

BEFORE THE HIGH COURT OF MUNAIN,
REPUBLIC OF BHARANESIA

O.S. No. 707/2014

B.Z. Mate University *.....Plaintiff*

V.

Bristo Pharmaceuticals Pvt. Ltd. *....Defendant 1*

Bristo Pharmaceuticals Inc. *.....Defendant 2*

BEFORE THE INTELLECTUAL PROPERTY APPELLATE BOARD
(IPAB) OF BHARANESIA

Bristo Pharmaceuticals Pvt. Ltd. *.....Appellant*

v.

B.Z. Mate University *.....Respondent 1*

Controller of Patents, Bharanesia *.....Respondent 2*

AND

ORA/14/2014/PT/DH

Bristo Pharmaceuticals Pvt. Ltd. *.....Applicant*

v.

B.Z. Mate University *.....Respondent*

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22. Pope Alliance Corp. v. Spanish River Pulp & Paper Mills Ltd., A.I.R. 1929 P.C. 38.
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- P. Narayanan, "*Patent Law*", 4th Edition, Eastern Law House
- Rama Sharma, "*Commentary on IPR Laws*" Vol. 1 Edn. 2007
- T.A. Blanco White, "*Patents for Invention and the Registration of Industrial Designs*", 3rd Edn, London Stevens & Sons
- Philip W. Grubb, "*Patents for Pharmaceuticals and Biotechnology*" 4th Edn, Oxford University Press

Statutes:

- The Indian Patents Act, 1970

LIST OF ABBREVIATIONS

1. & - And
2. ¶ - Paragraph
3. A.I.R – All India Report
4. Anr. – Another
5. API – Active Pharmaceutical Ingredient
6. Appln. - Application
7. C.A- Civil Appeal
8. Co. Ltd. – Corporation Limited
9. CS – Civil Suit
10. CCPA- Courts of Customs and Patent Appeals
11. Del. – Delhi
12. ECJ- European Court of Justice
13. ECR-European Court Reporter
14. Ed. - Edition
15. EWH – England & Whales High Court
16. FDA – Food and Drug Administration
17. FSR - Fleet Street reports
18. H.C.- High Court
19. Hon'ble- Honorable
20. Ibid- Ibidium
21. Inc.- Inclusive
22. IPAB – Intellectual Property Appellate Board
23. IPLR- Intellectual Property Law Review
24. No.- Number

- 25. Ors.- Others
- 26. Pg.- Page
- 27. Prof. - Professor
- 28. PTC - Patent Trademarks & Copyright
- 29. Pvt. Ltd.- Private Limited
- 30. RPC- Reports of Patent, Design and Trade Mark Cases
- 31. RTI – Right to Information
- 32. S.C.- Supreme Court
- 33. S.C.C.- Supreme Court Cases
- 34. Sec.- Section
- 35. Supra- Superimposed
- 36. V.- Versus

STATEMENT OF JURISDICTION

It is humbly submitted that the appellants have invoked the jurisdiction of The Hon'ble Intellectual Property Appellant Board of Bharanesia under Section 64(1) and Section 117A of The Indian Patent Act, 1970. The respondents submit to the same.

It is humbly submitted that the plaintiff has invoked the jurisdiction of The Hon'ble High Court of Munain, Republic of Bharanesia under Section 104 of The Indian Patent Act, 1970.

The defendants humbly submit to the same.

All of which is most respectfully submitted.

STATEMENTS OF FACTS

1. That B.Z. Mate University (hereinafter referred to as Mate) is a University based in the Republic of Bharanesia which is located in South Asian Region. Its Constitution, Laws, Institutions and Social Ethos are substantially similar to that of Union of India. Mate has a well established Intellectual Property Cell which protects its inventions in various fields. The research and development at Mate is mostly conducted by the Professors of Mate's various departments. It's a leading educational institute which applies for patent applications before the Patent Office of the Republic of Bharanesia and is amongst the top 100 PCT applicants in the world in the category of universities & educational institutes.
2. That Bristo Pharmaceuticals Pvt. Ltd. (hereinafter referred to as Bristo) is a company registered under the laws of Bharanesia. Bristo is a wholly owned subsidiary of Bristo Pharmaceuticals Inc. The business activities of Bristo Pharmaceuticals Pvt. Ltd. are controlled by Bristo Pharmaceuticals Inc and are registered under the laws of federation of Pandora whose constitution, laws and social ethos are substantially similar to that of the United States of America.
3. That Prof. Dr. M. Vaidya and Prof. Dr. P. Bhattacharya have been working with Mate for many years and are the most active researchers who are named as inventors in many PCT and national applications filed by Mate. The inventors published their provisional conclusion on a possible pain killer employing ABC Receptor antagonists in June 2008 in a leading publication, which was available to public on June 5, 2008. The research project continued at Mate after the said publication. After months of research, the Researchers were able to develop a line of pharmaceutical products and filed patent application 8456/MN/2009 on June 5, 2009 titled "Abc receptor

antagonist for the treatment of chronic pain". The inventors named in the application were Vaidya M. and Bhattacharya P.

4. That when the application 8456/MN/2009 was examined, the Examiner vide his letter dated December 12, 2011 objected the grant of patent. The copy of the First Examination Report is enclosed as Exhibit-A. On December 10, 2012 Mate, through their Attorneys' letter responded to the First Examination Report, regarding the missing signatures on Form 1 and assignment, Mate stated that the inventors moved to a company outside Bharanesia and their whereabouts are not known. Mate pointed out that the inventors were on the Rolls of the University. The Standing Rules of the Contract of Employment (which has the force of law) specifically stipulates that only the University will be the owner of any IP generated by their employees in the course of their employment. There were documents available with the Patent Office that the same inventors, during the past, had assigned all their inventions to the Mate University. Non-signing of Form 1 endorsement by the inventors in this case was due to an oversight. Hence, Mate was entitled to apply for the patent. Mate's submissions were taken on record by the Examiner. Before the final decision could be made by the Examiner, Bristo filed a pre-grant opposition against the grant of a patent for the application 8456/MN/2009 inter-alia on the following grounds:

- i. That Mate wrongfully obtained the invention from the inventors as duly signed Form 1/ assignment which are mandatory was not submitted;
- ii. That the claimed Compound of formula I is obvious in view of earlier disclosures known in the art;
- iii. That the invention does not involve an inventive step;

5. That the notice of opposition was taken on record and Mate was informed accordingly. Mate responded with a written statement with primarily the same submissions and evidence as provided at the time of responding to the First Examination Report. A hearing was held and both parties were allowed to present their arguments. Based on Mate's submissions, the Controller of Patents dismissed the pre-grant opposition proceedings filed by Bristo. The Controller, in an elaborate order, stated the reasons for dismissing the pre-grant opposition. A patent was granted to the application 8456/MN/2009 which was given the Patent No. 1234567 on January 11, 2013. A copy of the granted patent No. 1234567 is enclosed as Exhibit B. The decision of grant was published in the journal on March 10, 2013.
6. That on June 10, 2013, Bristo filed a post grant opposition to the Patent No. 1234567 with further documents claiming that the piperidine derivatives were obvious to a person skilled in the art.
7. Bristo relied upon several prior art documents to show that many compounds were structurally and functionally similar to Compound of formula I claimed and the latter is a new form of earlier compounds;
8. They further alleged that the inventors Vaidya M and Bhattacharya P were working on pain receptor antagonists for many years and hence their level of skill in the art was high. It was obvious for them to come up with the claimed piperidine derivatives when earlier compounds were known.
9. A lot of the inventors' own earlier publications and similar patents have been relied upon to state that the invention was obvious.
10. That while the post-grant opposition proceedings were going on, an RTI application by Mate revealed that Bristo had applied for a manufacturing licence before the Drug Controller Licensing Authority, Munain for manufacturing abc bulk drug. Also,

Bristo Inc.'s website has listed abc in their product list under 'developed antagonist APIs'. Mate also realized that Bristo Inc. had applied for marketing approval with the FDA of Pandora and has advertised its intention of launching the product abc in India and Pandora through various media. Mate, sent a letter dated September 15, 2013 through their Attorneys addressed to Bristo and Bristo Inc. which inter alia contained the following:

- i. that Mate is the owner of the patent bearing no. 1234567 which is registered with the Bharanesian Patent Office, in relation to Compound of formula I and compositions thereto;
- ii. that the impugned product is identical to the product which forms a part of the subject matter of Patent bearing No. 1234567 and the actions of Bristo and Bristo Inc. clearly amount to infringement of the said Patent;
- iii. that Bristo and Bristo Inc. should immediately cease and desist from advertising, manufacturing, marketing and using in any way the impugned product;

11. That the said letter was not responded to by Bristo and Bristo Inc. Mate filed a quia timet suit for infringement before the District Court of Suriya (a district in Munain) on 5 January 10, 2014 for restraining Bristo and Bristo Inc. from advertising, manufacturing, marketing and using in any way the impugned product. Mate, in its plaint also mentioned Bristo's zealous efforts at opposing the patent which indicated Bristo's intentions to launch the product. The Hon'ble District Court while taking note of Mate's submissions and evidence, vide an order dated January 15, 2014, granted a quia timet ex-parte injunction restraining Bristo and Bristo Inc. from manufacturing, marketing and in any way using the impugned product in Bharanesia and exporting the same outside Bharanesia.

12. That in the opposition proceedings, the Controller of Patents constituted an Opposition Board who conducted a fresh examination. Both parties made their submissions along with evidence by experts in the field of pharmaceuticals. After thorough examination, the Opposition Board recommended that the claimed invention was obvious.

13. That nonetheless, the Controller, after hearing both parties, ignored the recommendations of the Opposition Board and maintained the patent. The complete order of the Controller is enclosed as Exhibit D. The earlier order of the Controller under Sec. 25 (1) stated as follows:

- i. Compound of formula I is structurally different from compound T and the structural difference does not make Compound of formula I fall under section 3(d) by virtue of explanation to 3(d);
- ii. Compound of formula I is structurally and functionally advanced than compound T and all other known compounds. The inventor's own earlier publications cannot be considered for obviousness or lack of inventive step. Reliance is placed on decisions of other countries which state that the inventor's own publications should not be considered for determining obviousness;
- iii. Compound of formula I is more efficacious and has more beneficial properties than other known antagonists due to the positive effects such as mood elevation, lack of side effects and withdrawal symptoms as demonstrated in the specification and based on independent expert evidence submitted by Mate.

14. That Bisto was dissatisfied with the decision of the Controller, and appealed the decision at the IPAB. Simultaneously, it also filed for a revocation of the patent IN 1234567 at the IPAB on the following grounds:

a. that Mate was not entitled to apply for the patent as duly signed Form 1/ assignment which is mandatorily required to be submitted was not submitted. Bristo provided the whereabouts and details of the inventors and alleged that Mate had in fact made false submissions before the Patent Office that the inventors Vaidya and Bhattacharya were not traceable;

b. that the claimed compound is obvious in view of earlier disclosures and inventor's own earlier publications relating to neuropathic antagonists;

c. that the claimed compound is a new form of a known substance (compound T) disclosed in prior art. The claimed Compound of formula I has almost negligible structural and functional difference with compound T.

d. that the invention does not involve an inventive step;

15. That since the appeal and the application for revocation involved the same patent, both the matters were taken up simultaneously at the IPAB. While the IPAB matters were pending, Bristo challenged the claims of the patent IN 1234567 in a counter-claim of infringement. The suit, along with the counter- claim got transferred to the High court of Munain.

16. That he IPAB and the High Court matters are listed for final disposal on February 8, 2015.

ISSUES RAISED

1. Whether the patent Officer can conclude on ownership of a patent in absence of a valid assignment?
2. Whether the impugned invention can be termed “obvious” keeping in mind the high level of skill?
 - 2.1 Whether the impugned compound is obvious in view of the inventor’s earlier publications?
 - 2.2 Whether the compound falls within section 3(d)?
 - 2.3 Whether there exists an inventive step with regard to the impugned drug?
3. Whether prior publication by the inventors can defeat novelty?
 - 3.1 Whether the publication may be considered as an enabling disclosure?
4. Whether the dismissal of pre grant opposition bars a post grant opposition on primarily the same grounds?
 - 4.1 Whether Section 25(1) and 25 (2) are of the same nature?
6. Whether a quia timet injunction can be granted to protect the rights arising from a disputed patent?
 - 6.1 Whether the plaintiffs have a prima facie case?
 - 6.1.1 Whether the six year rule applies in the present case?
 - 6.2 Arguendo, even if the plaintiff establishes a prima facie case, whether the defendants present a credible challenge to the patent?

SUMMARY OF ARGUMENTS

1. Whether the patent Officer can conclude on ownership of a patent in absence of a valid assignment?

It is the humble submission of the respondent that where there exists an express contract stating that the Intellectual Property produced by the employee will belong to the employer the assignment of ownership rights becomes a mere formality. As in the present case, the contract of employment clearly states any discovery made during the course of employment by any employee would belong to the university, making them the owner of all the patents filed by them.

2. Whether the impugned invention can be termed “obvious” keeping in mind the high level of skill?

It is the humble submission of the respondent that the impugned invention is not obvious. An invention can be patented only when it is unique in nature and is not obvious to the person skilled in that art. The impugned invention had never occurred to the opposition or anybody else until the applicant’s device had received some publicity, thus the opposition may not succeed on the ground of obviousness.

3. Whether prior publication by the inventors can defeat novelty?

Prior publication has been stated as a ground for opposition of patentability under section 25 of the Indian patents act, 1970. However for a publication to be considered as a prior publication it must be enabling in nature, that is, it should enable the public to make or obtain the claimed invention. However it is the humble submission of the defendants that in the present case the inventors have only published conclusions of their provisional research and not made any such disclosures that could be considered enabling in nature. Ergo the publication doesn’t defeat novelty of the claimed compound.

4. Whether the dismissal of pre grant opposition bars a post grant opposition on primarily the same grounds?

- I. It is the most humble submission of the defendants in the present case that a pre grant opposition under section 25 (1) of the Act and a post grant opposition under section 25(2) of the act, although both remedies for objection to the grant of a patent,

are two different remedies, meant to be availed in different circumstances, and not by the same person. Hence, although not expressly barred by statute, rising of the same grounds in a post grant opposition which were raised and dismissed in the pre grant opposition will only result in wasting the time of the court.

5. Whether the same party has the twin remedies of revocation and challenging the patent in a counter claim for infringement having already filed a post grant opposition?

It is most humbly submitted that the defendant has filled for revocation and challenged the patent in a counterclaim for infringement after their post grant opposition filled at the Controller's office had failed. Persons "interested" within the meaning of Section 25(2) can file the 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 117A of the Patents Act." Hence the defendants should not be disentitles to claim the remedies provided under the patent act

6. Whether a quia timet injunction can be granted to protect the rights arising from a disputed patent?

It is the humble submission of the defendants that, the quia timet injunction granted by the district court of Munain to protect the impugned patent is invalid as the defendants have presented a credible challenge to the impugned patent on the grounds of obviousness and lack of novelty; in addition to this the impugned patent is not protected is not protected by the 6 years rule as it is a new patent and its validity is currently under the scrutiny of the IPAB and the High Court of Munain. Hence the injunction granted by the district court of Munain should be invalidated at the earliest to ensure that no Further injustice is done to the defendants.

ARGUMENTS ADVANCED

1. Whether the patent Officer can conclude on ownership of a patent in absence of a valid assignment?

I. It is the humble submission of the respondents that where there exists an express contract stating that the Intellectual Property produced by the employee will belong to the employer, as in the present case, the assignment of ownership rights becomes a mere formality. *The question as to whether the invention developed by the employee during the course of his employment should belong to the employee depends upon the contractual relationship, express or implied, between the employee and the employer.*¹

II. The court of appeals concluded that a patentable invention becomes the property of the employer if the employee was “hired or paid to invent” the intellectual property.² *An employee, performing all the duties assigned to him in his department of service, may exercise his inventive faculties in any direction he chooses, with the assurance that whatever invention he may thus conceive and perfect is his individual property. However this general rule is subject to following limitations. If one is employed to devise or perfect an instrument, or a means for accomplishing a prescribed result, he cannot, after successfully accomplishing the work for which he was employed, plead title thereto as against his employer. That which he has been employed and paid to accomplish becomes, when accomplished, the property of his employer and thereby whatever rights as an individual he may have had in and to his inventive powers, and that which they are able to accomplish, he has sold in advance to his employer.*”³

¹Pg 81 Rama Sharma, Commentary on Intellectual Property Laws, Vol. 1 Edn. 2007

²Hewett v. Samsonite Corp 502 pt.2 1119 Colo App 1973

³Solomons v. United States, 137 U.S. 342, 346 (1890)

- III. *Additionally, if the employee fails to reach his goal the loss falls upon the employer, but if he succeeds in accomplishing the prescribed result then the invention belongs to the employer even though the terms of employment contain no express provision dealing with the ownership of whatever inventions may be developed.*⁴
- IV. *An assignment agreement covering all inventions made by the employee may give a company (and a potential acquirer) significant comfort regarding ownership of patent rights. The company also may benefit from provisions effective without any further action on the employee's part and provisions requiring the employee to cooperate in assisting the company's efforts to patent the invention.*⁵
- V. In the present case, Standing Rules of Employment of Mate university clearly stipulate that all intellectual property produced by its employees will be the sole property of Mate. As has already been concluded by the controller of patents and designs in Exhibit D of the fact sheet, it is an undisputed fact that the applicant, Mate University, has filed hundreds of PCT applications all over the world and has done so in the position of an employer or an assignee.
- VI. Thus, the mere fact that this particular application does not contain Form 1 should not act as a hindrance in the grant of the patent as the true inventors, Professor Vaidya M. and P Bhattacharya were conclusively employees of Mate University, and were legally bound by the Standing Rules of the Contract of Employment which specifically stipulated that only the University would be the owner of any Intellectual Property generated by their employees in the course of their employment.⁶
- VII. Furthermore, the same inventors, during the past, had assigned all their inventions to Mate University⁷ which goes on to show that they were well aware of the patenting

⁴Nat'l Dev. Co. v. Gray, 55 N.E.2d 783, 787 (Mass. 1944)

⁵ Edward Zimmerman, New York Law Journal April 23 2001

⁶ ¶ 6, Moot Problem

⁷ Ibid

process as well as their statutory obligations with respect to the Standing Rules of employment. Being well aware of their rights as the true inventors, had they not intended for the applicant to be awarded the patent, they would most definitely have approached the patent office asking for a revocation of the applicant's patent on the grounds of wrongful obtaining at the Patent Office.

VIII. Hence, as is clear from the above submission, it must reasonably be concluded that the non -signing of form A was nothing more than a mere oversight.

IX. Thus, it is humbly submitted that the Standing Rules of Employment of the University, coupled with the knowledge of the two true inventors of the process of grant of patents and their past actions of assigning their past inventions to the applicants is sufficient to conclude on ownership of Patent No. 1234567.

2. Whether the impugned invention can be termed "obvious" keeping in mind the high level of skill?

- I. The plaintiff has put forth three major objections to the grant of the impugned patent :
 - a. that the claimed compound is obvious in view of earlier disclosures and inventor's own earlier publications relating to neuropathic antagonists;
 - b. that the claimed compound is a new form of a known substance (compound T) disclosed in prior art. The claimed Compound of formula I has almost negligible structural and functional difference with compound T.
 - c. that the invention does not involve an inventive step;⁸

These three objections are wholly dispensed with in the following sub issues.

⁸ ¶13, Moot Problem

2.1 Whether the impugned compound is obvious in view of the inventor's earlier publications?

- I.* It is the humble submission of the defendants that the mere fact that the true inventors, Dr. m. Vaidya and Dr. Prof P. Bhattacharya have years of experience in the pharmaceutical research. And that the level of their skill in the art is high, should in no way be equated to the fact that the invention was obvious to them. Although the applicant's device may seem obvious in retrospect, if it had never occurred to the opposition or anybody else until the applicant's device had received some publicity, the opposition may not succeed on the ground of obviousness.⁹
- II.* While deciding on the issue of obviousness, it was said that "it was proper for a patent examiner to rely on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference."¹⁰ An obviousness determination is not the result of a rigid formula disassociated from the consideration of facts of a case.¹¹ Instead of ascertaining what was subjectively obvious to the inventor at the time of invention, the court must ascertain what would have been objectively obvious to one of ordinary skill in the art at such a time.¹²
- III.* In I.T.S. Rubber Limited's Appln¹³, an application claiming a squash ball of a blue colour was allowed to proceed as colouring of the squash ball had added a desirable characteristic to the article, namely improved visibility in play.

⁹ Kruse's Appln (1972) RPC 777

¹⁰ Bozek reference, 416 F 2d 1385 CCPA 1969

¹¹ Leapfrog Enterprises Inc. v. Fisher Price Inc, 485 (Fed Cir 2007)

¹² Ryko Manufacturing Co. v. NuStarInc, US F.2d 714 1991

¹³ ITS Rubber Limited's Appln 1979 RPC 318

- IV. The question of obviousness should be essentially a practical sort of question decided by a practical man, instructed as to the information which was available.¹⁴
- V. Similarly in the present case, labelling the compound obvious simply because its inventors are highly skilled in the art is nothing short of a travesty- in fact, it is because of their high level of skill in the art that Dr. M Vaidya and Dr. Prof P. Bhattacharya have been able to provide solutions to the various side effects of the previous pain killers and increase the efficacy of the drug.
- VI. *The fact that the inventor himself may not have found difficulty in arriving at his invention is irrelevant. The question is whether the invention in legal sense, that is regarding the matter objectively made by him having regard to the existing state of knowledge? An inventor may well arrive at his invention by a flash of genius which causes him no difficulty or concentrated thought at all, but the invention may still be a most brilliant one which would never have occurred to the notional skilled man in the art at all or only after prolonged investigation and the concentrated exercise of his perhaps lesser inventive faculty. In such a case though it's in a sense obvious to the inventor nevertheless the invention may be worthy of patent protection.*¹⁵
- VII. Therefore, it is the humble submission of the defendants in the present case that the standard of obviousness be taken to be an objective one, on common knowledge and common sense of the person of ordinary skill in the art, and that this Hon'ble court declare the impugned invention not obvious.

¹⁴ Keller and Richter's Patent 1975 RPC 75

¹⁵Dow Corning Corporation's Appln. [1969] RPC 544 at 560

2.2 Whether the compound falls within section 3(d)?

- I. According to Section 3(d) of the Patent Act, the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Further, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.¹⁶*
- II. Thus, according to the aforementioned section, to be patentable, an invention which in structure is similar to prior art, must show an enhanced efficacy to be patentable. In terms of pharmaceuticals, this refers to therapeutic efficacy, which is defined as:*
- 1. the ability of a drug to achieve the desired effect.*
 - 2. the degree to which an intervention accomplishes the desired or projected outcomes.¹⁷*
- III. In the present case, the prior art in pain killers for chronic pain, the two following problems were encountered:*

¹⁶ Explanation to section 3(d)

¹⁷ Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition.

i. Side effects related to serotonin-norepinephrine reuptake inhibitors include drowsiness, dizziness, fatigue, headache, and increase in suicidal thoughts, nausea/vomiting, sexual dysfunction, and urinary retention¹⁸ were noticed. There was a need for medicines which provide for mood elevation which is necessary as the conditions such as chronic pain are often accompanied by depression or trauma. This problem was solved by the drug formulated by the impugned invention as the compounds of the present invention also result in mood elevation. Fig. 3 given on pg. 24 of the Fact sheet clearly shows that with time, the drug sought to be patented not only significantly reduces the chronic pain but also results in noticeable mood alleviation of the patient.

ii. Further the compounds of earlier medicines were difficult to administer especially for geriatric and pediatric patients as they were not available in different formulations.¹⁹ However, in an embodiment of the present invention the composition may be in the form of a liquid, powder, elixir, injectable solution, capsules, suspensions, syrups.

IV. In the aforementioned embodiments, the abc receptor antagonist can be formulated as a hard gelatin capsules or soft gelatin capsule, aqueous suspensions.²⁰

V. The compounds of the present invention are preferably used in pediatric and geriatric patients as it is non-toxic and there are no withdrawal symptoms observed.

VI. Thus, it is the humble submission of the defendants that there is sufficient proof of the therapeutic efficacy of the impugned drug so as to make it patentable.

¹⁸Pg 11, Exhibit B

¹⁹Pg 12, Exhibit B

²⁰Pg 15, Exhibit B

2.3 Whether there exists an inventive step with regard to the impugned drug?

- I. An invention is a new product or process involving an inventive step and capable of industrial application.²¹ Further, an inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and makes the invention not obvious to a person skilled in the art.²²
- II. In the present case, it is the humble submission of the defendants, that considering that the employment of a receptor and an antagonist to block the receptor has the twin advantages of interfering with pain transmission and mood elevation, it solves an existing problem which the person skilled in the art did not earlier know. Absence of withdrawal symptoms and possibility of pediatric and geriatric prescription of the same compound substantially increases the ease of administration and could revolutionize, in future, the treatment to pain. Further, the bioavailability of the drug is high as it can be taken by way of oral administration, intravenous, intramuscular, subcutaneous, intrathecal, epidural or intracerebroventricular injection. Preferably, the abc receptor antagonist is administered intravenously.
- III. Thus, it is the humble submission of the defendants that due to all these aforementioned reasons, there exists an inventive step for the impugned compound.

3. Whether prior publication by the inventors can defeat novelty?

- I. Its most humbly submitted, that in the present case the inventors published their provisional conclusion on a possible pain killer employing ABC

²¹ Section 2 (1) ((j))

²² Section 2 (1) ((ja))

Receptor antagonists in June 2008, in a leading publication²³. The same was raised as a ground for non patentability by the defendants who alleged that a lot of the inventors' prior publications and similar patents have been relied upon, thus in turn making the invention obvious. Under patent law, in order to render a document non novel due to a prior publication, it must be shown that it contains all information that is material to instruct the public on how to put the invention in practice²⁴. To defeat novelty a prior publication must be considered an enabling disclosure.

3.1. Whether the publication may be considered as an enabling disclosure?

I. An invention is said to be made public if it is an 'enabling disclosure'. An enabling disclosure will destroy novelty if the public is given sufficient information to enable the invention to be put into effect. That is, a disclosure will anticipate an invention if it enables the invention to be 'worked' or 'practiced'.²⁵ Or it contains clear and unmistakable directions to do what the patentee claims to have invented²⁶, that a person skilled in art must be able to make the compound from the description of or use to which the public has access²⁷ or the disclosure must disclose a method for working the invention. An invention is not made available to the public merely by a published statement of its existence, unless the method of working was so self-evident as to require no explanation²⁸.

²³ Pg. 2, Moot Problem

²⁴ Pope Alliance Corp. v. Spanish River Pulp & Paper Mills Ltd., A.I.R. 1929 P.C. 38.

²⁵ Merrel Dow Pharmaceuticals v. Norton (1996) RPC 76, 89(HL)

²⁶ M/s. Crompton Greaves Ltd. Mumbai v. M/s. Bharat Heavy Electricals Ltd. Hyderabad Pat. App. No. 221/BOM/96(184657)

²⁷ Asahi Kasei Kogyo KK's Appln. [1991] RPC 485 (HL) at 539-543

²⁸ Pall Corp v. Commercial Hydraulics [1990] FSR 329]

II. In the present case the inventors published their provisional conclusion on a possible pain killer employing ABC Receptor antagonists in June 2008 in a leading publication, which was available to public on June 5, 2008²⁹.

III. Thus, It is the humble submission of the defendant that this publication cannot be considered as an enabling disclosure as it neither discloses the method of invention or working of the patent nor does it disclose directions to make the impugned patent, therefore the publication made by the inventors is not enabling in nature

IV. *In a case the court held that a prior publication to defeat a patent, must exhibit substantial representation of the invention in such full, velar, and exact terms that one skilled in the art may make, construct and practice the invention without having to depend either on the patent or his own inventive skill³⁰.* However, contrary to this, in the present case the publication contained only a provisional conclusion of their research on a pain killer, thereby not disclosing any details about the method to make the patented product. Furthermore, the fact that even after the said publication the research project continued, goes on to prove that it was not possible to arrive at the patented product merely on the basis of the publication.

V. Novelty of a patent would only be defeated if the specification which is relied upon as an anticipation of the invention is the same knowledge as the specification of the invention itself³¹

VI. In a case³² it was held that , “ *No details had been given in the publication about the process and apparatus for removal of fibre from tyre wastes, as has been*

²⁹ Pg. 2, Moot Problem

³⁰ Phillips Electrical & Pharmaceutical Indus Corpn v. Thermal & Electronic Industries Inc. [450 F.2D 1164, 1169(3rd cir. (1971))]

³¹ Supra 2

disclosed in the applicants' specification. Accordingly, the disclosure contained in the said document, even if it is considered to have been published before the priority date of the applicants, the application does not anticipate the applicants' process and apparatus."

VII. It is most humbly submitted that the publication made by the inventors on June 2008 was publication containing only the provisional conclusions made by the two inventors and did not disclose any detail about the method or procedure to manufacture the product or contained anything which would lead to anticipation of the claimed patent. Therefore in no way affecting the novelty of the impugned compound.

4. Whether the dismissal of pre grant opposition bars a post grant opposition on primarily the same grounds?

II. It is the most humble submission of the defendants in the present case that since a pre grant opposition under section 25 (1) of the Act and a post grant opposition under section 25(2) of the act, although both remedies for objection to the grant of a patent, are quite dissimilar in nature, the former being much wider in its scope. Hence, although not expressly barred by statute, raising of the same grounds in a post grant opposition which were raised and dismissed in the pre grant opposition will only result in wasting the time of the court.

4.1 Whether Section 25(1) and 25 (2) are of the same nature?

I. It is put forth that the two remedies- a pre grant opposition under section 25 (1) and a post grant opposition under section 25 (2) are not of the same nature,

³² Gujrat Reclaim & Rubber Products Ltd. v. Kamani Metallic Oxides Ltd. 983(3) PTC 105 (PO)

as they are available to different groups of people. While “any person³³” may apply for a pre grant opposition before the date of grant of the patent, only an “interested person³⁴” may approach the patent office to file for a post grant opposition. The reason for this is that the remedy under section 25(1), available to any person, is a tool of public good and a summary procedure, while the remedy under section 25(2) comes into picture in case of a commercial dispute between rivals and is a proper hearing where both the sides are expected to give arguments and adduce evidence.

II. The remedy at the post-grant stage cannot be equated with the remedy at the pre-grant stage. One cannot be a substitute for the other. Therefore, advisedly right to object at a pre-grant stage has been given to any person by the Act. This is an illustration of statutorily broadening the concept of locus standi and widening the scope of objection procedure by giving access to any person, who has a concern for public interest in the area of public health and nutrition, to raise an objection. The objector may not be a rival in trade of the person claiming the patent. But the objector can raise the objection on much wider grounds of public policy and public interest. The grant of patent is virtually a grant of monopoly right against the whole world and that is why such wide ranging right of objection has been designedly given at a pre-grant stage.³⁵The Supreme Court in J Mitra& Co Pvt Ltd v. Assistant Controller of Patents & Designs³⁶ held that the provision of pre-grant under Section 25(1) is wider than the provisions of post grant under Section 25(2).

³³ Section 25(1)

³⁴ Section 25 (2)

³⁵ Pg. 7, Dr .Zakir Thomas, IP case Law Developments

³⁶ 2008 (38) PTC (6)

- III.* Furthermore, as the deciding authority for both the oppositions is the same, that is, the Controller of Patents, a post grant opposition can at no time whatsoever be interpreted as an appeal to the dismissal of a pre grant opposition. The law provides different routes of appeal for both – while section 117 A of the Act provides for a right to appeal to the IPAB against the decision of the controller in case of a post grant opposition, in case of a pre grant opposition no such appeal is envisaged in the Act; the Controller of Patents being a quasi judicial body, the only remedy available to the aggrieved party is to file a writ petition in front of the High Court under Article 226 of the Constitution.
- IV.* In the present case, as has also been stated by the controller of patents,³⁷ if the plaintiffs in the present case were aggrieved by the decision in the pre grant opposition, they should have availed the constitutional remedy available by way of a writ petition.
- V.* Thus, it follows that putting forth an objection under section 25(2) on the dismissal of the pre grant opposition, primarily on the same grounds, would only result in vexing the decision making authority and wasting its time without providing any solution to either party.

5. Whether the same party has the twin remedies of revocation and challenging the patent in a counter claim for infringement having already filed a post grant opposition?

- I.* It is the humble submission of the defendants that the plaintiff should not be allowed to monopolise the impugned product as it is obvious to the people skilled in the art and thus lacks novelty. To achieve the same, the defendants filed a post grant

³⁷ Exhibit D

opposition and revocation for the impugned patents in the IPAB and challenged the validity of the patent in a counter claim for infringement.

II. The Indian patent act provides an interested person with a remedy of filling for revocation either in the IPAB or in the high court as counter-claim in a suit for infringement of the patent³⁸. Nowhere does the statute disentitle a person who has filled a post grant opposition from filling for revocation of the same patent. The term interested person has been mentioned in both sections 25 as well as section 64, which further proves that if the claim of a person failed in a post grant opposition the next possible remedy available to him is filing revocation against the impugned remedy. Further the moot problem clearly says that the IPAB has clubbed the matters of revocation and appeal to post grant opposition filled by respondents to be heard collectively which acts as a sanction given by the IPAB itself for the simultaneous availing of the two remedies.

III. *The landmark Enercon³⁹ ruling states that a person is barred from filling a suit for revocation if, the post grant opposition is pending before the patent office. However in the present case the controller of patents has already given its decision on post grant opposition and the appeal against the same has been filled in the IPAB ergo it is not barred by the statute*

IV. Therefore it is most humbly submitted that the defendants should be allowed to avail the remedy of filling revocation even after filling of post grant opposition

6. Whether a quia timet injunction can be granted to protect the rights arising from a disputed patent?

I. It is humbly submitted before this Hon'ble court that as in the present case the impugned patent is relatively new and its validity is currently being questioned by the

³⁸ Section 64(1) Indian patent act, 1970

³⁹ Dr. Alloys wobben & Anr v. yogesh Mehra A.I.R. 2014 S.C. 2210

intellectual property appellate board, therefore injunction should not be granted in favour of the plaintiff as it would give an unfair advantage to the plaintiff over the defendant.

*II. In suits alleging patent infringement, the court ought not to grant any interim injunction in cases where either the plaintiffs fail to prove a prima facie case or where the defendant presents a “credible” challenge to either the validity of the patent or to the factum of infringement. Rather, the matter ought to go to the trial for a final decision on the merits.*⁴⁰ The Supreme Court was of the opinion that instead of a decision at the interlocutory state; the suit itself should be disposed of finally at an early date⁴¹.

6.1. Whether the plaintiffs have a prima facie case?

*I. The term Prima facie case has been explained by the Chancery division in the case of Challenger v. Royle*⁴². It means that if the evidence remains as it, there is a probability that at trial the plaintiff will be held entitled to the relief. The Supreme Court ruled in the Biswanath case⁴³ that there is no presumption about the validity of the patent by mere grant or sealing of patent, provided in section 13(4) of the Act, 1970. In another case the Delhi High Court ruled that “interlocutory order will be refused if there is a serious attack on validity of patent⁴⁴”. Similar are the facts in the present case where the validity of the patent granted to Mate is being questioned by the appellate board on the grounds of obviousness and lack of novelty or inventive step, therefore the plaintiff fails to establish a concrete prima facie case.

⁴⁰ Bajaj Auto Limited v. TVS Motor Company Limited 2008 ILLJ 726 Mad.

⁴¹ Ibid,

⁴² (1887)36 ChD 425

⁴³ A.I.R. 1928 S.C. 144

⁴⁴ Ram Narain Kher v. Ambassador Industries (AIR 1976 Del 87)

6.1.1. Whether the six years rule applies in the present case?

- I. *The six-year rule of Indian patent law can be traced to the 1965 decision of the Madras High Court⁴⁵, goes on to say that court will not grant an interim injunction in the case of recently granted patents – with 'recent' being less than six years. The rule presumes that patents older than six years are valid and therefore removes the need to examine the validity of the patent at the interim stage. The granting of injunction by the court examined the validity of the patent at issue in light of the prior art produced by the defendant and concluded that the validity of the patent was in serious doubt. Therefore, the court concluded that the patentee had failed to establish a prima facie case⁴⁶.*
- II. Thus it is the humble submission of the defendants, that in the present case, the patent is a relatively new, granted to Mate on January 11th, 2013; further the validity of the same patent is also under scrutiny by the appellate board on the grounds of Obviousness as in the present case the level of skill is high and therefore the plaintiffs don't have a prima facie case in their favour.

6.2. Arguendo, even if the plaintiff establishes a prima facie case, whether the defendants present a credible challenge to the patent?

- I. *Credibility of the challenge presented by the defendant against the plaintiff's claim is of immense importance to the court while taking a decision regarding grant of injunctions. Where the evidence disclosed a genuine intention to defend the action upon the grounds that the patents were invalid, it could not be said that the defence was frivolous or vexatious, it was held to be a serious triable issue⁴⁷*

⁴⁵ Manicka Thevar v. Star Plough

⁴⁶ 3M Innovative Properties Company v. M/S Venus Safety & Health Pvt Ltd

⁴⁷ Quantal v Sheima Sciki [1990] RPC 436

- II.* The Calcutta high court held that, even if the plaintiff could establish a prima facie case, where the patent is a new and recent one which has not been worked out as yet, the Court has to consider this aspect before allowing it⁴⁸. Ergo, in the present case even if we were to believe for the sake of argument that the plaintiffs are able to establish strong prima facie case in their favour, injunction cannot be granted as there is a validity of the patent is currently being examined by the appellate board of the country .
- III.* It is most humbly submitted that in the light facts presented, quia timet injunction should not have been granted in favour of the plaintiff for protecting rights arising out of a disputed patent.

⁴⁸ Godrej Soaps v. Hindustan lever (1994) IPLR 60 (Cal)

PRAYER

Wherefore, in the light of the facts stated, issues raised, argument advanced and authorities cited, it is most humbly prayed by the respondents in this matter that the Hon'ble Intellectual Property Appellate Board of Bharanesia maybe pleased to:

Declare the impugned patent valid and the objections raised by the appellants to be inpplicable.

For this act of kindness the Respondents shall forever humbly pray.

Wherefore, in the light of the facts stated, issues raised, argument advanced and authorities cited, it is most humbly prayed by the defendants in this matter that the Hon'ble High Court of Munain maybe pleased to:

Revoke the impugned patent.

Invalidate the quia timet injunction granted in favour of the plaintiff by the District Court Munain

For this act of kindness the Defendants shall forever humbly pray.

Respectfully Submitted by,

Counsel for the Respondent (IPAB)

Counsel for the Defendant (High Court)