

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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LIST OF AUTHORITIES

Cases Cited:

- Ajay Industrial Corporation v. ShiroKanao of Ibraki City, A.I.R. 1983 Del 496
- Antaryami Dalabehera v. Bishnu Charan Dalabehera 2002 I OLR 531
- Bristol-Myers Co's Application, [1969] RPC 146
- Hindustan Lever Ltd. v. Colgate Palmolive Ltd. And Anr. A.I.R. 1998 S.C. 526
- Dr Alloys Wobben & Anr v. Yogesh Mehra A.I.R. 2014 S.C. 2210
- Dubilier Condenser, 289 U.S. at 187
- Dyson v. Hoover, 2002 RPC 465
- Environmental Designs Ltd. v. Union Oil Co. (83 L Ed 2d 464 U.S. 1984)
- Fomento v. Mentmore 1956 RPC 87
- Gadd and Mason v. Manchester Corporation (1892) 9 RPC
- Hiyamizu Exp USPQ 1393 (Bd Pat App & Inter 1988)
- Interprise Railway Equipment Co. v. Pullman Standard Car Mfg. Co. 95 F (2d) CCA7 1938
- J.Mitra and Co. Ltd v. Asst. Controller of Patents & Designs A.I.R. 2009 S.C. 405
- Jawahar Eengineering Co. and Ors v. Javahar Engineering Pvt. Ltd. A.I.R. 1984 Del 1666
- LallubhaiChakubhai v. ChimanlalChunilal& Co. A.I.R. 1936 Bom. 99)
- M/s Bishwanath Prasad RadheyShyam v. M/s Hindustan Metal Industries A.I.R. 1982 S.C. 1444
- Mariappan v. A.R.Safiullah & Three Ors. 2008(5) CTC 97
- Mercksharp Dohme and Bristol Meyers v. Teva Farma Biwi [2012 EWHC 627(PAT)]
- Monsanto Brignac's Application [1971] RPC 153

- Mooney's Appln (1927) 44 RPC 294
- Novartis AG and Ors v. Alembic Pharmaceutical Ltd. CS (OS 1053/2014)
- Novartis AG and Ors v. Bajaj Healthcare Ltd. CS (OS 1053/014)
- Novartis AG and Ors v. Cadila Healthcare CS (OS 1052/2014)
- Novartis AG and Ors v. Glenmark Gnrics CS (OS 1054/2014)
- Novartis AG and Ors v. Wockhardt Ltd. CS (OS 1051/2014)
- Riber v. Marsden Smith & Others (1952) 69 RPC 230
- Sharp & Dohne v. Boots Pure Drug (1928) 45 RPC 153
- Solomons v. United States, 137 U.S. 342, 346 (1890)
- Vickers v. Siddell (1890) 7 RPC 292 (C.A)
- Wal Chand Nagar Industries Ltd v. Thermax Private Ltd. 1988 PTC 213

Books referred:

- 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
- Code of Civil Procedure, 1908

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. Del. – Delhi
11. ECJ- European Court of Justice
12. ECR-European Court Reporter
13. Ed. - Edition
14. EWH – England Whales
15. FDA – Food and Drug
16. H.C.- High Court
17. Hon’ble- Honorable
18. Ibid- Ibidium
19. Inc.- Inclusive
20. IPAB – Intellectual Property Appellate Board
21. IPLR- Intellectual Property Law Review
22. Mfg. – Manufacturing
23. No.- Number

- 24. OLR - Ontario Law Review
- 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.

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.

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 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 Section 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 the absence of a valid assignment?

1.1 Whether a contract of employment automatically awards ownership rights to an employer?

2. Whether the impugned invention can be termed “obvious” under the Indian Patent Act?

2.1 Whether the formula of compound 1 would be obvious to a person skilled in the art?

2.2 Whether there existed any inventive step in the synthesis of compound 1?

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

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

4.1 Whether Bristo Pharmaceuticals comes within the definition of the term “interested party”?

5. Whether the same party has a twin remedy of revocation and challenging the patent in a counter claim for infringement after a post grant opposition?

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

6.1 Whether the Plaintiff has a Prima Facie case?

6.2 Whether non granting of injunction would lead to irreparable injury to the plaintiffs?

6.3 Whether Balance of inconvenience is in favour of the Plaintiff?

SUMMARY OF ARGUMENTS

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

It is most humbly put forth that a formal assignment of the ownership rights to a patent, from the inventor to the applicant is a statutory requirement envisaged under the Indian Patent Act under Form 1, in the absence of which, ownership cannot be concluded. A mere contract of employment does not entitle the employer to all the intellectual property produced by the employee- there must be a valid assignment.

2. Whether the impugned invention can be termed “obvious” under the Indian Patent Act?

It is the contention of the appellants that in the present case, the invention is non patentable as it a mere new form of an already known substance, and falls under section 3(d). Furthermore, not only is the impugned invention obvious, it has already been anticipated by prior publication and also lacks inventive step. Thus, it is the humble submission of the appellants that it be declared invalid.

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

It is humbly submitted by the plaintiffs that novelty is one of the essentials of an invention. The definition of the term “invention” itself includes a “new” product or process.¹ Thus, the prior publication of an invention destroys its novelty- thus rendering it non patentable. The same applies to the present case where the publication of their invention in a newspaper by the inventors themselves has destroyed its novelty.

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

It is the humble submission of the appellants in the present case that as Bistrop pharmaceuticals comes within the definition of the term ‘interested party’ given in the act, it has the locus standi for applying for a post grant opposition under section 25(2), regardless of

¹ Section 2 (1) ((j))

the dismissal of the pre grant opposition. Nowhere in the Act has it been stated that once a pre grant opposition has been dismissed, a post grant opposition of the same ground is barred.

5. Whether the same party has a twin remedy of revocation and challenging the patent in a counter claim for infringement after a post grant opposition?

In the present case the defendants have filled for revocation of the impugned patent of the high court and the IPAB. However Section 64(1) of the Indian patent act read with section 10 and section 151 of the CPC disentitles the defendant from bringing the same matter in the high court and the IPAB simultaneously as it would lead to overlapping of the jurisdiction of the court and waste time of both the court. Thus it is the humble submission of the plaintiffs that the defendant cannot be allowed to simultaneously avail the two abovementioned 2 remedies

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

In the present case the defendants have questioned the validity of the quia timet injunction granted by the high court on the grounds validity of the patent being in question under the high court and the IPAB. However this is invalid argument as grant of injunction depends on the existence of a prima facie case, possibility irreparable injury and balance of convenience. All these essentials are being fulfilled in the present case therefore the granting of injunction was important to prevent the defendants from continuing to infringe the patent. Therefore it is the humble submission of the plaintiff to declare the granted injunction as valid.

ARGUMENTS ADVANCED

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

- I. It is most humbly put forth that a formal assignment of the ownership rights to a patent, from the inventor to the applicant is a statutory requirement envisaged under the Indian Patent Act, in the absence of which, ownership cannot be concluded.

1.1 Whether a contract of employment automatically awards ownership rights to an employer?

- I. *The mere existence of a contract does not itself disqualify the employee from protecting the intellectual property generated by him during the course of his employment even though the intellectual property generated may relate to a subject matter useful for the employer or the employee may have made use of the time and materials for creating the intellectual property.*² The courts in *Dubilier Condenser*³ said “We have rejected the idea that mere employment is sufficient to vest title to an employee’s invention in the employer.”
- II. *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.*⁴

²Pg. 81, Rama Sarma, Commentary on IPR Laws Vol. 1 Edn. 2007

³*Dubilier Condenser*, 289 U.S. at 187

⁴*Solomons v. United States*, 137 U.S. 342, 346 (1890)

- III. Thus, whether in a particular case, the invention made by the employee should belong to the employer depends upon the contractual relations, express or implied, between the employee and the employer.⁵
- IV. Section 6 of the act lays down 3 types of people who may apply for a patent:
- 1) The true inventor of the patent
 - 2) The assignee of the true inventor
 - 3) The legal representative of the true inventor after his death.
- V. It is humbly submitted that in the present case, the respondents claim to come in the second category, as assignees of the true inventors, Dr. Vaidya and Professor Bhattacharya. However. Without a valid assignment, there can be no assignee- no rights of ownership arise where there exists no valid assignment.
- VI. Furthermore, the fact that the same inventors had assigned all their inventions to Mate⁶ in the past cannot be taken as a presumption that they would do the same in the present case- on the contrary, being inventors of a large number of patents, they would be closely acquainted with the patenting process and would not overlook such an essential requirement- even the claim of the defendant that their whereabouts are not known has fallen flat as the appellants have been successful in locating the two real inventors.
- VII. As has previously been stated, no ownership rights can arise out a mere contract of employment. A patent is property and title to it can pass only by assignment⁷.
- VIII. Thus it is the humble submission of the appellant that in the present case, Form 1 is a sine qua non to conclude ownership of the impugned patent.

⁵Riber v. Marsden Smith & Others (1952) 69 RPC 230

⁶ ¶6, Moot Problem.

⁷Supra 2

2. Whether the impugned invention can be termed “obvious” under the Indian Patent Act?

- I. The fundamental principle of Patent Law is that a patent is granted only for an invention which must be new and useful. That is to say, it must have novelty and utility. It is essential for the validity of a patent that it must be the inventor's own discovery as opposed to mere verification of what was already known before the date of the patent. Thus, 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 reactant⁸ is not patentable, as is the present case.
- II. Thus, the two essentials listed under Section 3(d) are:
- a. The invention should not be obvious knowledge to one skilled in the art.
 - b. There must exist, an inventive step which renders novelty to the invention.

2.1 Whether the formula of compound 1 would be obvious to a person skilled in the art?

- I. Though not explicitly defined, an invention would be obvious if it was so that it would at once occur to anyone acquainted with the subject and desirous of accomplishing the end.⁹ To determine obviousness is to find out whether the person, with ordinary skill in the art, would have come up with similar

⁸ Section 3(d) of the IPA

⁹ Vickers v. Siddell (1890) 7 RPC 292 (C.A)

innovation for the technical problem under similar circumstances without being provided with the solution.

- II. The courts in examining an invention will assume that the inventor who made it was thoroughly acquainted with the entire prior art.¹⁰ *Thus, the material question to be considered is whether the alleged discovery lies so much out of the track of what was known before as not naturally to suggest itself to a person thinking on the subject; it must not be the obvious or material suggestion of what is precisely known*¹¹.
- III. In the present case, it is clear from a glance that the formula of compound 1¹² is nothing more than a mere derivative of compound T as taught by Hensky¹³. As correctly analysed by the opposition board, pharmaceuticals, especially pain killers, are among the highly researched areas and a person skilled in the art can arrive at the composition after reasonable trial and error.¹⁴
- IV. *The person skilled in the art is someone with a wide knowledge of the technology within which the invention lies. The question is would the invention be obvious to such a person? The court, in considering the skills of the notional “person skilled in the art” for the purpose of obviousness will have regard to the reality of the position at that time.*¹⁵ The hypothetical person having ordinary skill in the art to which the claimed subject matter pertains would, of necessity, have the capability of understanding the scientific and engineering principles applicable to the pertinent art.¹⁶ *Some of the standards which help in determining the level of ordinary skill in the art are the*

¹⁰Interprise Railway Equipment Co. v. Pullman Standard Car Mfg. Co. 95 F (2d) CCA7 1938

¹¹ Supra 7

¹²Pg.5, diagram 1 of moot problem

¹³Pg.5, diagram 2 of moot problem

¹⁴ ¶3, Exhibit- C

¹⁵ Dyson v. Hoover, 2002 RPC 465

¹⁶Hiyamizu Exp USPQ 1393 (Bd Pat App & Inter 1988)

*educational level of the inventor, prior art solutions to the problems encountered, rapidity with which the inventions are made, sophistication of the technology and educational level of active workers in the field*¹⁷.

- V. Applying these standards to the present case, we see that the level of skill in this instance is particularly high – the inventors are scientists, having years of experience, numerous patents and a thorough knowledge of the prior art; the level of sophistication of the technology involved is also higher than what is expected from an average person. Thus it logically follows that where the level of skill in the prior art is high, the chances of an invention being obvious increases manifold, as has happened in the present case.

2.2 Whether there existed any inventive step in the synthesis of compound 1?

- I. “Invention” means a new product or process involving an inventive step and capable of industrial application¹⁸. The term “inventive step” has been defined as 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.¹⁹
- II. *Therefore, an "inventive step" which is a necessary ingredient of invention in order to make an applicant eligible for grant of patent under the Act, must be relating to an invention involving technical advance or having economic significance or both along with a necessary factor that such invention should make it not obvious to a person skilled in the art.*²⁰

¹⁷ Environmental Designs Ltd v. Union Oil Co.83 L Ed 2d 464 US 1984

¹⁸ Sec. 2 (1)(j)

¹⁹ Sec. 2(1)(ja)

²⁰Mariappan v. A.R.Safiullah & Three Ors. 2008(5) CTC 97

- III.* The fundamental principle of Patent Law is that a patent is granted only for an invention which must be new and useful. That is to say, it must have novelty and utility. It is essential for the validity of a patent that it must be the inventor's own discovery as opposed to mere verification of what was already known before the date of the patent.²¹
- IV.* Thus, the mere discovery of a new property of a known substance will not result in an inventive step. The ascertainment of valuable properties of a chemical substance, although important from the point of view of utility, is not itself a patentable invention, but at most a discovery²². In the present case, compound I is derived from substituting methylbenzene in the cyclopentane ring in place of ethyl on the piperidine ring which is no more than mere substitution of one element for another. The explanation to Section 3(d) clearly provides that 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, which is clearly not the matter in the present case.
- V.* *A patent for the mere new use of a known contrivance, without any additional ingenuity in overcoming fresh difficulties is bad, and cannot be supported. If the new use involves no ingenuity, but it is in manner and purpose analogous to the old use, although not quite the same, there is no invention, no manner of a new manufacture within the meaning of the statute*²³. Hence, it is the humble submission of the appellant that patent of compound formula I be revoked.

²¹ M/s Bishwanath Prasad RadheyShyam v. M/s Hindustan Metal Industries A.I.R. 1982 S.C. 1444

²² Sharp & Dohne v. Boots Pure Drug (1928) 45 RPC 153

²³ Gadd and Mason v. Manchester Corporation (1892) 9 RPC

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

- I. It is humbly submitted by the appellants that novelty is one of the essentials of an invention. The definition of the term “invention” itself includes a “new” product or process.²⁴ Thus, the prior publication of an invention destroys its novelty- thus rendering it non patentable.
- II. *Where the invention so far as claimed in any claim of the complete specification, has been anticipated by publication before the date of filing of the applicant’s complete specification in any specification filed in pursuance of an application for a patent made in India²⁵, it will amount to prior publication.* One of the first and foremost conditions for the grant of patent is that the invention should be new or novel. In other words, it can be said that the invention should not be anticipated by any publication.
- III. When the matter in question is distributed with the object of spreading knowledge among the interested parties, it would constitute publication²⁶. The communication to a single member of the public without inhibiting fetter is enough to amount to making available to the public²⁷. There is no need even to show that a member of the public has actually seen the document. For example, in Monsanto Brignac’s Application²⁸, it was held that a company had published a document by supplying it to its salesmen, since it had been given to them with no restriction on disclosure; indeed it had been put into their hands with the intention that they should make the information available.
- IV. In the present case, the true inventors of the compound, Dr. M. Vaidya and Dr. Professor P. Bhattacharya have published their findings on a pain killer employing ABC Receptor antagonists in June 2008 in a leading publication, which was available

²⁴ Sec. 2 (1) (j)

²⁵ Sec.13 of IPA

²⁶ Mooney’s Appln (1927) 44 RPC 294

²⁷ Bristol-Myers Co’s Application, [1969] RPC 146

²⁸ [1971] RPC 153

to public on June 5, 2008.²⁹ Thus, the fact that the information regarding Compound I was available to the public is indisputable. Once there was publication, the novelty of the impugned invention was destroyed, rendering it non patentable.

- V. Section 13 of the act, which provides for prior publication, does not at any point differentiate between inventors and third parties; neither does the act in any Section exempt publications made by inventors from the ambit of Section 13. Thus, even the prior publication made by inventors can defeat novelty of their own invention.
- VI. *In a case where the applicant had applied for patenting the nib for a ballpoint pen, which makes continuous and uniform flow of ink, the case was that the patentees themselves had published a description of making ballpoint pens which would be taken as the performance of invention. It was held that this act would amount to anticipation of the invention, through priority publication thus defeating the requirement of novelty*³⁰.
- VII. If the prior publication is contained in a document, it may not be necessary that members of the public should have actually read the document. It is enough if the document is accessible to the public without much trouble³¹. An invention should be deemed to be made publicly known if a document containing an adequate description of it, whether issued as a general publication or not, has in the course of ordinary business and without imposing any secrecy, reached an appreciable Section of the public interested in the art to which the invention relates.³²

²⁹ ¶ 4, Moot Problem

³⁰ Fomento v. Mentmore 1956 RPC 87

³¹ Lallubhai Chakubhai v. Chimanlal Chunilal & Co. A.I.R. 1936 Bom. 99)

³² Decision of the Controller (1938) Re. Patent Application No. 23077

VIII. Therefore it is humbly put forth by the appellants in the present case that the publication of their findings on ‘ABC receptor pain killers’ in a leading newspaper constitutes prior publication under Section 13 of the Act and hence defeats the perceived novelty of the present invention.

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

I. The appellant humbly submits that according to the Indian Patent Act, at any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner³³. In the event that the controller is not satisfied with the evidence produced by the person making the representation under 25(1) and grants a patent thereon, an interested person can oppose the grant on the grounds prescribed in 25(2) of the above mentioned act.³⁴

4.1 Whether Bristo Pharmaceuticals comes within the definition of the term “interested party”?

I. A “person interested” is defined as one who is “engaged in, or in promoting, research in the same field as that to which the invention relates³⁵. The meaning

³³ Sec. 25(2), IPA

³⁴ Wal Chand Nagar Industries Ltd v. Thermax Private Ltd 1988 PTC 213

³⁵ Sec. 2(t), IPA

of the term was considered by the Delhi High Court³⁶ wherein it was adjudicated that an “interested person” must be a person who has a direct, present and tangible commercial interest which is affected by the continuance of the patent.

II. In the present case, the appellant, Bristo Pharmaceuticals, is a company which derives its profits primarily from the sale and manufacture of drugs. It has applied for a manufacturing licence before the Drug Controller Licensing Authority, Munain for manufacturing abc bulk drug. Also, Bristo Inc.’s (the parent company of Bristo Pharmaceuticals) website has listed abc in their product list under ‘developed antagonist APIs’³⁷.

III. Thus, both the companies clearly come within the ambit of the term “interested party” as not only are they engaged in or in promoting research in the pharmaceutical field, they have a direct, present and tangible commercial interest which will clearly be affected by the continuance of the Patent No. 1234567.

IV. Lastly, a plain reading of Section 25 shows that the grounds of opposition given under Section 25(1) [for pre grant opposition] and Section 25(2) [for post grant opposition] are completely identical; thus, the question of dismissal of a pre grant opposition on the same grounds barring the subsequent post grant opposition is quite ill founded . Bristo Pharmaceuticals, in the pre grant opposition filed against the granting of the patent listed two grounds of opposition, namely :

³⁶ Ajay Industrial Corporation v. ShiroKanao of Ibraki City, A.I.R. 1983 Del 496

³⁷ ¶9, Moot Problem

- a. that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;³⁸
- b. that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;³⁹

V. However in the post grant opposition On June 10, 2013, Bristo filed a post grant opposition to the Patent No. 1234567 on only one ground, with claiming that the piper dine derivates were obvious⁴⁰ to a person skilled in the art.

VI. *Where the pre grant opposition is rejected, it is apparent from the decision in J.Mitra and Co. Ltd v. Asst. Controller of Patents & Designs⁴¹, and from a reading of Sec. 25 that as long as the person who has filed the opposition happens to be a person interested, he would, have the remedy of filing a post grant opposition. 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 now has two remedies- if his post grant opposition is also rejected, he an thereafter file an appeal to the IPAB under Section 117 A. The same was used by Bristo when its post grant opposition was rejected by the Controller of Patents.*

VII. Thus, the appellant in the present case humbly submits that the dismissal of a pre grant opposition does not bar a post grant opposition on the same grounds.

³⁸ Sec. 25 (1) ((a)), IPA

³⁹ Sec. 25 (1) ((e)), IPA

⁴⁰ Sec. 25 (2) ((e)), IPA

⁴¹ J.Mitra and Co. Ltd v. Asst. Controller of Patents & Designs AIR. 2009 S.C. 405

5. Whether the same party has a twin remedy of revocation and challenging the patent in a counter claim for infringement after a post grant opposition?

- I. It is most humbly submitted, in the present case the defendants had, filled a post grant opposition with the controller under Sec. 25(2) and the decision of the same was given in favour of the plaintiff, dismissing the post grant opposition. Subsequently which the defendants filled for revocation of the impugned patent at the IPAB and challenged the validity of same in the High court as a counter claim in an infringement suit. However according to the Indian Patent Act, 1970 both these remedies cannot be availed simultaneously by the defendants⁴².
- II. Once a patent has been opposed under Section 25(2) of the Indian Patents Act and has been granted thereafter, it cannot be attacked again, by the same person, for revocation under Section 64(1) of the Indian Patent Act, either as revocation proceedings under the Act or as a counter claim against infringement claim.
- III. *The Court averred “that if “any person interested” has filed proceedings under Section 25(2) of the Patents Act, the same would eclipse all similar rights available to the very same person under Section 64(1) of the Indian Patents Act. This would include the right to file a revocation petition in the capacity of “any person interested”⁴³, as also, the right to seek the revocation of a patent in the capacity of a defendant through a “counter-claim”⁴⁴”*
- IV. The Court also held that “if a “revocation petition” is filed by “any person interested” in exercise of the liberty vested in him under Section 64(1) of the Patents Act, prior to the institution of an “infringement suit” against him, he would be disentitled in law

⁴² Sec. 64(1), Indian Patent Act, 1970

⁴³ *ibid*

⁴⁴ *Supra*

from seeking the revocation of the patent in “infringement suit” filed against him through a “counter-claim⁴⁵.”

- V. The Hon'ble Court further explained that simultaneous remedies to assail the same patent are not available under the Indian Patents Act and under Section 10 of the Code of Civil Procedure (CPC), 1908 read with Section 151 of the CPC that provide that “where an issue is already pending adjudication between the same parties, in a Court having jurisdiction to adjudicate upon the same, a subsequently instituted suit on the same issue between the same parties, cannot be allowed to proceed”.
- VI. The use of the word “or” in Section 64(1) demonstrated that the liberty granted to any person interested to file a revocation petition, to challenge the grant of a patent to an individual, could not be adopted simultaneously by the same person filing a counter-claim in a suit for infringement. The word “or” used therein clearly separates the different remedies provided, and bars their simultaneous use for the same purpose.
- VII. The facts of the present case are almost identical; the defendants opposed the patent under Section 25(2) of the Indian Patents Act however despite the opposition it had been granted, thereafter the defendants filled for revocation of the patent in the IPAB and challenged the claims of the patent in a counter-claim of infringement⁴⁶. Thus by doing this the defendants have availed all possible remedies available to them, thus overlapping the jurisdiction of the IPAB and the high court by raising the same matter about the validity of the impugned patent. The same being barred under the CPC and Indian Patent Act, 1970.
- VIII. Therefore in the light the authorities cited, it is the humble submission of the plaintiff that, the defendants should not be allowed to file for revocation and counter claim for infringement after a post grant opposition has already been filled.

⁴⁵ Dr Alloys Wobben & Anr v. Yogesh Mehra A.I.R. 2014 S.C. 2210

⁴⁶ Pg. 7, Moot Problem

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

- I. Its most humbly submitted, in the present case, the defendants have expressed their strong desire to market the patented drug and as a result infringing the patentee's right. Non granting of the injunction would have encouraged infringement of this right and caused irreparable injury to the plaintiff.
- II. A quia timet injunction is an interim injunction based on a fear of possible injury and therefore based on mere threat of an infringement act⁴⁷. Therefore in such cases the court assesses whether a cause of action has arisen and then go on to decide injunctive relief. In order to obtain an interim injunction from an Indian Court, a plaintiff has to establish the following:
 - A prima facie case against the defendant
 - That if the injunction is not granted, the plaintiff would face an irreparable injury
 - Whether balance of inconvenience is in favour of the plaintiff⁴⁸

6.1 Whether the Plaintiff has a Prima Facie case?

- I. In an English case where the claimant was the patentee of efavirenz, a non-nucleoside reverse transcriptase inhibitor⁴⁹ (used in the control of HIV infections), the patent was due to expire in August 2013. The patentee prayed for a quia timet injunction in 2012, as it feared that Teva, a generic manufacturer, intended to infringe its patent. This fear was based on the fact that in October 2011 Teva had applied for marketing authorization for a generic version of efavirenz in January

⁴⁷ Jawahar Engineering Co. and Ors v. Jawahar Engineering Pvt. Ltd. A.I.R. 1984 Del 1666

⁴⁸ Hindustan Lever Ltd. v. Colgate Palmolive Ltd. And Anr. A.I.R. 1998 S.C. 526

⁴⁹ Mercksharp Dohme and Bristol Meyers v. Teva Farma Biwi [2012 EWHC 627(PAT)]

2012. This authorization was granted and lastly. The court found that these were valid grounds that created a legitimate threat to the patentee's rights. The fact that Teva applied for marketing authorization twenty-two months before the expiration of the patent coupled led the court to admit the application and grant a *quia timet* injunction. The court observed:

- II. *“To justify an order for interim relief one does not need to know precisely when Teva intend to launch, all one needs to know is that they intend to launch before expiry and before a full trial could be heard.”*⁵⁰
- III. The Indian Patent Act, 1970 confers upon the patentee the exclusive right to prevent third parties who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes the product⁵¹. Therefore, where in the present case, Bisto has applied for a manufacturing licence before the Drug Controller Licensing Authority, Munain for manufacturing abc bulk drug, the patent of which is held by Mate, its intention to market the drug can be clearly established which is a clear infringement of the right provided under Section 48 (a) of the Act.
- IV. In addition to the above submissions, Bristo Inc.'s website has listed abc in their product list under 'developed antagonist APIs' and 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 media⁵². In the light of the above facts, it can be concluded that the plaintiff has a prima facie case

⁵⁰ Ibid.

⁵¹ Section 48(a) Indian Patent Act, 1970

⁵² Pg. 4, Moot Problem

6.2 Whether non granting of injunction would lead to irreparable injury to the plaintiffs?

- I. As recently as April 2014 the Delhi High Court granted a host of interim quia timet injunctions to Novartis against several generic manufacturers such as Bajaj healthcare⁵³, Alembic Pharmaceutical⁵⁴, Glenmark Generics and Cadila healthcare⁵⁵ over the anti diabetic drug Vildagliptin⁵⁶. This dispute is over Novartis's Patent which is valid till 2019. In the first two cases⁵⁷ the court expressly ordered ex-parte interim injunctions against the generic manufacturers. On the basis to the reply filed with the State Drug Controller, Novartis learnt that both Bajaj Healthcare as well as Alembic Pharmaceuticals had obtained manufacturing license as well as permission to sell generic Vildagliptin from the drug controller in early 2014. Novartis contended on the basis of this information the two generic manufacturers were in the process of launching the drug and irreparable damage would arise if injunction were not issued. Merely on the basis of this submission, the court restrained the defendants from manufacturing importing, selling, offering for sale, exporting and directly or indirectly dealing in Vildagliptin and its combination except as provided under Section 107A of the Patent Act.
- II. Novartis obtained another set of quia timet injunction against Bicon and Wockhardt⁵⁸. Wockhardt had initiated revocation proceedings before IPAB in an attempt to annul the patent over Vildagliptin. Two infringement suits were filed before the Delhi High Court against Bicon and Wockhardt. In both cases

⁵³ Novartis AG and Ors v. Bajaj Healthcare Ltd CS (OS 1053/014)

⁵⁴ Novartis AG and Ors v. Alembic Pharmaceutical Ltd. CS (OS 1053/2014)

⁵⁵ Novartis AG and Ors v. Glenmark Generics CS (OS 1054/2014)

⁵⁶ Novartis AG and Ors v. Cadila Healthcare CS (OS 1052/2014)

⁵⁷ Supra 8&9

⁵⁸ Novartis AG and Ors v. Wockhardt Ltd. CS (OS 1051/2014)

injunctions were granted and generics were prevented from selling, manufacturing, exporting, etc. the impugned product.

III. Similar is the matter in the present case, Bistro Inc. had filled for revocation proceedings to invalidate Mate's right over the impugned product, however the patent has been granted in Mate's favour by the controller. Coupled with this, is the fact that Mate spent their time and resources for a long period over the discovery of the drug and thus it is clear that the non granting of injunction will give an unfettered right to Bistro to manufacture, sell and export their product and thus causing irreparable injury to the Mate.

6.3 Whether Balance of inconvenience is in favour of the Plaintiff?

- I.* The Court will consider the extent to which each party would be disadvantaged by the granting or non granting of an interim injunction and the extent to which damages would be an inadequate remedy i.e. would it cause greater hardship (financial or otherwise) to grant or refuse the injunction. *In Antaryami Dalabehera v. Bishnu Charan Dalabehera*⁵⁹ the Orissa High Court held that balance of convenience, means, comparative mischief for inconvenience to the parties. The inconvenience to the petitioner if temporary Injunction is refused would be balanced and compared with that of the opposite party, if it is granted. If the scale of inconvenience leans to the side of the plaintiff, then alone interlocutory injunction should be granted.
- II.* In the present case the controller of Patents found the compound to be patentable and hence granted the patent to Mate, non granting of injunction will allow defendants from manufacturing the product and selling the impugned product in

⁵⁹ 2002 I OLR 531

the market and motivating others to do the same thus causing balance of convenience to shift in favour of the defendants.

III. Ergo it is the humble submission of the plaintiff in the light of the facts of the present case, granting of quia timet injunction was necessary remedy to prevent the defendant from committing any further act infringing plaintiff's right over their patented product.

PRAYER

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

Declare the impugned patent invalid in light of its obviousness, lack of novelty and inventive step and revoke the same.

For this act of kindness the Appellants 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 plaintiff in this matter that the Hon'ble High Court of Munain maybe pleased to:

Declare the simultaneous filling of revocation of the patent in the IPAB as well as the High Court as invalid.

Declare the grant of quia timet injunction as valid in the present case.

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

Respectfully Submitted by,

Counsel for the Appellants (IPAB)

Counsel for the Plaintiff (High Court)