE III) (herein after referred to as D1)
2) CH 694034 A5 (ANNEXURE IV) (herein after referred to as D2)
3) US Patent No. 5554650 (ANNEXURE VI) (herein after referred to as D3)
4) Indian Patent No. INI92711 (ANNEXURE VII) (herein after referred to as D4)
5) US Patent No US4711906 (ANNEXURE VIII) (herein after referred to as D5)
6) US Patent No. 5389681 (ANNEXURE IX) (herein after referred to as D6)
7) Article titled “A New Injectable Solvent (Glycofurol)" (Annexure X) and (English

translation of the said article) Annexure (ANNEXURE X (a)) (herein after referred to as D7)

The Patentee had submitted two experts Affidavits of (Mr. Ketal Patel and Dr. Rajesh Parikh) with detailed data and explanations, which were already on record.

The Opponent has submitted a document from Dr. M.M. Patel, however, the same does not satisfy the bear minimum legal standards of an affidavit, and hence the said document cannot be legally considered to be an Affidavit. Clearly, there is no Affidavit by any expert by the Opponent on record. Therefore, there is No Affidavit in Reply on record by the Opponent as Per Rule 59.

Before proceeding with the technical arguments, the Patentee reiterated that the Patentee had submitted two Affidavits of experts (Mr. Ketan Patel and Dr. Rajesh Parikh) with detailed data and explanations, which were already on record. The patentee further reiterated that none of these affidavits have been challenged by the opposition with and expert affidavits from their side. Therefore, it is stated and accepted that the Opponent has fully conceded to the expert opinions in the Affidavits provided by the Patentee. In all arguments put forth by the Opponent, neither reference has been made to the Affidavits of the Patentee that are on record, nor has the Opponent provided any reasoned explanations by way of challenging them.

The Patentee submits that the Opponent has submitted a document from Dr. M.M. Patel, however, the same does not satisfy the bear minimum legal standards of an affidavit, and hence the said document cannot be legally considered to be an Affidavit. Clearly, there is no Affidavit by any expert by the Opponent on record. Therefore, there is No Affidavit in Reply on record by the Opponent as Per Rule 59.

E. ARGUMENTS ON MERITS AND HEARING SUBMISSIONS

1. After hearing both the parties and considering the written submissions made in this regards, now I will discuss the arguments of the Opponent & its rebuttal by the Applicant on the opposition grounds.

2. As far as Preliminary Issues are concerned, all the relevant issues are taken into consideration while deciding the case.

Regarding the P atentee's contention that the documents filed by the opponent cannot be considered as evidence since they have not been filed as an affidavit as mandated by

section 79 of The Patents Act, it is a settled position that lack of novelty has to be judged only on the basis of prior publication and/or use, whereas inventive step has to be looked into on the basis of prior art in combination with the common general knowledge. Moreover, rule 57 of The Patents Act requires the filing of the written statement and the facts on which the opponent makes out his case. The requirement of evidence to be filed is optional. If the opponent is successful in proving obviousness on the basis of documents in combination with the common general knowledge, then additional evidence may not be required. Section 79 does not appear to have any relevance in the present case as the evidence filed by the Opponent i.e. the document filed by the Opponent of Dr. M.M. Patel is not in the form of affidavit, therefore not taken on record. When evidence is filed then Section 79 has to be looked into. **In this regard, the opponent has pleaded his case on the various documents relied upon by them in their written statement. Whether these documents relied upon by the opponent in combination with the common general knowledge will be adequate to establish their challenge on the ground of obviousness will be dealt with hereinafter.**

Techno-legal Analysis and Conclusions;

From the above pleadings, it appears that the Opponent and the Applicant have cited a number of grounds and case laws to establish their stand. Some of the points are irrelevant /superfluous and some of the points are relevant and worth discussing in the instant patent application under post- grant opposition. As far as the time line and procedural part of the procedure as defined in the law are concerned, both the opponent and the applicant are well disciplined. However, the plethora of grounds, prior art documents and case laws put forth by both the parties are irrelevant in nature need not be addressed. Both the parties have unnecessarily overburdened the Controller by citing different case laws. However, I am concerned with the relevant documents, relevant grounds of opposition and relevant case laws. Following Decision is based on the outcome of invention disclosed, analysis of the relevant documents, affidavits and case laws, and the argument made by both the opponents and applicant.

Having considered the detailed arguments of both the parties, the opposition boards opinion, comments of both the parties on the opposition board recommendations, the teachings of

the various prior art documents on record, the affidavit (s) filed by both the parties, I shall now deal with each ground of the opposition as discussed during the hearing.

The grounds of section 25(2) (d) and 25(2) (f) i.e. Section 3(d) of The Patents Act were dropped by the Opponent and accordingly, these grounds of Opposition are treated as withdrawn and therefore I am not going into these grounds for further consideration.

f) <u>GROUND 1: NOVELTY UNDER SECTION 25(2) (B) OF THE PATENTS ACT, 1970</u>

That the invention so far as claimed in any claim of complete specification has been published before the priority date of the claim (Section 25 (2) (b) of The Patents Act, 1970)

Determination of novelty, for a new invention to be patentable as specified in Section 2(1) (j) of The Patents Act, 1970, is that the new invention has to be any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.

To prove this ground of Opposition U/s. 25(2) (b) Novelty, the Opponent relied on the cited documents D6/D2/D3.

The Opponent contented that the impugned patent under opposition claims more than one invention i.e. in Claim 1 as well as Claim 2, there are more than one novelty destroying prior art documents against elements of the invention claimed in impugned patent under opposition (for e.g. US5389681(D6), CH694034(D2) and US554650(D3).

At this juncture, I would rely on the decision of Hon'ble IPAB, In OA/8/2009/PT/CH(250/2012) rejected novelty ground *"to defeat novelty, the appellant should show that an earlier document, disclosed all that the patentee is seeking to patent. And that each limitation of the claimed invention is found in a single prior art reference. The appellant has not done this. So, the ground of novelty is rejected.*

Thus, it is a well settled law in patents that in order to destroy the novelty of an invention each and every particular feature of the invention must be disclosed in a single document. D6 or D2 or D3 fails to disclose each and every particular feature of the claimed injectable diclofenac solution and hence the present invention is clearly novel over each and every

particular cited document especially with respect to cited document D6/D2/D3.None of this cited prior arts i.e. D6/D2/D3, in *toto* discloses all the features injectable diclofenac solution as claimed in the impugned patent under opposition. I agree with the opposition Board joint recommendations in respect of the Novelty objection U/s. 25(2)(b). *Accordingly, I conclude that such a ground of opposition is not validly established by the Opponent.*

G) GROUND 2: INVENTIVE STEP UNDER SECTION 25(2) (e) OF THE PATENTS ACT, 1970

a) The technical analysis of impugned patent under opposition for the purpose of Section 25(2) (e) assessment of inventive Step /obviousness.

1. Upon scrutiny, and thorough analysis of the complete specification and claims available on record that an original and as granted claims, it is clear that the field of invention as disclosed in the complete specification at Page 2 is high concentration preparation of injectable diclofenac salts that are capable of being administered by intradeltoid route, over and above the intragluteal and slow intravenous route.

Further the background of the invention clearly mentions that the Diclofenac is used, most commonly, as the Sodium or potassium salt for relief from pain and inflammation such as Musculoskeletal and joint disorder including rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis. It is also useful in peri-articular disorders such as renal coli, acute gout, and dysmenorrhea following surgical procedures. It has also been used in some countries for the management of fever. The back ground also mentions at Para 2 pages no 2, that the British National Formulary recommends intramuscular injection into the gluteal muscle. Likewise, Martindale, the pharmacopoea recommends intragluteal injections. And the other route of administrations recommended is by IV infusion.

The background also discloses that the Diclofenac injections have to be administered deep intramuscularly and are generally administered intragluteally as the injection causes substantial pain at the site of injection and its administration in the deltoid (Upper arm) region is generally avoided.

It clearly indicates that the pain at the site of injection is due to relatively large volume of the injection (3ml) and the fact that the injection solution contains relatively high volumes of propylene glycol. It's a known irritant upon parenteral administration. However, Applied Nursing Research , Vol 16 No.2 August , 2002 empirical data from published research reports, recommendations that of established advisory panels and generally accepted

scientific principles conclude that only small volumes of medication (2ml or less) should be given in the deltoid site. But, the Nursing, Jan 1997 recommends the use of deltoid muscle only for volumes of 1 ml or less.

At the last Para clearly indicates intramuscular injection volumes above 2 ml and upto 5 ml must be administered into the gluteal muscle, because the gluteal muscle is larger as compared to the deltoid muscle and hence can accommodate the relatively larger injected volume (3-5) on the other hand if this relatively larger volume is injected into the deltoid muscle, which has relatively lesser muscle mass, the injected solution will cause excessive stretching of the muscle fibre , thereby damaging the local muscle tissue and hence, cause pain and discomfort to the patient. As mentioned in the specification at page 3, Para 2 that the injectable diclofenac preparation contains relatively high amounts (18 to 40%) of propylene glycol, which is a known irritant, most importantly the Hand book of excipients, further reports that aqueous solution of 2% propylene glycol iso-osmotic with serum causes 100% haemolysis of erythrocytes in 45 min.

Therefore, the formulators subject patent have attempted to eliminate propylene glycol from the formulation in order to minimize pain at site of the injection by reducing the volume of injection (Para 3 page 3) of the complete specification.

2. Accordingly, the inventors of the subject patent set an object, that a main object of the invention is to provide injectable formulations of water soluble salts of diclofenac, which cause significantly less pain at the site of injection and that can be administered by intradeltoid route, in addition to intragluteal and slow intravenous route. Another object of the invention as enumerated in the specification is to provide single doses of less than 2ml. Another object of the invention as seen is to provide injectable preparation containing 75 mg and 100 mg of water – soluble salts of diclofenac , in about 1 ml injection solution.

Also another object of the invention is to provide a full therapeutic dose of 75 mg & 100 mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac in 1 ml without substantially increasing the viscosity.

Another object of the invention disclosed is to provide an injectable preparation of water-soluble salts of diclofenac, without the use of surfactants, and preferably, a minimized quantity of co-solvents to avoid any possible side effects.

Finally, the formulations are adjusted to pH 6 to 10 containing up to 75mg or 100mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac, in a medium comprising of water, in combination with one or more class of co-solvent(s) / solubiliser(s), antioxidants, preservatives, buffers, alkali and stabilizers.

In the background Section, the complete specification discloses of diclofenac uses and problems associated with administration routes particularly, the pain associated due to large volume of injection. Also some prior arts are discussed which discloses certain injectable preparations of diclofenac and its salts thereof.

3. On scrutiny of the complete specification, it is observed the the crux of the invention drowned from the plain reading of complete specification including field of the invention, back ground, and objects thereto described in the specification. Primarily, the invention intended to reduce the pain at site by eliminating an irritant that caused by "propylene glycol" while injecting the formulation through the routes of intradeltoid and intragluteal, in order to meet the said object. The inventors have attempted to prepare formulation using known diclofenac salts, water soluble- Diclofenac salts in solvent system. The solvent system consisting of two or more co-solvents / solubiliser selected from differing classes , wherein the Monohydric alcohol(s) is upto 15% v/v, preferably 4-8% , polyhydric alcohol(s) is upto 25% v/v, preferably upto 15%, tetrahydrofurfuryl alcohol, and propylene glycol ether (glycofurol) upto 25% v/v of preferably upto 15%, with water as principal solvent, such that the total amount of co-solvent / solubiliser does not exceed 35% of the composition.

Hence, the primary claim as granted which reads as under"

1. Injectable preparations of viscosity ranging from about 1.5 to 3.50 CPS and pH of ~8-9 containing 75 -100 mg/ml of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac in a solvent system comprising combinations of at least two or more co-solvents / solubilisers selected from differing classes, wherein the monohydric alcohol(s) is upto ~15% v/v, preferably 4-8%, polyhydric alcohol(s) is upto ~25 % v/v, preferably upto 15%, tetrahydrofurfuryl alcohol, propylene glycol ether (glycofurol) up to ~25 % v/v of preferably upto ~15%; with water as principal solvent, such that the total amount of co-solvent/solubilisers does not exceed 35%v/v of the composition.

However, the claims 4 as granted which reads as under,

4. Injectable preparations of pharmaceutically accepted salts of diclofenac as claimed in claims 1-3, wherein the co-solvents / solubilisers are selected from differing classes of monohydric alcohols such as benzyl alcohol, ethyl alcohol, polyhydric alcohols such as propylene glycol, polyethylene glycols with molecular weight 300 to 600 Dalton, glycerin and 1, 3-butylene glycol.

Therefore, it's apparent from the reading of claim 1 with its dependant claim 4, wherein the propylene glycol is used.

4. In accordance with well settled principle, that the inventor should follow the steps to obtain a patent, that they shall initially identify the problem associated with prior art. As per as the problem is concerned the inventor has identified that a pain caused during the

administration through intradeltoid and intragluteal route, the reason found for causing a pain due to injection of high volume of the formulation. In addition to that the inventor has also found a problem that the pain caused by use of Propylene glycol (page 3 Para 3 of specification) which acts as irritant, consequently, patentee tried to eliminate the irritant (page 3 Para 3 of specification). The patentee formulated a formulation consisting of Diclofenac Salts, in defined solvent system taking care of reduced volume without increase of the viscosity that is maintained between 1.50 CPS to 4.7 CPS in less volume less than 2 ml with an active ingredient selection between 75 & 100 mg/ml. It is observed and found that entire specification describes and directed to reduce the pain at site during injection by routes of intradeltoid and intragluteal. However, the specification do not describes un-expected advanced therapeutic efficacy with respect to an active compound called Diclofenac salt, because the formulation is been made out using the Diclofenac salts in different solvent system.

5. Further the Complete Specification (page 5) discloses that it has surprisingly been found that it is possible to prepare high concentration injection solution containing 75 mg/ml of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, having viscosities ranging from about 1.50 to 4.7 CPS, capable of being administered by intradeltoid route, the intragluteal and slow intravenous route using co-solvents/solubilisers such as a monohydric alcohol ~ 4 % to 25% % v/v, or a polyhydric alcohol ~27 % to 45 % v/v, or tetrahydrofurfuryl alcohol, propylene glycol ether (glycofurol) ~18 % to 35% v/v , in combination with water as principal solvent,

or,

using a solvent system comprising of combinations of at least two or more co- solvents solubiliser selected from differing classes, wherein the monohydric alcohol(s) are upto ~15% v/v, preferably 4%-8%, polyhydric alcohol(s) are upto ~25 % v/v, preferably 15%, tetrahydrofurfuryl alcohol propylene glycol ether (glycofurol) upto ~25% v/v preferably upto 15%; with water, such that the total quantum of co-solvent/solubiliser does not exceed 35% v/v of the composition.

It has also been found that, it is possible to prepare high concentration injection solution containing upto 100 mg/ml of diclofenac sodium or its therapeutically equivalent amounts of water-soluble salts of diclofenac, having viscosities ranging from about 2.60 to 3.50 CPS, capable of being administered by intradeltoid route, the intragluteal and slow intravenous route, using a solvent system comprising of combinations of at least two or more co-solvents solubiliser selected from differing classes, wherein the monohydric alcohol(s) is upto ~15%

v/v, preferably 4-8%, polyhydric alcohol(s) is upto ~25 % v/v, preferably upto 15%, tetrahydrofurfuryl alcohol propylene glycol ether (glycofurol) up to ~25% v/v of preferably upto -15%; with water, as principal solvent, such that the total quantum of co-solvent/solubiliser does not exceed 35% v/v of the composition.

The co-solvents/solubiliser when used in judicious synergistic combination are selected from three classes of solvents such as monohydric alcohols, polyhydric alcohols and glycofurol, to achieve solubilisation of the diclofenac salt in high concentrations without substantially increasing the viscosity.

6. Further the specification clearly discloses 10 examples for the parental preparations and the invention has 16 claims as seen in the earlier part of the decision. From the above analysis it is clear that the present invention provides preparations of concentrated solutions of water-soluble salts of diclofenac and tried to reduce the volume of injection to 1ml without substantially increasing the viscosity of the injectable that are easily administered with minimization of pain at site of injection. Further, smaller volume enables administration in the deltoid muscle teaches judicious selection and synergistic use of minimum amount of different classes of co-solvents/solubiliser, in combination with water to formulate novel high concentration injection solutions of 75mg and 100 mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac, in about 1 ml without substantially increasing the viscosity, thereby minimizing pain and any possible side effects.

b) The technical analysis/findings of the cited Prior Art documents [8(1) to 8(2)] for the purpose of Section 25(2) (e) assessment of inventive Step /obviousness.

The opponent has cited 7 prior art documents published before making the present patent application, out of 7 prior art documents 5 documents which are cited were also cited during pre-grant proceeding, However, in the post - grant opposition there are two more new prior art documents cited to oppose the patent under section 25(2) mainly in the ground of obviousness for assessment. These are 1) INDIAN PHARMACOPOEIA (IP) 1996 (ANNEXURE III) (herein after referred to as D1) and 2) US Patent No. 5554650 (ANNEXURE VI) (herein after referred to as D3)

1) INDIAN PHARMACOPOEIA (IP) 1996 (ANNEXURE III) (herein after referred to as D1)

2) CH 694034 A5 (ANNEXURE IV) (herein after referred to as D2)

3) US Patent No. 5554650 (ANNEXURE VI) (herein after referred to as D3)

4) Indian Patent No. INI92711 (ANNEXURE VII) (herein after referred to as D4)

5) US Patent No US4711906 (ANNEXURE VIII) (herein after referred to as D5)

6) US Patent No. 5389681 (ANNEXURE IX) (herein after referred to as D6)

7) Article titled “A New Injectable Solvent (Glycofurol)" (Annexure X) and (English translation of the said article) Annexure (ANNEXURE X (a)) (herein after referred to as D7)

The opponent had relied upon all above cited prior art documents to asses an inventive step and argued during the course of hearing and after hearing both the parties have submitted post hearing written submission thereof. Accordingly, the cited prior arts (7) have been considered to arrive a decision underground of opposition, as the assessment of the inventive step been assessed by reading each elements in individual prior art documents or in combination of prior art documents are being assessed to arrive a decision. Therefore, that two new prior art cited document are being assessed in combination with remaining prior art documents to arrive a decision on the said ground.

1) INDIAN PHARMACOPOEIA (IP) 1996 (ANNEXURE III) (herein after referred to as D1)

The document D1 is an Indian Pharmacopoeia 1996 Edition and relates to monograph of Diclofenac injection. This document discloses; Diclofenac Sodium Injection Diclofenac Injection

Diclofenac Injection is a sterile solution of Diclofenac Sodium in Water for Injections. It may contain Propylene Glycol, Benzyl Alcohol and sufficient Sodium Hydroxide to adjust the pH of the solution. Description: Clear, colourless to yellowish liquid Usual Strength: 25mg per ml.

Standards: Diclofenac Sodium Injection contains not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of diclofenac sodium, C14H10C12NNa02. pH: Between 8.1 and 9.0"

It is clear from this Indian Pharmacopeia (IP) document (D1), that Diclofenac Sodium Injection is known in the art along with use of benzyl alcohol, propylene glycol and sodium hydroxide and water in its preparation and having a pH between 8.1 and 9.0.

The Indian Pharmacopoeia is a statutory document and has to be complied by every pharmaceutical manufacturer for all drugs that are manufactured, sold and administered to patients in India as per the provisions of The Drugs and Cosmetics Act, 1940 and Rules thereunder. Therefore Diclofenac Sodium Injection has to be necessarily manufactured as per standards prescribed in Indian Pharmacopoeia (IP) and approved by the Government of India.

The impugned invention under opposition also claims the similar Diclofenac Sodium Injection (25ml) as mentioned in the above document which specifically requires the use of Alcohols such as Benzyl Alcohol (Monohydric Alcohol) and Propylene Glycol (Polyhydric Alcohol) and water as well as requires having statutory pH of 8.1 to 9.0.

In this aspect, the patentee has reiterated that regulatory standards of the product available in the market, it does not provide any teaching on how to formulate a high concentration Diclofenac injection with a desired viscosity by using minimum amount co-solvents. In this regard an affidavit filed by the patentee referred at Para 6 pages no 4 of (Parikh) affidavit and sr, no 1 of Table in page 7. "**I say that the Diclofenac Sodium injection Monograph from Indian Pharmacopoeia 1996 lays down the standards of quality and purity and other parameters of the Diclofenac Sodium Injections for the manufacturers. The said monograph also discloses two of the excipients (benzyl alcohol and propylene glycol) that may be included in the Diclofenac Sodium Injections but without mentioning the quantities/proportions thereof"**. The said monograph states usual strength of the Diclofenac Sodium injection to be 25 mg per ml. The said literature does not teach Diclofenac Sodium Injection containing 75 - 100 mg per ml. It also does not talk about viscosity of the said injection much less that the viscosity should be on lower side".

Thus, from the teaching of above (D1) document, an ordinary person skilled in the art can, easily be motivated to prepare a Diclofenac Sodium Injection along with use of benzyl alcohol, propylene glycol and sodium hydroxide and water in its preparation and having a pH between 8.1 and 9.0, because, the object of the alleged invention to reduce the pain by decreasing the volume of the injection without reducing the viscosity. To achieve the above said object, the Patentee had selected the water –soluble Diclofenac salt, and the co-solvent system more particularly, pinpointing the use of water as a primary solvent system.

It is to be noted that the co-solvent system developed by the patentee using a water as an important solvent to reduce the injection volume without increasing the viscosity of formulation and to reduce the pain at site. However, the pharmacopeia (D1) may have not given the quantities of the ingredient but a motivation, suggestion, or teaching's (TSM) are being described to make formulation using water as a solvent. Consequently, the water is being used in the prior art document.

2) CH 694034 A5 (ANNEXURE IV) (herein after referred to as D2)

This document relates to an injection of Diclofenac Potassium, which is suitable for the treatment of acute pain. This document also discloses that the invented solution is stable and is characterized by good tolerability. An object of the alleged patent summarise as under, that

> Another object of the present invention is to provide solutions to diclofenac injection with very low volume and with the same therapeutically sufficient amount of drug per injection available to allow a possible pain -free injection.
>
> It has now surprisingly been found that the application rate of 75 mg of diclofenac potassium in 1 ml of injection solution can be obtained as a stable solution, help with the aids both in style and in the low number means that the allergenic risk is minimal.
>
> The present invention is a pharmaceutical composition in the form of a parenterally administered injection solution comprising a therapeutically effective amount of diclofenac potassium in 1 ml of aqueous solution.
>
> The novel injectable solutions are clear, colorless and free from visible foreign particles with the naked eye.
> They generally contain 40-100 mg of diclofenac potassium, preferably 50-75 mg, and particularly preferably 75 mg diclofenac potassium per ml solution for injection.
>
> Preferably, the novel diclofenac potassium injection solutions, a solvent mixture of propylene glycol and polyethylene glycol.
> The share of the solvent mixture is preferably 20-50 wt.-%, based on the total weight, wherein the weight ratio of propylene glycol, polyethylene glycol, preferably between about 9,5:0,5 and 0,5:9,5, preferably between 3:1 and 1:3, more preferably 1:1.
>
> The pH is preferably from 8.0 to 8.5 with sodium hydroxide, preferably set to 8.3.
> It lies within the physiological range of pH from 4.0 to 9.0 limit.

Thus, the above object of alleged invention is to provide diclofenac injection with low volume and with therapeutically sufficient of the drug per injection available to allow a possible pain free injection. The teaching's that flows from D2 prior art document is that, it discloses stable injectable solution of 75-100 mg of Diclofenac in l ml of aqueous solution maintaining pH of 8.0-8.5 along with the use of two polyhydric alcohol such as propylene glycol and polyethylene glycol in an amount of 20-50%. More, importantly the formulation contains the use of active ingredient 75mg or 100mg/ml, for intramuscular injection, it is also desirable to keep the less volume and with the same therapeutically sufficient amount of drug per injection available to allow possible pain free injections, as being suggested at objects of the invention. It's also clearly discloses the use of 75mg in 1 ml of injections solution can be obtained as a stable solution, helps with the aids both in style and in the low number means that the allergic risks is minimal. Most importantly the said prior art discloses the use of diclofenac salt in 1 ml of aqueous solution. The said prior art also covered the active in the range of 40mg to 100mg preferably, 50 – 75mg and particularly, preferably 75mg per ml solution of injection, is being clearly discloses in the specification. The solvent mixture comprising of propylene glycol, polyethylene glycol, the share of the solvent mixture is preferably 20-50% based on the total weight of the weight ratio of propylene glycol,

preferably, between about 9.5 and 0.5:9.5 preferably between 3:1 and 1:3 more preferably 1:1.

The composition contains the stabilisers such as cysteine, N-acetylsteine or N-Acetyl cysteinhydrochloride and preferably N-acetylcysteine. Finally, the pH of the formulation maintained at 8.0 to 8.5. With NaOH, the said formulation administered parentally particularly administered intramuscularly. The additives such as benzoyl alcohol, mannitol, and sulphides, that can be used for making stable composition, however, without use of above additives, the composition is stable as disclosed " Table 1 -3 indicates the novel injectable solution are stable, despite the absence of sulphites and benzoyl alcohol. However, the document is silent about the viscosity, either the examples discloses the viscosity or specification.

The patentee submitted a table showing the differences between the subject patent and prior art document as under, at the written submission at page no .46

The patentee submitted in the post hearing written submission that "the formulations of CH694034 used as solvent mixture of propylene glycol and polyethylene glycol (co-solvent belonging to same chemical class) to arrive are 75mg per ml aqueous solution of diclofenac potassium, whereas the combination of co-solvents in the patentee's invention does not use two alcohols belong to the same class of polyhydric alcohols but uses two alcohols belonging to different class " it's also reveals that the example 1 , 2 , the viscosity of the pharmaceutical preparation made as per Example 1 is 6.32 CPS and as per Example 2 is 6.65 CPS. The Patentee submits that high viscosity injections are unacceptable to the industry as they are painful. An advantage over known injection solutions is the lack of problematic auxiliaries, such as benzyl alcohol, mannitol and sulphites. The references clearly recognize that benzyl alcohol is a "problematic" additive and teaches not to use Benzyl alcohol in injection solutions.

Further the reference CH694034 is discussed at Sr. no. 2 of Table on page no. 7 of Mr. Ketan R. Patel's Affidavit dated 21st Aug 2012 as follows:

Sr. No.	Summary of Prior Arts	Comparison between formulations in patent no 231479 and Prior Arts		
		Features	Prior Art	Patent No 231479
2	CH694034 Discloses a parentally administered injection solution containing diclofenac potassium, using solvent mixture comprising propylene	Solvent system	Two solvents of same chemical class used in combination i.e. PG&PEG resulting in high viscosity solution. (See next feature)	Comprises single solvent or two or more solvents selected from different chemical classes to provide low viscosity solution

Sr. No.	Summary of Prior Arts	Comparison between formulations in patent no 231479 and Prior Arts		
		Features	Prior Art	Patent No 231479
	glycol (PG) and polyethylene glycol (PEG). Optionally adding local anesthetic like lignocain. The Patent does not offer teaching regarding viscosity of solutions disclosed			(See next feature)
		Viscosity	Viscosity value not reported in said cited prior art however, viscosity of the example disclosed is very high i.e. 6.32 CPS and 6.65 CPS of example 1 & 2 respectively .	Viscosity range of injection solution of high concentration diclofenac salts, claimed by us is 1.5 to 4.7 CPS
		Composition	In addition to diclofenac salt, local anaesthetic included in formula to ease the pain by high viscosity injection	No Local anaesthetic in the formula, since injection solution has low viscosity and hence does not cause pain.

10.10 A table comparing the key contrasting features of the present invention with that of CH694034 is as follows:

Table no. 9 - Comparison of Key contrasting features between Prior art - CH694034 and Granted patent IN231479

Key contrasting Features	Prior art - CH694034	IN231479
Solvent System	Two solvents of same chemical class used in combination i.e. PG&PEG	Comprises single solvent or two or more solvents selected from different chemical classes
Addition of local anesthetic for Therapeutic use	Yes	No
Viscosity	High (6.32 CPS and 6.65 CPS of example 1 & 2 resp.)	Low (1.5 to 4.7 CPS)
Benzyl alcohol	recommends not to use	Used as a co-solvent

The elemental differentiation in the abovementioned tables clearly demonstrate the irrelevance of the cited prior art "CH694034" with regard to the discussion on the inventive step of the invention disclosed in IN 231479.

3) US Patent No. 5554650 (ANNEXURE VI) (herein after referred to as D3)

This prior art document(D3) which describes the present invention relates to an antiphlogistic, analgesic, antipyretic parenteral preparation, and, in particular, to an antiphlogistic, analgesic, antipyretic parenteral preparation comprising diclofenac, its salt, or both, as effective components. The parenteral preparation of the present invention provides a sustain release of the drug, along with substantial reduction of side effects upon and after administration.

The back ground of the prior art (D3) describes that the Diclofenac and its salts possess excellent antiphlogistic, analgesic, antipyretic activities, and are widely used for treating various inflammatory diseases, such as acute and chronic rheumatoid arthritis, osteoarthritis, and the like. They are typically formulated for oral administration, as a suppository, in an ointment, or the like.

For these preparations, however, i.e., oral dosage forms, suppositories, and ointments, the pharmaceutical effects fluctuate due to differences between the amount of drug administered and the amount of drug absorbed by the body. In addition, these preparations require a certain period of time for the active components to exhibit their effects because of a time-lag

between the administration and absorption. Therefore, intravenous or intramuscular administration is desirable to obtain immediate antiphlogistic, analgesic, or antipyretic effects in the case of serious symptoms requiring an urgent treatment, e.g., for effecting an anti-inflammatory or analgesic action after an operation or injury, or visceral pain associated with an attack, cancer, or the like.

For these reasons parenteral preparations comprising diclofenac and/or its salt have been developed. These compositions comprise diclofenac, its salt, or both, and an alcohol, such as propylene glycol, benzyl alcohol, or the like, and water. These conventional parenteral preparations containing diclofenac and/or its salt have the following side effects. First, they produce pain at the injection site during injection. Second, they induce side effects, such as precordial anxiety, ague, cold sweat, breathing difficulty, numbness of extremities, and the like, due to the rapid increase in drug concentration in the plasma immediately after the injection. In addition, the therapeutic effect of these conventional injectable preparations lasts for a short period of time because the drug is eliminated from the plasma quickly.

The present inventors, therefore, have developed antiphlogistic, analgesic, antipyretic parenteral preparations comprising diclofenac, its salt, or both, which gives reduced side effects upon parenteral administration. Moreover, these new parenteral preparations sustain the release of the drug to achieve long-lasting therapeutic effects.

Summary of the invention discloses that, Diclofenac parenteral compositions have been developed by the present inventors that comprise a therapeutically effective amount of diclofenac, and/or pharmaceutically acceptable salt thereof, a surfactant, a co-surfactant, water and having a pH of 3-10. In addition, according to preferred aspects of the present invention, the composition also contains an oily component.

This document further in detailed description of the invention and preferred embodiments discloses the amount of surfactant(s) in the parenteral preparation of the present invention varies depending on the type(s) of surfactants used. In general, a preferable range is about 2-60 wt %, with the particularly preferable range being about 5-45 wt %. In the parenteral preparation of the present invention, compounds that function as solubiliser or co-solvents as well as surfactants are preferred. Such compounds can be referred to as co-surfactants. Monohydric or polyhydric alcohols may be used as such co-surfactant either alone or in combination with one or more of the like. Given as examples of monohydric alcohols are benzyl alcohol, ethyl alcohol, and the like; and as examples of polyhydric alcohols are propylene glycol, glycerine, 1,3-butylene glycol, polyethylene glycols with molecular weights of 300-4,000 Dalton. Specific examples of such polyethylene glycols include

polyethylene glycol 300; polyethylene glycol 400, polyethylene glycol 600, and polyethylene glycol 4,000. Such a co-surfactant may be incorporated in the parenteral preparation of the present invention in an amount of about 0.5-30 wt %, and preferably 2-15 wt %. and the claim 9 which claims that the composition comprising 2-200mg /ml, or diclofenac , its salt or both 2-60 wt % surfactant , and 2-15 wt % or co-surfactant , in the claim 11, wherein it is discloses that the surfactant and co-surfactant, an only component along with water having a pH 3-10

According to preferred embodiments of the present invention, such as co-surfactant which includes benzyl alcohol. The amount of benzyl alcohol is up to about 25 wt %, and preferably less than 25 wt %. When benzyl alcohol is employed the co-surfactant component, the amount of co-surfactant component is about 0.5 wt % to about 25 wt %, preferably about 1 wt % to about 20 wt %, and most preferably about 2 wt % to about 15 wt % of the total composition. When a second co-surfactant is employed with the benzyl alcohol as the co-surfactant component, ethyl alcohol is preferable. The amount of the ethyl alcohol is preferably about 0.5 wt % to about 15 wt % of the total composition. The ethyl alcohol reduces the viscosity of the preparation which makes administration easier.

In addition, benzyl alcohol should be less than about 25 wt %, and preferably about 20 wt % or lower, to prevent undesired reactions with body tissue upon administration. This document further discloses that in the parental preparations of the present invention compounds that function as solubiliser or co-solvents as well as surfactants are preferred. Such compounds can be referred to as co-surfactants. Monohydric or polyhydric alcohols may be used as such co-surfactant either alone or in combination with one or more likes. The document further points that the Monohydric alcohols may be such as benzyl alcohol, ethyl alcohol and a like and the Polyhydric alcohols such as propylene glycol, polyethylene glycol, glycerine, 1,3 - butylene glycol. Such co-surfactant may incorporate in the parental preparation in an amount of about 0.5-30 wt% and preferably 2-15 wt %.

Thus, it is clear that this document discloses an antiphlogistic, analgesic and antipyretic parenteral preparation comprising a therapeutically effective amount of diclofenac in the range of 2-200 mg/ml, in a pharmaceutically acceptable salt, or both, a surfactant, a co-surfactant and water having a pH of 3-1O. The co-surfactant ranging from 0.5 to 30 wt% and preferably between 2-15 wt % is selected from the group consisting of monohydric alcohols and polyhydric alcohols. Co-surfactant used (as solubiliser or co-solvents) are used to aid in the dispersion and dissolution of diclofenac, its salt, or both.

4) Indian Patent No. INI92711 (ANNEXURE VII) (herein after referred to as D4)

This document relates to "A Novel Method of Preparation of Diclofenac Injection" and is a granted Indian Patent to the same Patentee. This document in its abstract discloses as under,

(57) Abstract:
The water soluble salt of Diclofenac e.g. Sodium Diclofenac is used as an Anti-inflammatory agent in injection form. In this invention, Diclofenac injectable preparation is made by using Diclofenac salt, water for injection,. Benzyl Alcohol, buffer/alkalis, antioxidants and stabilizers without using propylene glycol. In this invention Nitrogen gassing is used to impart stability. Diclofenac is susceptible to oxidation, and Nitrogen prevents its oxidation. The present injection is given intramuscularly in case of inflammation. This injection is less viscous and less painful to the patient as compared to present available preparations of Diclofenac injection. 19

It is clear from the abstract that this document discloses water soluble salt of diclofenac. The abstract further discloses the diclofenac injectable is made by using diclofenac salt, water for injection, benzyl alcohol, buffer/alkalis, antioxidants and stabilizers. It also points the injection is less viscous and less painful as compared to presently available preparations of diclofenac injection.

Further the claims 1, 3, 7 and 9 of this patent claims that,

1. The method of preparation of Diclofenac injection comprises mixing of 0.5% to 3.5% water (solvent) soluble salt of Diclofenac with 4% to 6% Benzyl Alcohol, under nitrogen gassing along with stabilizers, antioxidants and suitable buffers/alkalis such as NaOH to maintain the pH range of 8.1 to 9.0.

3. The method as claimed in claim 1 and 2 wherein slurry of Diclofenac salt in Benzyl Alcohol made under nitrogen gassing is dissolved in water for injection which is free from bacteria and pyrogens.

7. The method as claimed in claim 1 wherein pH is maintained or adjusted in the range of 8.1 to 9 by adding suitable alkalis such as NaOH in the mixture of Diclofenac salt, Benzyl Alcohol, water for injection, stabilizers and antioxidants.

9. The method as claimed in claim 1 wherein Diclofenac salt, Benzyl Alcohol, water for injection, stabilizers, antioxidants and buffers/alkalis are mixed in any sequence.

From the above claims, it is clear that claim 1 claims the method of preparation of Diclofenac injection with water as principal solvent and benzyl alcohol as preservative. Claims 1, 3 and 7 claims the use of benzyl alcohol (4-6%) as a single solvent. Further, Claim 9 claims that stabilisers, antioxidant and buffer/alkalis are added into the mixture of injectable preparation under nitrogen gassing. The pH of the Diclofenac injection is maintained / adjusted in the range of 8.1 to 9.0 using suitable buffer or alkalis.

This document also discloses the viscosity of various brands ranging from 1.10 to 5.42 CPS. It is further disclosed that different brands contain different amount of polypropylene glycol as solvent (page 5, brands 1-9) along with their viscosities (brands 1-9 and injection which is prepared by process of this document page 11). It is clearly reflected from the data provided on page 5 (brands 1-9) and on page 11 (brands 1-9) and injection which is prepared by the process of this document, the viscosity depends on the ratio of the solvents (organic solvents: water).

5: US Patent No US4711906 (ANNEXURE VIII) (herein after referred to as D5)

This document relates to "Liquid diclofenac preparations" discloses a stable, liquid diclofenac preparation for parenteral administration.

The claims disclose

1. A stable, liquid diclofenac preparation, especially for the parenteral application, consisting of a solution of diclofenac or one of its salts in an amount of 1.5–6.0 weight % diclofenac in a solvent, wherein the solvent consists of 10–70 weight % of a mixture of (a) propylene glycol and (b) polyethylene glycol and 30–90 weight % water, and the weight ratio of (a) propylene glycol to (b) polyethyelene glycol is between 9.5:0.5 and 0.5:9.5.

2. The diclofenac preparation according to claim 1, wherein the weight ratio of (a) propylene glycol to (b) polyethylene glycol is between 2:1 and 1:2.

3. The dicyclofenac preparation according to claim 1 having a pH value of 5.5–9.

4. The diclofenac preparation according to claim 1 containing a polyethylene glycol 400 as the polyethylene glycol component.

5. The diclofenac prparations according to claim 1 which further consists of 0.1–5 weight % of a local anesthetic.

6. The diclofenac preparation according to claim 5, wherein the local anesthetic is lidocaine.

7. The diclofenac preparation according to claim 6 having a pH value of 7.5–8.

D5 further discloses solution of diclofenac or one of its salts in an amount of 1.5-6.0 wt % in a solvent mixture, wherein 10-70 wt % of solvent mixture contains polyhydric alcohols such as propylene glycol and polyethylene glycol [two solvents of same class] and 30-90 wt% water having pH of 6.5 to 8.0. US4711906 discloses major elements claimed in the impugned patent.

6) US Patent No. 5389681 (ANNEXURE IX) (herein after referred to as D6)

This document relates to "Parenteral solutions for diclofenac salts" It discloses a pharmaceutical composition in the form of a parentally administrable composition comprising pharmaceutically acceptable salt of Diclofenac and 1, 2-propylene glycol or polyethylene glycol 300-400 wherein the pH is maintained at 8.0. This document further discloses parenteral preparation having 50/75/100 mg of Diclofenac in 1 to 5ml. Further, Example 2, 3 and 4 discloses 2 ml or 3 ml injection comprising diclofenac along with co-solvent from differing classes i.e. Polyethylene glycol and benzyl alcohol.

The parenteral solution disclosed in this document compasses 50-100 mg of diclofenac, falls within the range (75 mg/ml -100 mg/ml) claimed in the impugned patent, in 1 to 5ml preferably 1 to 2 ml of injection solution. Further, Example 2,3 and 4 by way of experiments clearly demonstrates 2 ml /3ml injection comprising diclofenac along with cosolvent from differing classes i.e. polyethylene glycol and benzyl alcohol. Hence, it is clear from this document that the claim of diclofenac concentration in the range of 75 mg/ml-100 mg/ml along with the use of cosolvents/stabilisers from differing classes is substantially similar as claimed in the impugned patent under opposition and is very well known when compared with the said prior art.

7) Article titled "A New Injectable Solvent (Glycofurol)" (Annexure X) and (English translation of the said article) Annexure (ANNEXURE X (a)) (herein after referred to as D7)

This article in its summary discloses that;

> **Summary**:
>
> A new injectable solvent (glycofural):
>
> *Tetrahydrofurfuryl alcohol polyethylene glycol ether containing an average* of two ethylene glycol groups (trade name: Glycofurol) is a new solvent for drugs injectable without water. It is miscible with water in any proportion.
>
> Its tolerability equals that of 1,2-propylene glycol. Contrary to 1,2-propylene glycol, it can be used for the preparation of stable injectible solutions in combination with 3-pyridine carbinol (trade name: Ronicol), acetyl choline chloride and dimethyl carbamic acid ester of 1-methyl-3-hydroxy pyridinium bromide (trade name: Mestinon).

Thus, this document reveals that Tetrahydrofurfuryl alcohol polyethylene glycol ether containing an average of 2 ethylene glycol groups (Trade Name: Glycofurol), is the new

solvent for injectables without water. It is miscible with water in any proportion. Its tolerability equals that of 1, 2- propylene glycol.

Hence, inference can be drawn from the said prior art document that, it clearly discloses the use of glycofurol as a solvent in injectable preparation that the use of Tetrahydrofurfuryl alcohol Polyethylene glycol ether as cosolvent, as claimed in the impugned patent, is well known in prior art.

After considering teachings of the cited prior art and conclusions drawn on them, I further proceed with the grounds of opposition.

c) Finding's and assessment on Inventive step (Section 25(2) (e) vis-à-vis cited prior art documents to arrive at a decision as under;

1. The opponent contented that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve inventive step having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim(section 25(2)(e)). The opponent further contented that the claimed invention in present patent under opposition is devoid of technical advancement or economic significance as compared to the existing knowledge i.e. in view of the teachings of the cited prior art documents D1-D7, therefore, obvious for an ordinary person skilled in the art and hence the claims lacks inventive step.

2. In this regard the opponent had relied upon few prior art documents, wherein Documents D1, D2 , D3 found to be most similar, It is clear that the impugned patent under opposition claims an injectable formulation having viscosity ranging from about 1.5 to 3.50 CPS and pH of 8-9 containing active ingredients between 75-100mg/ml of diclofenac sodium, particularly at 75 gr/ml or 100gr/ml or its therapeutically equivalent amount of water-soluble salts of diclofenac in a solvent system comprising combinations of at least two or more co-solvents/solubilisers selected from differing classes, wherein the monohydric alcohol(s) is upto~15% v/v, preferably 4-8%, polyhydric alcohol(s) upto~25% v/v, preferably upto 15%, tetrahydrofurfuryl alcohol, propylene glycol ether (glycofurol) up to ~25 % v/v of preferably upto~15%; with water as principal solvent, such that the total amount of co-solvent/solubilizes does not exceed 35%v/v of the composition.

3. Injectable preparations of above formulation having viscosity ranging from about 1.50 to 4.7 CPS and pH of -8-9, containing 75 mg/ml of diclofenac sodium or its therapeutically equivalent amount of water-soluble salts of diclofenac, comprising, cosolvents /solubilisers such as a monohydric alcohol ~ 4 % to 25% % v/v, or a polyhydric

alcohol ~ 27 % to 45 %v/v, or tetrahydrofurfuryl alcohol propylene glycol ether (glycofurol)~18 % to 35"% v/v, in combination with water as principle solvent.

4. The cited prior art documents are elaborately discussed in detail in analysis part, at above para (8) using these finding's and considering the teachings of each independent document or in combination of those disclosure of prior arts D1, D2, D3 and D4 considered of most similar document's for the analysis and assessment of inventive step as under. The impugned claims as granted, along with original claims are thoroughly analysed vis-a-vis, the cited prior art documents to arrive a decision on the opposed ground of lacking of inventive step under section 25(2) (e). In the pre-grant opposition the few prior art documents were cited, apart from these documents, the opponents have cited few new documents along with these prior art documents. Thus , on consideration and retrieval of description from that of old prior art documents individually , as well as considered the features of the new prior art documents in combination with old prior art documents(cited in pre-grant), that mosaicking of the documents is being considered for the assessment of an inventive step.

5. Prior art D1 (The Indian Pharmacopoeia), this document discloses that Diclofenac Sodium Injection is known in the art along with use of benzyl alcohol, propylene glycol and sodium hydroxide and water in its preparation having pH between 8.1 and 9.0. The Indian Pharmacopoeia is a statutory document and has to be complied by every pharmaceutical manufacturer for all drugs that are manufactured, sold and administered to patients in India as per the provisions of The Drugs and Cosmetics Act, 1940 and Rules thereunder. Therefore, Diclofenac Sodium Injection has to be necessarily manufactured as per standards prescribed in Indian Pharmacopoeia (IP) as approved by the Government of India. The impugned invention under opposition also claims similar Diclofenac or salt or both Injection as mentioned in the above document which specifically requires the use of Alcohols such as Benzyl Alcohol (Monohydric Alcohol) and Propylene Glycol (Polyhydric Alcohol) , water in the solvent system, as well as required statutory pH of 8.1 to 9.0.

6. Thus, using the teachings of the above document (D1), an ordinary person skilled in the art can easily be motivated to prepare a Diclofenac Sodium Injection by use of benzyl alcohol, propylene glycol and sodium hydroxide and water in its preparation and having a pH between 8.1 and 9.0. However, the affidavit (Applicant's) wherein it mentioned that the proportions have not been mentioned in the prior art document in D1, I do not agree with statement, so as to assess the inventive step, a person skilled in the field could however, can perform by reading the document or not, since, the major part's that all essential ingredients including active ingredients are being suggested in the D1 to make injection including the

pH. It is seen that the main object mentioned in the alleged invention so as to eliminate irritant propylene glycol (page 3 of the specification), preparation of less volume, and pain free injection at the site. However, impugned claims have the similar ingredients, such as active ingredient. Solvents, solubiliser, water, and use of these ingredients independently or in combination thereof. D1 has clearly suggested and motivated to a skilled person, thus, the skilled person could be motivated to prepare the formulation using above said ingredients Thus, from the teaching of above(D1) document, an ordinary person skilled in the art can, easily be motivated to prepare a Diclofenac Sodium Injection by using benzyl alcohol, propylene glycol and sodium hydroxide and water in its preparation and having a pH between 8.1 and 9.0, because, the object of the alleged invention to reduce the pain by decreasing the volume of the injection without reducing the viscosity. To achieve the above said object, the Patentee had selected the water –soluble Diclofenac salt, and the co-solvent system more particularly, pinpointing the use of water as a primary solvent system.

7. It is to be noted that the co-solvent system developed by the patentee using a water as an important solvent to reduce the injection volume without increasing the viscosity of formulation and to reduce the pain at site. However, the pharmacopeia (D1) may have not given the quantities of the ingredient but a motivation, suggestion, or teaching's (TSM) are being described to make formulation using water as a solvent. Consequently, the water is being used in the prior art document to prepare desired formulation and the document is addressed to the person skilled in the art obviously can try to make formulation with or without combination of known prior arts.

8. Prior art D2: CH 694034 (ANNEXURE V) (a) relates to an injection of Diclofenac Potassium, which is suitable for the treatment of acute pain. This document also discloses that the inventive solution is stable and is characterized by good tolerability. The object of this invention is to provide diclofenac injection with very low volume and with therapeutically sufficient of the drug per injection available to allow a possible pain free injection.

The teachings that flows from this document is that, it discloses stable injectable solution of 75-100 mg of Diclofenac in l ml of aqueous solution with pH of 8.3 along with the use of two polyhydric alcohol such as propylene glycol and polyethylene glycol in an amount of 20-50%. Further claim 1 of document D2 specifies monohydric alcohol and polyhydric alcohol which clearly discloses that more than one monohydric alcohol and polyhydric alcohol are used in the claimed formulation. Document D2 on page 74, paragraphs 8-10, explains the significance of employing 75mg/ml diclofenac stable solution. Further the solvent mixture 20-50 % w/v as disclosed on page 74, paragraph 13 of D2 also falls within

the ambit of Claim 1 of impugned patent under opposition which recites that the total amount of co-solvent/solubilizes does not exceed 35% v/v of the composition. Therefore, it is clear that applying the teachings of this document (D2), ordinary person skilled in the art can arrive at the Claim 1 of impugned patent under opposition due to following reason.

Thus, primary object of alleged invention is to provide diclofenac injection with low volume and with therapeutically sufficient of the drug per injection available to allow a possible pain free injection. The teachings of D2 (CH 694034 A5) reveals that, a stable injectable solution of 75-100 mg of Diclofenac in l ml of aqueous solution maintaining pH of 8.0-8.5 along with the use of two polyhydric alcohol such as propylene glycol and polyethylene glycol in an amount of 20-50% most, importantly, the formulation contains the use of active ingredient 75mg or 100mg/ml, for intramuscular injection. It is also desirable to keep the less volume and with the same therapeutically sufficient amount of drug per injection available to allow possible pain free injections. It's also clearly discloses the use of 75mg in 1 ml of injections solution which can be obtained as a stable solution, helps with the aids both in style and in the low number means that the allergic risks is minimal. Most importantly the said prior art discloses the use of diclofenac salt in 1 ml of aqueous solution. The said prior art also covered the active in the range of 40mg to 100mg preferably, 50 – 75mg and particularly and preferably 75mg per ml solution of injection, is being clearly disclosed in the specification. The solvent mixture comprising of propylene glycol, polyethylene glycol, the share of the solvent mixture is preferably 20-50% based on the total weight of the weight ratio of propylene glycol, preferably, between about 9.5 and 0.5:9.5 preferably between 3:1 and 1:3 more preferably 1:1.

9. The composition contains the stabilisers such as cysteine, N-acetylcysteine or N-acetylcysteine hydrochloride and preferably N-acetylcysteine. Finally the pH of the formulation maintained at 8.0 to 8.5, with NaOH, the said formulation administered parentally particularly administered intramuscularly. Additives such as benzoyl alcohol, mannital, and sulphides that can be used for making stable composition. However, without use of above additives, the composition is stable as disclosed "Table 1 -3 indicates the novel injectable solution are stable, despite the absence of sulphites and benzoyl alcohol. However, the document is silent about the viscosity, either the examples discloses the viscosity or specification either higher side or lower side, but it is not the case that the composition viscosity is not maintained, thus, by use of similar ingredients at particular proportion the desired viscosity could be maintained in the composition. The solvent mixture of propylene glycol and polyethylene glycol (co-solvent belonging to same chemical class) to arrive at

75mg per ml aqueous solution of diclofenac potassium. Whereas the combination of co-solvents in the patentee's invention does not use two alcohols belong to the same class of polyhydric alcohols but uses two alcohols belonging to different class " it's also reveals that the example 1 , 2 , the viscosity of the pharmaceutical preparation made as per Example 1 is 6.32 CPS and as per Example 2 is 6.65 CPS. The Patentee submits that high viscosity injection is unacceptable to the industry as they are painful. It is to be noted that the different class of alcohol as submitted is not accepted, as they may be divided into different class, but the use of alcohol are similar to that of monohydric and polyhydric which have been used in the alleged patent. Therefore, the ingredients such as Monohydric, polyhydric alcohol, with water, have been disclosed in D2 and also suggested in the D1 read along with D3-D7, and the obvious features as claimed in the formulation of solvent system, are obvious to the person skilled in the art at the time of making the invention, it is obvious to a person skilled in the art to arrive at invention by plain reading of D2 alone or in combination of D1, D3-D7.

10. Prior art (D3) US Patent No. 5554650- Annexure VI, as analysed above at Para 8(3), this document clearly discloses an antiphlogistic, analgesic an antipyretic parenteral preparation comprising a therapeutically effective amount of diclofenac in the range of 2-200 mg/ml, its pharmaceutically acceptable salt, or both, a surfactant, a co-surfactant and water having a pH of 3-1O. The co-surfactant ranging from 0.5 to 30 wt.% and preferably between 2-15 wt percent is selected from the group consisting of monohydric alcohols and polyhydric alcohols. Co-surfactant used (as solubilizes or co-solvents) are to aid in the dispersion and dissolution of diclofenac, its salt, or both.

Thus, the important ingredients selected in the prior art are active between 2-200mg/ml, Surfactant, Co surfactant, water, and maintained pH between3-10. Accordingly, discloses benzyl alcohol should be less than about 25% preferably about 20°/o or lower, to prevent undesired reactions with body tissue upon administration. Similarly, the claims 6 and 7 of the impugned patent under opposition claims that an incorporation of benzyl alcohol in the range of 4 to 25% when used as sole co-solvent and up to about 15 % when used in combination with other co-solvents. Further, these document points that ethyl alcohol reduces the viscosity of the preparation which makes administration easier and claims ethyl alcohol used in the range from 0.5 to 15wt %, in the system, the water is also used to make desired results.

Prior art D3 clearly discloses in its formulation preferably for the diclofenac or its salt or both. Basically this document resolve the drawback associated with convention composition such that (a) they produce pain while injection (b) the completely reduces the side effects

associates with this that the precordial anxiety, ague, cold sweat, breathing difficulties numbness of extremities. The formulation addressed the issue using the solvents selected from monohydric and polyhydric alcohol may be used as such co-surfactant either alone or in combination with one or more of the like. Given examples of monohydric alcohols are benzyl alcohol, ethyl alcohol, and the like; and as examples of polyhydric alcohols are propylene glycol, glycerine, 1,3-butylene glycol, polyethylene glycols with molecular weights of 300-4,000 Dalton. Specific examples of such polyethylene glycols include polyethylene glycol 300; polyethylene glycol 400, polyethylene glycol 600, and polyethylene glycol 4,000. Solvents, being disclosed including use of water. Obviously the similar solvents in small changes in same proportion will have similar property to maintain the viscosity and the active amount used between 2-200mg. therefore, in view of above findings the features of impugned patent claims are obvious to the person skilled in the art, while reading D3 alone or in combination of co-prior art documents.

11. Prior art D4 Indian Patent No. INI92711 -Annexure VII. This document clearly discloses water soluble salt of diclofenac. The abstract further discloses the diclofenac injectable is made by using diclofenac salt, water for injection, benzyl alcohol, buffer/alkalis, antioxidants and stabilizers. It also points injection is less viscous and less painful as compared to present available preparations of diclofenac injection. Further the claims 1, 3, 7 and 9 of this patent claims also claim the method of preparation of Diclofenac injection with water as principal solvent and benzyl alcohol as preservative. Claims 1, 3 and 7 claims the use of benzyl alcohol (4-6%) as a single solvent. Further, Claim 9 claims that stabilisers, antioxidant and buffer/alkalis are added into the mixture of injectable preparation under nitrogen gassing. The pH of the Diclofenac injection is maintained /adjusted in the range of 8.1 to 9.0 using suitable buffer or alkalis. This document also discloses the viscosity of various brands ranging from 1.10 to 5.42 CPS. It is further disclosed on page 5, brands 1-9 that different brands contain different amount of polypropylene glycol as solvent along with their viscosities (brands 1-9 and injection which is prepared by process of this document page 11). It is clearly reflected from the data provided on page 5 (brands 1-9) and page on page 11 (brands 1-9) and injection which is prepared by the process of this document, the viscosity depends on the ratio of the solvents (organic solvents: water). This document clearly suggests that by lowering the % amount of organic solvent (polypropylene glycol and increasing the % amount of water in solution, the viscosity of solution can be reduced. Accordingly, skilled person can select the proportion to maintain desired viscosity.

This document further teaches advantages of injection prepared by process which is free from polypropylene glycol or replace with benzyl alcohol i.e. polypropylene glycol causes pain, irritation at the site of subcutaneous or intramuscular injection being free from polypropylene glycol the injection is less viscous as compared to diclofenac injection prepared by the process which uses polypropylene glycol as a solvent. It is clear from the examples 1-10 on pages 8-10 of the impugned application under opposition follows the same trend that by lowering the % amount of organic solvents and increasing % amount of water to achieve an injection of lower viscosity. This document also suggests that polypropylene glycol can replace with benzyl alcohol similar to claim 6 of the impugned invention where benzyl alcohol is used as a sole co-solvent to prepare the said formulation.

The range of the solvent (4% to 25%) employed in the impugned patent under opposition falls within the range (4% to 6%) claimed in the Patentee's own prior Patent. Furthermore, the process disclosed in D4 is noticeably same as disclosed in the impugned patent under opposition. From the above findings with regards to this prior art document it is adequately obvious for a skilled person to arrive at the impugned patent under opposition therefore lacks inventive step.

Thus, it is clear that benzyl alcohol is employed as sole co-solvent in the range of 4% to 6% in diclofenac injection with the viscosity of diclofenac injection 1.10 CPS. This document on page 11 clearly states that "This lower viscosity of the present invention helps in faster diffusion of the drug from the site of the injection and also contributes to ease of administration resulting in lesser pain at site of injection". This clearly points the significance of lower viscosity in injectable formulations.

The main object as disclosed in the complete specification of the impugned patent under opposition lies in formulating 75mg/ml diclofenac with low viscosity, wherein the formulation contains either combination of co-solvents or single co-solvent. Thus, it is clear that the novelty and inventive step resides in obtaining 75mg/ml with low viscosity. However, the same teaching is clearly disclosed in this document which discloses diclofenac injection with single co-solvent having lower viscosity (1.10) than the impugned patent under opposition's claimed viscosity (1.5 to 4.7 CPS). Also the range of benzyl alcohol when used as single co-solvent is in the range of 4% to 6% and clearly falls in the range (4 to 25%) claimed in the impugned patent under opposition. From the above findings it is clear this document has lower viscosity than the impugned patent under opposition. Therefore it is clear that there is no technical advancement or economic significance in obtaining 75mg/ml diclofenac injection having higher viscosity than the prior art document D4.

The viscosity (1.50 to 4.7CPS) of the formulation claimed in the impugned patent is higher than the viscosity (1.10) disclosed in the prior art D4 in despite of using single co-solvent in the impugned formulation. For instance, the viscosity of the formulation of example 8 (page 9 of the impugned complete specification) using glycofurol as a single co-solvent in the formulation is 3.99 CPS. Similarly the viscosities of the formulation of example 9 (page 10 of the impugned complete specification) using propylene glycol as a single co-solvent are 4.38 and example 10 using polyethylene glycol as a single co-solvent is 4.69.

The Patentee has failed to achieve the object of the impugned invention. Further the viscosity of diclofenac injectable formulations containing combination of solvents such as glycofurol and benzyl alcohol of example 1 is 2.64 CPS, propylene glycol and glycofurol of example 2 is 2.23, glycofurol and benzyl alcohol of examples 3, 4, 5, 6 and 7 are 2.95. 2.38, 1.72. 1.57 nd 1.59 CPS respectively. Hence, the viscosities of all the examples are above 1.10 CPS of the diclofenac injection of D4 containing combination of solvents. Therefore the product claimed in the prior art (D4) is much more preferable than the impugned product.

D4 discloses viscosities, of the marketed branded products (containing benzyl alcohol and propylene glycol) ranging from 2.03 to 5.42 CPS which overlaps with the alleged claimed range of 1.5 to 3.50 CPS (at least two or more co-solvents) and 1.5 to 4.7 CPS (single co-solvent) in IN231479.

Additionally surprising effect, visa-a-visa the prior art formulations, is not provided by the Patentee in the specification which is required to substantiate advanced therapeutically effective over the prior art would be considered for patentability in the claimed formulation.

12. D4 clearly suggests that by lowering the % amount of organic solvent polypropylene glycol and increasing the % amount of water in solution, the viscosity of solution can be reduced.

This document further teaches advantages of injection prepared by process which is free from polypropylene glycol or replace with benzyl alcohol i.e. polypropylene glycol and causes pain, irritation at the site of subcutaneous or intramuscular injection being free from polypropylene glycol the injection is less viscous as compared to diclofenac injection prepared by the process which uses polypropylene glycol as a solvent. It is clear from the examples 1-10 on pages 8-10 of the impugned application under opposition follows the same trend that by lowering the % amount of organic solvents and increasing % amount of water to achieve an injection of lower viscosity. This document also suggests that polypropylene glycol can replace with benzyl alcohol similar to claim 6 of the impugned invention where benzyl alcohol is used as a sole co-solvent to prepare the said formulation.

The range of the solvent (4% to 25%) employed in the impugned invention under opposition falls within the range (4% to 6%) claimed in the Patentee's own prior Patent. Furthermore, the process disclosed in D4 is noticeably same as disclosed in the impugned patent under opposition. From the above findings of this prior art document it is obvious to a skilled person to arrive at the impugned patent under opposition. Therefore lacks inventive step considering the document alone or reading in combination of D1-D3 or D5-D7.

13. Prior art D5: US Patent No US4711906- Annexure VII, this document discloses a stable, liquid diclofenac preparation for parenteral administration. D5 further discloses solution of diclofenac or one of its salts in an amount of 1.5-6.0 wt % in a solvent mixture, wherein 10-70 wt % of solvent mixture contains polyhydric alcohols such as propylene glycol and polyethylene glycol [two solvents of same class] and 30-90 wt% water having pH of 6.5 to 8.0. The document D5 discloses major elements claimed in the impugned patent under opposition.

D5 discloses preferable use of propylene glycol along with other co-solvents in the injectable preparation of diclofenac solution for reducing viscosity of the formulation if highly-concentrated active ingredient is employed <Page 107, Coll, lines 47 to 5D. Page 107, Col 1, lines 10-14 of US4711906 states "Due to the relatively large "First-pass-effect" of the substance and for faster flooding it is desirable to use injection solutions, in which amount of 75mg should be used per injection ". Hence significance of employing 75mg diclofenac per injection is taught in D5.D5 thereby it discloses 75mg/2ml of diclofenac injection.

Additionally, Patentee is very well aware the teaching of 1997 article that if the injection is to be administered via deltoid route, injection volume of l ml or less is recommended, as admitted by the Patentee in the specification at page 6.

Hence, teaching of 1997 article coupled with US4711906, US5389681 and CH694034 skilled person can easily lead to arrive at 75mg/ml diclofenac injections. D5 itself or in combination or remaining prior art, therefore destroys inventive step of claim 1 of impugned patent under opposition.

14. Prior art (D6) US Patent No. 5389681- Annexure IX. This document relates to "Parenteral solutions for diclofenac salts" It discloses a pharmaceutical composition in the form of parentally administrable composition comprising pharmaceutically acceptable salt of Diclofenac and 1, 2-propylene glycol or polyethylene glycol 300-400 wherein the pH is maintained at 8.0. This document further discloses parenteral preparation having 50/75/100 mg of Diclofenac in 1 to 5ml. Further, Example 2, 3 and 4 discloses 2 ml or 3 ml

injection comprising diclofenac along with co-solvent from differing classes i.e Polyethylene glycol and benzyl alcohol.

The parenteral solution disclosed in this document compasses 50-100 mg of diclofenac, falls within the range (75 mg/ml -100 mg/ml) claimed in the impugned patent, in 1 to 5ml preferably 1 to 2 ml of injection solution. Further, Example 2, 3 and 4 by way of experiments clearly demonstrates 2 ml /3ml injection comprising diclofenac along with co-solvent from differing classes i.e. polyethylene glycol and benzyl alcohol. Hence, it is clear from the above prior art US538961 that the claim of diclofenac concentration in the range of 75 mg/ml-100 mg/ml along with the use of co-solvents/stabilisers from differing classes is substantially similar and is well known when compared with the said prior art.

This document teaches an injectable preparation comprising 75mg of Diclofenac sodium, 780. It is observed that the formulation of this application performs the same function, in substantially the same manner, to obtain a formulation differing with respect to solvent systems. Although this document is silent about the viscosity range claimed, however in case of obviousness exists where the claimed ranges of components of formulation and prior art do not overlap but are very close enough that a person skilled in the art would expect them to have the same properties, therefore the injectable formulation of this would necessarily have a viscosity about 1.5 to 4.7 CPS as cited in the instant claim 1. The use of tetrahydrofurfuryl alcohol propylene glycol is very common in the prior art and a person skilled in the art can replace glycofurol in place of propylene glycol

US5389681 USS389681 CANNEXURE IX) (page 112, column 3, lines 55-58) discloses diclofenac injection solutions 50, 75 or 100 mg in 1-5 ml co-solvents such as monohydric alcohol, polyhydric alcohol and stabilizers. Examples taught in US5389681 teach the pH of the formulation as 8.0- 8.3. It states "In preferred forms, injection solutions comprising the customary doses of 75 or 100 mg of diclofenac sodium have a total volume of approximately from 1 to 5 ml. preferably 3 ml". US5389681 (page 112, column 3, lines 55-58) discloses. "The volume of the liquid in admixture with components a), b) and c) is, for example, approximately from 1 to 5ml, preferably from 1to2ml". Page 111, Bridging paragraph of columns 2 and 3 discloses the range of propylene glycol or polyethylene glycol to be employed as 5 to 50% which falls within the range claimed in Claims 1 and 2 of IN231479. Page 113, Examples 1 and 2 (column 5) of US'681 disclose diclofenac injection (75mg/3ml) comprising single co-solvent such as propylene glycol and polyethylene glycol respectively. Example 3 (column 5) discloses diclofenac injection (75mgllml or 75mg/3ml) comprising combination of co-solvents such as polyethylene glycol and benzyl alcohol and Example 4

(column 5) discloses diclofenac injection (75mg/2ml or 75mg/3ml) comprising propylene glycol and benzyl alcohol. Hence US5389681 clearly destroys inventive step of the invention claimed in Claims 1 and 2 of impugned patent No. IN231479.

15. It is observed that the formulation of this application performs the same function, substantially in the same manner, to obtain a formulation differing with respect to solvent systems. Although this document is silent about the viscosity range claimed, however, a case of obviousness exists where the claimed ranges of components of formulation and prior art do not overlap but are very close enough that a person skilled in the art would expect them to have the same properties, therefore the injectable formulation of this would necessarily have a viscosity about 1.5 to 4.7 CPS as cited in the instant claim 1. The use of tetrahydrofurfuryl alcohol propylene glycol is very common in the prior art and can replace glycofurol in place of propylene glycol.

16. It is to be noted that the object of the impugned patent is reduces pain at site, which is usually causing due to propylene glycol also acts as irritant (page 3 of the specification). The formulators of the alleged invention attempted to eliminate the irritant (propylene glycol) thereby pain can be reduced. However, claim 4 of the impugned patent uses the same in the class of polyhydric alcohol. Thus, in view of above the impugned claims failed to attain the object. Hence, the use of polyhydric glycol is well known and obvious solvent can be used with water for formulation an impugned patent.

17. Specification clearly made an object to reduce pain while injecting at the site, no wherein in the specification has been described/supported the mechanism to measure the pain, and to what extent the pain is being reduced. The prior art documents (D1-D6) addressed different problems including pain relief at site , and succeeded by using alleged solvents as claimed in the impugned patent. Because, the active ingredient is same, and the solvents used in the impugned claims are well disclosed in the prior arts in relation to reduce the pain while injecting. The advantageous property over known composition with or without incorporation of known solvents has not been substantiated in the specification. Therefore, the specification failed to prove improved efficacy over the known formulation, and also failed to prove the pain at site, since, the therapeutic efficacy and the pain relief have already been addressed in the prior art documents.

18. D7: Article titled “A New Injectable Solvent (Glycofurol)" - Annexure X and (English translation of the said article) Annexure X (a)

This article in its summary discloses that; Thus, this document reveals that Tetrahydrofurfuryl alcohol polyethylene glycol ether containing an average of 2 ethylene glycol groups (Trade Name: Glycofurol), is the new solvent for injectable without water. It is miscible with water in any proportion. Its tolerability equals that of 1, 2- propylene glycol.

Hence, inference can be drawn from the said prior art document that clearly discloses the use of glycofurol as a solvent in injectable preparation that the use of Tetrahydrofurfuryl alcohol Polyethylene glycol ether as co-solvent, as claimed in the impugned patent, is well known in prior art.

1956 article (Annexure X) 1956 article (summary page 126 of annexure) teaches tolerability of propylene glycol is equivalent to glycofurol. Additionally, the article discloses that glycofurol can be used as solvent in preparing stable injectable solutions. Hence inventive step does not reside in employing glycofurol as co-solvent in formulating diclofenac injection.

Thus, the position is clearly established in the case Law of Boards of Appeal for the enhanced effect, selection from obvious alternative,

For Enhanced effect

In T308/99 the claimed use was based on a thoroughly obvious property of known substances. The slightly enhanced effects associated with the claimed use in comparison with substances used in prior art emerged from obvious tests.

In T104/92 the board held that work involving mere routine experiments, such as merely conventional trial-and-error experimentation without employing skills beyond common general knowledge, lacked inventive step.

In T253/92 the subject-matter of claim 1 related to a process for the manufacture of a permanent-magnet alloy. In the board's view, a skilled person would have regarded it as obvious to try out a variety of alloys known from the prior art to be of similar composition to those of the better examples and to measure their magnetic properties.

In T423/09 the board stated that the enhanced effect did not emerge from routine tests but from the practice to be followed according to the rules and recommendations of the handbook. The skilled person following the recommended practice prescribed in this

handbook, and thus acting only routinely would inevitably obtain this enhanced effect, which therefore could not be taken as an indication of inventive step.

For Selection from obvious alternatives

In T1072/07 the application related to an oxygen-fired front end for a glass forming operation. The prior art documents proposed two possibilities for solving the problem of choosing the fuel for the burners and thus two types of burners, an air-gas fired burner or an oxygen-gas fired burner. The board concluded that to solve the problem (how to select a suitable type of burner), the person skilled in the art had to make a choice between two well-known possibilities. Either choice, which in a particular situation would be based on balancing the advantages of the specific type of burner being selected, such as efficiency in its operation, with its disadvantages, such as technical adaptations required and costs involved, was obvious, since the types of burner to be chosen from were well-known.

In view of the foregoing disclosures, it is noted that the diclofenac injection 75mg/ml of impugned patent under opposition does not impart any technical advancement or economic significance as compared to the prior; hence, it is obvious and does not involve any inventive step under the Act.

19. The position itself is clear in the landmark judgment which has been aptly applied by the Hon'ble Supreme Court for judging Inventive step. I do rely on the landmark judgment with respect to inventive step, which goes as under,

In Bishwanath Prasad Radhey Shyam Appellant vs. Hindustan Metal Industries the Supreme Court of India laid down the importance of assessing inventive step, as follows:

"It is important that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an 'inventive step'. To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before. The combination of old known integers may be so combined that by their working interrelation they produce a new process

or improved result. Mere collection of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent."

From the aforesaid, I am of the opinion that the Diclofenac Sodium Injection is known in the art along with use of solvents such as benzyl alcohol, propylene glycol and sodium hydroxide and water in its preparation and having a pH between 8.1 and 9.0 (Document D1). The main object of the invention (Page 4) to provide injectable formulations of water soluble salts of diclofenac which cause significantly less pain at the site of injection and that can be administered by intradeltoid route, in addition to intragluteal and slow intravenous route. The same object is achieved in the documents D 1-D7 either by reading alone or in combination of these prior art and there is no inventive contribution of the patentee at least in this arena. Now, taking up the question of whether identifying the suitable solvent system that reduces the pain at the injection, I see from the various documents that there is a disclosure of the Diclofenac Sodium Injection with less viscosity than as claimed in the impugned patent under opposition and yet reduces the pain at the injection. Now, while judging obviousness any factor that will lead to reasonable expectation of success is relevant and a person skilled in the art has a sound knowledge in this field and not completely ignorant. This being the opinion of the Hon'ble IPAB, I am convinced that having known the Diclofenac Sodium Injection along with use of solvents such as benzyl alcohol, propylene glycol and sodium hydroxide and water in its preparation and having a pH between 8.1 and 9.0 and which cause significantly less pain at the site of injection and that can be administered by intradeltoid route, in addition to intragluteal and slow intravenous route and has low viscosity. These characteristics will be routine experimentation and cannot be considered as inventive. The position of the patentee that non-analogous prior art is irrelevant while judging obviousness is incorrect since all knowledge before the priority date of the patent which is not specific to this field will be held to constitute common general knowledge. I therefore, hold that the claimed diclofenac injection & dependent claims are found to be obvious.

20. I agree with the technical views of Opposition Board constituted comprising of three technical experts under Rule 56 of the Patent Rules, have conducted the examination analysed all documents filed under Rule 57 to 60. The findings of joint recommendation of the Opposition Board report at Para (4) clearly pointed out and given recommendation on obviousness U/s. 25 (2) (e) that the ground of Opposition under Section 25 (2) (e) of the Patents Act, 1970 as amended has been established by the opponent as has been recommended by the Opposition Board.

21. In view of above findings and technical analysis, the impugned invention clearly lacks inventive step and is obvious to a person of ordinary skill in the art in view of the teachings of the prior art documents when taken individually or together as discussed herein above. A person of ordinary skill in the art will be easily motivated to arrive at the invention of the impugned patent without exercising inventive skills and without having to call for or to refer to any additional literature and source. The impugned patent neither involves technical advancement nor has any economic significance as compared to the existing knowledge in the public domain pertaining to the impugned invention. In fact, the objective of the impugned invention has already been met as discussed above. From the aforesaid, I am of the opinion that the Diclofenac Sodium Injection as claimed in the alleged invention could be easily arrived by combining of the teachings of D1-D7. **Therefore, I conclude that the invention as claimed in the claim 1 and its dependent claims lack inventive step & is obvious for a person skilled in the art & the ground of opposition under section 25 (2)(e) is validly established by the Opponent.**

H. GROUND 3 OF THE OPPOSITION: CLAIMS NOT PATENTABLE UNDER SECTION 25(2) (f)

1. The opponent has challenged the impugned application under the ground of opposition U/s. 25(2) (f) on the above ground i.e. Under Section 3(e) of The Patents Act, 1970, the subject matter of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under Section25(2)(f):

2. The “Section 3(e) of the Act, states that 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 substance is not an invention within the meaning of the Act."

3. After going through the post hearing submissions and the documents available on record of the Opponents and Applicant with respect to this ground and also referring to Section 3(e) of The Patents Act, 1970. Accordingly, came to conclusion that the impugned patent claims under opposition clearly has a pharmaceutical composition comprising salts of Diclofenac with polyethylene glycol or propylene glycol and/or benzyl alcohol and/or glycofurol in certain proportion/ranges as disclosed. In accordance with main object of the

invention (Page 3 & 4) is to provided injectable formulations of water soluble salts of diclofenac which cause significantly less pain at the site of injection and that can be administered by intradeltoid route, in addition to intragluteal and slow intravenous route. Yet another object of the invention as explained in the complete specification is to provide single doses of less than 2ml that a less volume of the injection. Further another object of the invention as seen is to provide injectable preparation containing 75 mg/ml and 100 mg/ml of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac in about 1 ml injection solution.

4. Also another object of the invention is to provide a full therapeutic dose of 75 mg to 100 mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac in one ml without substantially increasing the viscosity. Another object of the invention as stipulated in the specification to provide an injectable preparation of water-soluble salts of diclofenac, without the use of surfactants, and preferably, a minimized quantity of co-solvents to avoid any possible side effects. Very important object of the invention as mentioned in specification at page 3 para 3 of the specification that the pain causing element/irritant that the propylene glycol needs to be eliminated from the formulation to avoid the pain at site.

5. Finally, the formulations are adjusted to pH 6 to 10 containing up to 75mg or 100mg of diclofenac sodium or its therapeutically equivalent amounts of water soluble salts of diclofenac, in a medium comprising of water, in combination with one or more class of co-solvent(s) I solubiliser(s), antioxidants, preservatives, buffers, alkali and stabilizers.

6. In order to prove that the patented composition is not an admixture, the Patents law mandates the Patentee to show that the invention is not an admixture and primarily compelled to reveal noteworthy synergy between the components used in the preparation of the composition. The composition must not only show any additive effects, but must exhibit surprising effect that an unexpected results which is not known and must be surprising result that is called synergistic mixture over the existing knowledge, other than obvious result. After the meticulous review of the prior arts cited by the opponent, it is apparent that the prior art discloses formulations with their constituent which are very alike as claimed in the present patent. The same can be seen from Monograph of Diclofenac Injection from Indian Pharmacopeia 1996 edition discloses therapeutic Diclofenac Injection 25mg/ml with two

solvents such as Propylene glycol (polyhydric alcohol) and Benzyl alcohol (monohydric alcohol), water in combination thereof. The similar constituents are also well disclosed in the prior art documents. Considering main object of the invention to provide injectable formulations of water soluble salts of diclofenac which cause significantly less pain at the site of injection is also achieved from the teachings of US 5554650A (Annexure vi)and co - prior arts as well.

7. Thus, from the above findings it is clear that the Diclofenac injection claimed in the impugned patent claims prior known co-solvent(s)/solubiliser (s) in known concentration. The impugned patent doesn't contain any vital or comprehensive data is being provided in the complete specification to establish or to substantiate unexpected synergistic effect between the components used in the formulation when taken individually or in combination thereof. Because the synergy has already been provided in the prior art which can be said to be inherent property, so that the object of the Patent is achieved i.e. reduction of pain at the site of injection. Further it is not clear as to how the reduction in pain is measured and how the patentee has come to the conclusion about this object of the Patent is achieved i.e. reduction in the pain at the site of injection. However, it is apparent that the prior art documents are also reduced the pain at site drastically using the recommended solvents, what level of pain is left to reduce is not been proved and the data in support the same has not been substantiated. Similarly, the data with regard to that effect must be clearly incorporated in the description by way of comparison. All of the above components used in the composition are well known in the art and the fact is also admitted by the Applicant.

8. Thus, from the above findings, it is clear that the composition of the impugned application under opposition does not must meet the above requirements that the composition is a not mere admixture and has the synergistic effect. Explicitly, the composition must noticeably show synergistic effect in respect of 'reduction of pain' as the same has claimed to address the said problem. However, there is no data provided in the specification which proving that there is a reduction in pain at the site of injection. In fact, not a single example provided in the composition which could prove there is reduction in pain while injecting. No clinical data of the claimed formulations is presented in the complete specification to show less pain when increased therapeutic dose of 75mg in l ml is used over the prior art diclofenac injections.

9. In absence of any such concrete evidence/ efficacy data in support of above fact, the Applicant's claim that the efficacy lies in the reduction of pain at the site of injection is not

plausible. On the other side the patent does not have any improvement in therapeutic efficacy or data proving to be advancement in comparison with the known efficacy.

10. The Opposition Board rightly analysed and recommended with respect to this ground of opposition, given technical analysis with respect to section 3(e), concluding that the composition is not proved to be synergistic. This can be seen from exhaustive findings relating of inventive step and also from above findings, the composition as claimed in the impugned application under opposition is not a synergistic in selection and falls within the scope of Section 3(e) of the Patents Act. **Therefore, in view of above findings, I came to conclusion that such ground of opposition is validly established by the Opponent U/s.25 (2) (f).**

I. Ground of Opposition U/s. 25(2) (g); states that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed.

1. The opponent have challenged the impugned application under opposition on the above ground, i.e. Under Section 25(2)(g) of The Patents Act, 1970 i.e. the impugned application under opposition does not sufficiently and fairly describe the invention in a manner so as to enable a person skilled in the art to perform or work the invention.

2. After going through the submissions of the Opponent and Applicant in a context of this ground, it is clear that the composition as claimed in the claims is fairly based on the matter disclosed in the complete specification of the impugned application under opposition along with examples and embodiments and ordinary person skilled in the art can perform the invention without any ambiguity.

3. As per Section 10(4) of the Patents Act, 1970, it is the duty on the Applicant to disclose the best mode/method of practicing the invention known to the Applicant, and the Applicant has clearly disclose the best mode/method of practicing the invention known to the Applicant.

4. From the above findings, I am of the opinion that the impugned application is sufficiently and fairly described the invention in a manner so as to enable a person skilled in the art could perform the said work of invention and does not lead to insufficiency of disclosure in any aspect of the invention. Therefore, there is no violation of any provisions of Section 10(4) of the Patents Act, 1970. I conclude that this ground of opposition U/s. 25(2) (g) is not validly established by the Opponent.

Order

After having considered all the circumstance of this case, post grant representation of the Opponent, affidavits and reply statements of the Applicant and arguments made by the Opponent & Applicant during hearing followed by written submissions, Recommendations of the Opposition Board and also from my discussion and findings as mentioned above, I am of the opinion that the Applicant has failed in proving the grounds relied upon by the Opponent. The ground of oppositions and documents relied by the Opponent, are not in any way destroying novelty, however the said granted claims clearly lack Inventive step in view of the teachings of cited prior art documents and also fall under the ambit of Section 3(e) of The Patents Act, 1970.

I, therefore accept the post-grant opposition and further revoke the Patent no. IN231479 granted on the Patent Application no. 96/MUM/2005. There is no order as to costs.

J) Any party aggrieved with this decision can file an appeal before Hon'ble Intellectual Property Appellate Authority (IPAB) under section 117-A of the Patents Act, 1970 (as amended).

Dated 1st Day of December, 2020

(N. Ramchander)
Deputy Controller of Patents & Designs

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