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DEL HC

IN THE HIGH COURT OF DELHI

I.A. No. 15720/2009 in CS(OS) No. 2303/2009 and I.A. No. 5910/2013 in CS(OS) No. 679/2013

Decided On: 29.06.2015

Appellants: **Bristol-Myers Squibb Company and Ors.**
Vs.
Respondent: **J.D. Joshi and Ors.**

Hon'ble Judges/Coram:
Manmohan Singh, J.

Counsels:
For Appellant/Petitioner/Plaintiff: Pravin Anand, Nishchal Anand and Aman Taneja, Advs.

For Respondents/Defendant: Rajeshwari H., Adv.

JUDGMENT

Manmohan Singh, J.

1. The plaintiffs have filed the above mentioned two suits for permanent injunction restraining infringement of Indian Patent No. 203937 and for damages against the defendants. The invention claimed by the plaintiffs inter alia for the treatment of cancer.

2. By way of this common order, I propose to decide the pending injunction applications filed by the plaintiffs under Order XXXIX Rules 1 and 2 read with Section 151 CPC in both the matters. The first suit was filed in November, 2009. The second suit was filed in April 2013 on the basis of fresh cause of action. The suit patent remains the same.

3. Both suits are quia timet actions. The first suit, being CS No. 2303/2009, was filed against the defendants namely (i) Mr. JD Joshi, Director of defendant No. 2 and M/s. MJ Chempharm Private Limited (now known as BDR Lifesciences Private Limited) as the plaintiffs have reasonable apprehension that the defendants are going to launch the generic product which would infringe the claims of IN 203937 and they may violate the exclusive rights of the plaintiffs granted under Section 48 of the Indian Patents Act, 1970.

4. Common facts as per plaints:

> "i) Plaintiff No. 1, Bristol-Myers Squibb Company is a company incorporated under the laws of the State of Delaware, USA founded under its present name in the year 1989 as a result of a merger between two pharmaceutical companies namely, Bristol-Myers Company founded in 1887 by William McLaren Bristol and John Ripley Myers and Squibb Corporation founded by Edward Robinson Squibb in 1858.

ii) Plaintiff No. 2, Bristol-Myers Squibb India Private Limited, is a private limited company incorporated in 2004 and is a subsidiary of plaintiff No. 1 and markets pharmaceutical products in the domestic market.

iii) Plaintiff No. 1 along with its subsidiaries is a leading biopharmaceutical company dedicated to discovering, developing and delivering innovative medicines that help patients prevail over serious diseases. The plaintiffs have a strong presence in various therapeutic areas including cancer, cardiovascular disease, diabetes, obesity, psychiatric disorders, Alzheimer's disease, hepatitis, HIV/AIDS and rheumatoid arthritis.

iv) Plaintiff No. 1 is the exclusive owner of DASATINIB and its pharmaceutically acceptable salts, solvates, isomers and prodrugs which is covered by the claims of IN 203937 in India. Plaintiff No. 1's patent 203937 is valid and subsisting and has a term of 20 years from 12th April, 2000 in India. Plaintiff No. 1, enjoys patent protection for the said patent in several other countries such as United States, Australia, New Zealand, Japan etc.

v) DASATINIB which is the INN name of N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-,pyrimidinyl]amino]-5-thiazolecarboxamide) is an anti-cancer molecule used in the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib, as well as, in the treatment of adults who have a particular form of acute lymphoblastic leukaemia (ALL) called Philadelphia chromosome positive (Ph+) ALL. In both the suits I.A. No. 11344/2014 and I.A. No. 11336/2014 have been filed stating that the plaintiff No. 1 has assigned its rights, titles, interests in the suit patent by virtue of Assignment Deed dated 1st December, 2012 in favour of Bristol Myers Squibb Ireland and its request filed on 7th November, 2013 is pending. (Both the applications have been allowed by separate orders passed and assigning party is impleaded as plaintiff No. 3 in the suits)."

5. It is claimed that Chronic Myeloid Leukemia (CML), one of the most common forms of leukemia, arises from the excessive production of abnormal stem cells in the bone marrow, which eventually suppress the production of normal white blood cells. The development of imatinib mesylate, a small-molecule tyrosine kinase inhibitor (TKI), was the first rationally designed drug for CML. While imatinib mesylate has undoubtedly had, and continues to have, a major impact in the treatment of CML, cases of 'imatinib-resistant CML' are emerging. (Combating imatinib-resistant CML is an important therapeutic challenge and one for which a new generation of TKI inhibitors, such as DASATINIB, address.)

6. It is also claimed that the plaintiff No. 1's invention, DASATINIB, addresses the above challenge by reducing the activity of one or more proteins responsible for the uncontrolled growth of the leukemia cells of patients with CML or Ph+ALL. This reduction allows the bone marrow to resume production of normal red blood cells, white blood cells, and platelets. The compounds of the present invention inhibit protein tyrosine kinases and are thus useful in the treatment, including prevention and therapy, of protein tyrosine kinase-associated disorders such as immunologic disorders, oncologic disorders and diabetic retinopathy. In vitro, DASATINIB is active in variants of imatinib mesylate sensitive and resistant leukemic cell lines. DASATINIB inhibited the growth of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL) in cell lines over expressing BCR-ABL.

7. It is alleged in the plaint that Dasatinib and its pharmaceutically acceptable salts (which is the INN name of N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1 -piperazinyl]-2-methyl-4-yrimidinyl]amino] -5-thiazolecarboxamide) is covered by claim 1 of IN 203937 and in particular claim 7. The patent specification in example 455 exemplifies Dasatinib and the method for manufacturing the same is provided in the patent specification. (The copy of the complete specification is filed in the present proceedings.) Apart from the above plaintiff No. 1 has also made an application in India for crystalline monohydrate form of Dasatinib. The said application is numbered 4309/DELNP/2006 dated 4th February, 2005 and is currently pending before the Indian Patent Office. The monohydrate form of Dasatinib has been granted patents in 45 countries and is an improvement patent of Indian Patent No. 203937. The said application relates to crystalline monohydrate form of Dasatinib and if granted would confer the plaintiff an additional layer of protection, although the present patent and in particular claim 7 is broad enough to cover all the salts, prodrugs, solvates isomers as explained in the patent specification, irrespective of the fate of the pending application. It is stated that any person who makes use, sell etc Dasatinib monohydrate form will infringe not only Indian Patent No. 203937 but also Indian Patent Application No. 4309/DELNP/2006 as and when granted.

8. It is also stated in the plaint that the plaintiff No. 1's product DASATINIB was approved by the US Food and Drug Administration on 28th June, 2006. It is presently sold in approximately 50 countries throughout the world. A marketing approval for DASATINIB was also granted by the Drug Controller General of India ("DCGI") or 30th August, 2006 to plaintiff No. 2, who has since that time been marketing DASATINIB under the brand name "SPRYCEL" across India.

Plaintiff No. 2 has marketed SPRYCEL™ in India since November 2006. In India, SPRYCEL™ is made available to patients across the country through a Centralized Vendor System which ensures delivery of the product at the door-step of the patients.

The plaintiffs efforts to make SPRYCEL™ more accessible and available to patients across India have lead to substantial sales which are indicated in the table below:

Year	Quantitative Sales
2006-07	21,883,437.39
2007-08	72,790,946.44
2008-09	120,563,305
2009-10	164,781,842
2010-11	224,984,638
2011-12	268,453,314

9. It is averred in the plaint that during the past five years, plaintiff No. 1 has donated nearly $260 million of medical products, valued at wholesale, to support partner programs throughout the world. Plaintiff No. 2 has taken initiatives for addressing the specific needs of physicians and their imatinib-resistant patients in India who may benefit from Sprycel and runs commercial patient access programmes with respect to Dasatinib. Dasatanib is not an Over-the counter drug but a prescription drug. Ever since the launch of Dasatinib in India, the plaintiffs have addressed the access and affordability needs of the patients by an aggressive commercial Patient Access Program (PAP) through which prices of the drug is reduced to a fraction of the MRP. This has evolved over time thereby consistently reducing the cost of drug to patients. The program is available through a third party service provider, for the self paying patients prescribed Dasatinib, by an Oncologist. The service provider of plaintiff No. 2, through a centralized call center, delivers the drug to the prescribed patients at the door step anywhere in India with no additional

delivery cost.

The plaintiffs' Patient Access Program (PAP) is publicized to all the oncologists of the country through regular advertisements in medical journals like India Journal of Cancer. The availability of this Program has been broadly communicated to help to ensure patients do not experience treatment hurdles/interruptions. The commercial program of plaintiffs has strong utilization and support from the medical community. In addition to offering Dasatinib at a reduced price, this Program also provides patient education to facilitate compliance to therapy.

10. In the first suit, it was stated by the plaintiffs that around December 2008, they received information that defendant No. 2 ("M.J. Chempharma Pvt. Ltd.") had applied to the DCGI for the marketing approval for Dasatinib. The plaintiffs sent a 'cease and desist' letter dated 12th January 2009 to defendant No. 2 asking them to restrain from infringing IN 203937. (For a long time, no response was received from the defendants-Company.) In the meantime, plaintiffs also filed a Right to Information ("RTI") Application with the DCGI on 12th May 2009 enquiring as to whether the defendants-Company had filed an application seeking marketing approval for Dasatinib. The plaintiffs received a reply from the DCGI on 25th June 2009 which stated that two companies have applied for the marketing approval for Dasatinib but did not disclose the name of the companies. The plaintiffs thereafter sent a reminder to its letter dated 12th January 2009. A response was received from the defendants on 6th August 2009 in which it admitted to have applied for a marketing approval for Dasatinib. In view of the apprehension that the defendants may not infringe the plaintiffs' exclusive right of the patent, the plaintiffs filed a suit being CS(OS) No. 2303/2009 in the nature of a quia timet action against the defendants on 3rd December 2009 for the infringement of IN 203937.

11. The suit was listed before this Court on 4th December 2009 along with interim injunction application being I.A. No. 15720/2009.

12. The Court while issuing the summons in the main suit restrained the defendants by passing the following injunction:--

> "I have heard the learned counsel for the plaintiffs. I am of the view that they have made out a prima facie case at this stage. The balance of convenience also appears to be in favour of the plaintiffs. In the event, the plaintiffs are not protected their interests may be jeopardized. In these circumstances, defendants, their directors, employees, officers, servants, agents are restrained from manufacturing, selling, distributing, advertising, directly or indirectly any product which infringes the plaintiffs' registered patent 203937."

13. The defendant No. 1 neither appeared nor filed the written statement despite of service of summons in March, 2010. Defendant No. 2, i.e. the Company filed its written statement wherein it was admitted that they have applied for the marketing approval of Dasatinib having the same chemical structure as disclosed in example 455 of the patent specification and claim 7 of the patent claims. It is also stated that it would launch the generic version of Dasatinib when it obtains the marketing approval to manufacture it from the DCGI. The name of defendant No. 2 was changed to BDR Life Sciences Private Limited ("BDR Life Sciences") on 7th September 2010. By a separate order, the defendants' application under Order 1 Rule 10 CPC in respect thereof has been allowed.

In para 26 of their Written Statement, it was admitted that the defendant is intending to launch the generic version of Dasatinib only if the DCGI grants licence to the

defendant to manufacture under the provisions of DCA. In para 5 and paras 20, 21, 23, 24, 28 and 29 of the parawise reply of the Written Statement the defendants admitted having made an application for grant manufacturing licence for generic DASATINIB. In paragraph 13 of the reply on merits of the Written Statement the defendant No. 2 further admitted that their impugned drug has the same chemical structure as that of the plaintiffs.

14. During the pendency of the first suit, in the meantime, on 2nd February 2012 (the defendant No. 2 in CS(OS) 679/2013), BDR Pharmaceutical Pvt. Ltd. (hereinafter referred to as the BDR or BDR Pharma), a group company of BDR Life Sciences and under common control and management as alleged, wrote to the plaintiffs requesting for a voluntary license for IN 203937 to manufacture and market Dasatinib. The extracts of the said letter are reproduced hereunder:--

> "We, BDR Pharmaceuticals Int'l Pvt. Ltd. are a pharmaceutical company registered under the Indian Companies Act, 1956. We hold license under the Drugs and Cosmetics Act, 1940 with manufacturing facilities located at Vadodara which are GMP certified.
>
> We are fully equipped to manufacture Active Pharmaceutical ingredient and formulation under GMP facilities that meets international standards. We are interested to manufacture DASATINIB in India. We understand that you have the know-how for manufacturing the product and we also understand that you have been granted patent(s) in India.
>
> We are pleased to request you to grant us a license for manufacturing the said product in India. In view of our interest for in-licensing from you for manufacturing the product in India, we request you to let us have your confirmation as well as detailed terms and condition to enable us to take forward this proposal, which you will agree could help abundant availability of the said product in India."

15. The plaintiffs responded on 13th March, 2012 asking for certain details to evaluate its decision to grant the voluntary license. The said details sought by the plaintiffs are produced as under :

> "March 13, 2012
>
> Mr. Dharmesh M. Shah
> Chairman and Managing Director
> BDR Pharmaceuticals International Private Limited
> 407/408, Sharda Chambers
> 15, New Marine Lines
> Mumbai-400 020
>
> Subject: Application for Voluntary Licence
>
> Re: Indian Patent No. N 203937 (DASATINIB); Our Ref: 13217(G-1)
>
> Dear Mr. Shah,
>
> We have received your letter dated 2nd February, 2012 in which you have requested a license for manufacturing DASATINIB in India.
>
> Our comments are as follows:--
>
> **1.** Before we answer your request for a voluntary license, we would

naturally like to know a few facts about your company and in particular those given below:

a) Facts which demonstrate an ability to consistently supply high volume of the API, DASATINIB, to the market;

b) Facts showing your litigation history or any other factors which may jeopardize Bristol-Myers Squibb's market position;

c) Facts showing any history of not honoring patents or other intellectual property;

d) Capability of handling the ultimate demand for DASATINIB;

e) Facts showing your ability to supply API for other Anti Cancer Drugs;

f) Your ability to meet timelines;

g) Quality related facts and in particular compliance with local regulatory standards and basic GMP requirements;

h) Demonstrated successful technology transfer and filings;

i) Quality Assurance Systems due Diligence (having quality management systems that include Change Control, Deviations, Validations, Qualifications, Training, Packaging, Labeling and Laboratory systems to include QC Testing capability and COA management);

j) Ability to formulate and distribute;

k) Established relationships with NGOs and local Governments and experience in navigating through emerging market bureaucracy;

l) Ability to develop new and more efficient chemistry;

m) Financial transparency;

n) Pricing proposals;

o) Commercial supply terms;

p) History of working with pharma innovators;

q) Robust IP protection and compliance policies;

r) Safety and environmental profile;

s) Risk of local corruption;

t) Any other relevant issues that might enable us to form a business decision.

2. We may point out that BMS is commercially working the patent in

India and the patented product is available to the public in abundance.

In any event, we have requested information with an open mind and look forward to receiving the same at your earliest convenience."

16. However, the said Company did not respond for over 14 months. During this period and without informing the plaintiffs or this Court, the said Company and BDR Life Sciences (earlier name was M.J. Chempharm Pvt. Ltd.) applied and obtained a manufacturing license for Dasatinib Tablets 20/50/70 mg from the Food and Drug Control Administration Maharashtra on 18th January, 2013. BDR Life Sciences applied for a manufacturing license for Dasatinib BULK to the Food and Drug Control Administration Gujarat on 18th January, 2013 and obtained the same on 13th March, 2013. BDR Life Sciences did not inform the Court of the same despite threatening to launch the generic version of Dasatinib upon receiving approval in its Written Statement.

On 4th March, 2013, BDR Pharma applied for a compulsory license for IN 203937 before the Patent Controller. BDR Pharma did not inform the plaintiffs of the compulsory licensing application but as per the plaintiffs, they got to know about the same from newspaper reports. In the same period BDR also started advertising and offering for sale of Dasatinib Tablets under the head "Finished formulations" on its website.

17. The above said acts of BDR and BDR Life Sciences created further apprehension in the mind of the plaintiffs that BDR or BDR Life Sciences intend to circumvent the ad-interim injunction granted in the first suit and they may introduce the drug by infringing the suit patent. The plaintiffs immediately filed fresh action being a suit bearing CS(OS) No. 679 of 2013 against the defendants in the nature of a qui timet action for the infringement of IN 203937 ("Second Suit") on 11th April, 2013.

18. In Suit No. 679/2013, the defendant No. 1, Mr. Dharmesh Shah, is the Chairman and Managing Director of defendant No. 2 who is also impleaded being key person involved in making all decisions including manufacturing and marketing of generic products. The defendant No. 1 is a key player controlling Companies and is stated to be necessary for the purposes of the present proceedings.

19. Defendant No. 2, M/s. BDR Pharmaceuticals International Private Limited, is a private limited company incorporated in 2003 under the Companies Act, 1956, having its principal place of business at 407/408 Sharda Chambers, 15 New Marine Lines Mumbai but carrying on business of selling and/or offering for sale various generic pharmaceutical products and Active Pharmaceutical Ingredients (API) across the country including at Delhi though its office located at C4F/117, 1st Floor, Janak Puri, New Delhi-110 058.

20. In the para of cause of action, it is alleged that recently in the last week of March, 2013 the plaintiffs came to know that defendant No. 2 company i.e. BDR Pharmaceuticals International Private Limited, in violation of the plaintiffs' rights under Section 48 of the Patents Act, 1970 was/is advertising and/or offering for sale generic version of DASATINIB on their website http://www.bdrpharma.coni/FinisliFormuations.aspx under the heading, 'Finish Formulations. The defendants have not launched the impugned product in the market as per admission made by the counsel at the time of hearing.

21. Admitted position is that both the suits have been filed for permanent injunction restraining infringement of plaintiffs Indian Patent No. 203937. The plaintiff under

Section 48 of the Patents Act, 1970 has the right to take appropriate steps to restrain third parties from the act of making, using, offering for sale, selling or importing any product which infringes the subject matter of Indian Patent No. 203937. At the time of filing of suit the defendants were still pursuing their application for marketing and manufacturing licence before the DCGI.

22. In the meantime, on 5th May, 2013 the Patent Controller considered the compulsory license application filed by BDR Pharma and opined that the BDR Pharma had not made out a prima face case for grant of a license as the applicant/BDR Pharma did not make efforts to obtain a licence from the patentee on reasonable terms and conditions and relegated the applicant/BDR Pharma to approach the plaintiffs for voluntary licence. Thereby, the learned controller by his order dated 29th October, 2013 rejected the application filed by BDR Pharma seeking compulsory licence holding that BDR Pharma did not follow the due procedure in law prior to making the application under Section 84 and thus the occasion to entertain application seeking compulsory licence has not arisen. In the meantime, BDR Pharma again contacted the plaintiffs to revive its negotiations for a voluntary license with the plaintiffs and they responded to letter of 13th March, 2012 on 10th May, 2013. The plaintiff responded to the said communication of 10th May, 2013 by way of letter dated 1st July, 2013 are reproduced here as under:

"Our Ref: 13250

July 1, 2013

To
Mr. Dharmesh Shah
Chairman & Managing Director
BDR Pharmaceuticals International Pvt. Ltd.
407/408, Sharda Chambers
New Marine Lines
Mumbai - 400 020
India

Re: Application for Voluntary licence - Indian Patent No. IN203937 (Dasatinib)

Dear Mr. Shah,

Thank you for your letter dated 10th May 2013.

Our response is as follows:--

> In the first instance, we have come to learn through newspaper reports of a compulsory license application having been filed by you on the 4th of March 2013. We are surprised you have not informed us about this application at any time during our correspondence starting in February 2012 and terminating with your present letter which is under reply.
>
> Second, it appears that you had already announced the launch of your product commercially at about the time when you applied for a compulsory license and therefore your application is not bonafide. As you are well aware, an application for a compulsory license must be founded in good faith by a person genuinely desiring to manufacture goods in larger public Interest. On the other hand, someone who

starts infringing a patent and simply applies for a compulsory license to test the waters not only seriously lacks bonafides but the entire compulsory license process is vitiated by this conduct.

Your initial letter for a voluntary license was dated 2nd February 2012 and promptly responded by us by our letter of 13th March 2012. We are quite surprised that for 14 months you did not deem it fit to respond to our letter of 13th March 2012 and all this while you kept preparing to commercially launch the product. Hence, even your request for a voluntary license lacks bonafides and stands vitiated by your dubious conduct.

Without prejudice to the above, since there is an injunction operating in civil suit being CS(OS) No. 2303 of 2009 titled Bristol Myers Squibb Company & Anr. v Mr. JD Joshi and Anr. and a statement given by you in civil suit being CS(OS)No. 679 of 2013 titled Bristol Myers Squibb Company & Anr. v Mr. D Shah and Anr to the effect that you are not currently manufacturing or marketing the drug in question, we would like you to give an undertaking before the Delhi High Court in the pending suits being CS(OS) No. 679 of 2013 that you will not manufacture and sell the drug in question during the time period that the dasatinib patent (IN203937) remains in full force and effect in India and BMS has an opportunity to fully consider your request."

The talks again continued till 20th September 2013 when BDR abruptly ended the correspondence as they did not provide the information asked by the plaintiffs.

23. After that, it came to the knowledge from one sources that BDR Pharma and BDR Life Sciences had obtained manufacturing licenses for Dasatinib Tablets and Dasatinib BULK respectively and the plaintiffs filed an application seeking discovery in both the suits.

24. By order dated 1st October, 2013 passed in the first Suit, the Court directed BDR Life Sciences to disclose the manufacturing license for DASATINIB BULK.

25. As already mentioned, defendant No. 1 did not appear despite of service of summons in March, 2010 in the first suit. In April, 2010, defendant No. 2 sought time to file the written statement but the same was filed in January, 2011. No counter claim was filed by the defendant No. 1 along with the written statement. It was filed in November, 2013 i.e. after the expiry of three years from the date of service of summon and positive knowledge of infringement suit. Although, the Court directed the plaintiffs to file the written statement to the counter-claim but the objection was raised by the plaintiffs that it is time barred and cannot be condoned.

26. In the Second Suit, this Court recorded an undertaking of BDR Pharma on 3rd October, 2013 that it shall not launch Dasatinib till the injunction application is disposed of. The said undertaking has been in operation till date. Upon clarification, the Court also directed BDR Pharma to disclose the manufacturing license for Dasatinib Tablets by its order dated 13th November, 2013.

27. On 28th October, 2013 the Controller of Patent rejected BDR Pharma's application for obtaining the compulsory license. The relevant extracts of the said decision of the Controller in his order in paras 8, 9, 21 to 23, 29 & 30 are reproduced here as under:--

"8. In the present case, the applicant sent a letter dated 2nd February, 2012, to the patentee requesting for a voluntary licence for manufacturing Dasatinib. By letter dated 13th March 2012, the patentee raised certain queries such as ''facts which demonstrate an ability to consistently supply high volume of the API, DASATINIB, to the market", "facts showing your litigation history or any other factors which may jeopardize Bristol-Myers Squibb's market position", "quality related facts and in particular compliance with local regulatory standards and basis GMP requirement", "quality assurance system due diligence", "commercial supply teams", "safety and environmental profile", "risk of local corruption". The applicant took this reply of the patentee as 'clearly indicative of the rejection of the application for voluntary licence' and did not pursue the matter and made no further effort to arrive at a settlement with the patentee. The present application for compulsory licence was filed on 4th March 2013 i.e. after almost one year from the date receiving reply from the patentee.

9. By notice dated 4th March, 2013, the applicant was informed that a prima facie case has not been made out for the making of an order under Section 84 of the Act as 'the applicant has not acquired the ability to work the invention to the public advantage', in the absence of the requisite approval from the DCGI, and 'the applicant has also not made efforts to obtain a licence from the patentee on reasonable terms and conditions' (hereinafter referred to as the 'efforts'). The applicant was informed that in accordance with the provisions of Rule 97(1) of the Rules, a request for being heard is required be filed within one month from the date of this order failing which the application shall be rejected.

21. In the present case, the applicant made the request for a voluntary licence on 2nd February, 2012 to the patentee who, by letter dated 13th March 2012, raised some queries. More than four and a half months remained unutilized out of the 'reasonable period' prescribed by the legislature for the purpose of mutual confabulations but the applicant chose not to take any action during this precious time period that was available with the applicant. In fact, after receiving the reply from the patentee, dated 13th March, 2012, the applicant waited for 1 year to file the present applicant, which demonstrates that the applicant did not intend to engage in any kind of dialogue, whatsoever, after making the initial offer to the patentee.

22. On the face of the record, I am of the view that the applicant's contention that the said letter is 'clearly indicative of the rejection of the application for voluntary licence' does not hold good, as the aforementioned queries raised by the patentee appear largely to be reasonable. Even if the applicant was under an impression that the patentee was engaging in delaying tactics, the omission of not replying at all to the patentee's said letter dated 2nd February 2012 is unexplainable as it goes against the golden threat apparently visible in Section 84(6)(iv). Applicant ought to have appreciated that the provisions relating to compulsory licence are to be invoked as the last resort, i.e., if the mutual deliberations do not lead to a result within six months, in accordance with the scheme of the law.

In my opinion, the applicant did not make efforts to obtain a licence from the patentee on reasonable terms and conditions.

23. The applicant by letter dated 10th May 2013, i.e. after receiving the

notice dated 4th May 2013, replied to the patentee's letter dated 13th March 2012. It is pertinent to mention that this reply was sent after a delay of about 14 months. It was submitted by way of petitions under rule 137 that correspondence that took place between the applicant and the patentee subsequent to the filing of the application for compulsory licence, be taken on record.

29. The applicant sought to argue that the three substantive requirements under clause (a), clause (b) and clause (c) of sub-section (1) of Section 84 of the Act have been met singularly and independently satisfied by the applicant due to which any irregularity in procedure/timeline may be either waived or condoned or declared to be not applicable.

30. The stage of making a ruling on the applicability of clause (a), clause (b) and clause (c) of sub-section (1) of Section 84 of the Act on merits has not yet arrived. I am of the considered opinion that the deliberate intent on part of the applicant to refrain from entering into any kind of dialogue with the patentee from the purpose of securing the grant of a voluntary licence, and the exercise of a deliberate choice to only invoke the provisions relating to compulsory licences without taking the requisite steps laid down by the law, cannot be classified as an 'irregularity in procedure/timeline', which can be waived or condoned or declared to be not applicable."

28. As alleged in the plaint, defendant No. 2 claims to be involved in the field of manufacturing, selling and offering for sale generic finished formulations and Active Pharmaceutical Ingredients (API) in therapeutic areas such as Oncology, Cardiology, Gynecology, Antifungal, Antibacterial etc within the domestic and global markets.

29. It is alleged in the plaint that defendant No. 2 claims to be involved in the field of manufacturing, selling and offering for sale generic finished formulations and Active Pharmaceutical Ingredients (API) in therapeutic areas such as Oncology, Cardiology, Gynecology, Antifungal, Antibacterial etc within the domestic and global markets.

30. It is not denied by the defendants about a connection between the present defendants and M/s. MJ Chempharma Private Limited (the company which was restrained by this Court from infringing the plaintiffs Patent No. 203937 in CS(OS)No.2303 of 2009). It is pleaded by the defendants that name of M/s. MJ Chempharma Private Limited, was changed to BDR Lifesciences Private Limited. Furthermore, defendant No. 1 J.D. Joshi in earlier suit was also one of the Directors on the Board of the said BDR Lifesciences Private Limited who has equity of M/s. M.J. Chempharma Private Limited as appeared from the annual report of defendant No. 2 showing BDR Lifesciences Private Limited.

31. It is contended by the plaintiff that M/s. MJ Chempharm Private Limited in order to surpass and over-reach the order dated 4th December, 2009 passed by this Court and to disguise its infringing activities had adopted a strategy to act through defendant No. 2. It is further submitted that defendant No. 1 and 2's conduct in the past with respect to the invention claimed in the suit patent has been dishonest and deceitful. It is done between the defendants and its sister concern/associate company to circumvent the orders of this Court as it is also evident from the fact that in February, 2012, defendant Nos. 1 and 2 knowing full well that plaintiff No. 1 was the proprietor of Indian Patent No. 203937 approached plaintiff No. 1 for obtaining a voluntary license for manufacturing DASATINIB in India. Defendant Nos. 1 and 2 through their letter dated 2nd February, 2012 also requested plaintiff No. 1 to send

detailed terms and conditions.

32. The plaintiffs had shown their interest for entering into a commercial transaction in order to take the matter forward requested the said defendants to furnish certain details relating to the matter by the letter dated 13th March, 2012. But the plaintiffs thereafter did not receive any response from defendant No. 1 and 2 with regard to the queries raised in their letter dated 13th March, 2012 and thus, considered the matter as closed as they may not be more interested to deal with the plaintiffs. However, in the second week of March, 2013, after almost one year from the aforementioned correspondence, the plaintiffs came to know that the defendants had filed an application under Section 84 of the Patents Act, 1970 before the Controller of Patents for grant of a Compulsory Licence with respect to DASATINIB. As defendant Nos. 1 & 2 started advertising and/or offering for sale the impugned product on their website, the plaintiffs had an apprehension that defendant No. 1 and 2 are in the process of manufacturing generic DASATINIB and are soon going to sell DASATINIE across the country including within the jurisdiction of this Court.

33. It is argued by the plaintiffs that the letter dated 2nd February, 2012 for a voluntary licence was just an eye-wash in order to conceal the real intention of the defendants of infringing the plaintiffs' Patent. Rather defendant Nos. 1 and 2 along with their associate company/sister concern have systematic way to violate the restraining order dated 4th December, 2009 passed by the Court in CS(OS) No. 2303 of 2009 by using, manufacturing, selling and/or offering for sale a generic version of DASATINIB through defendant No. 2 company. It is submitted that the impleadment of defendant Nos. 1 and 2 in civil suit being CS(OS) No. 2303 of 2009 was not possible on account of the present action being a fresh cause of action and earlier proceedings are four years old. Therefore the plaintiffs had decided to file a fresh suit which has been filed. The interim protection in the fresh second suit was granted and still continues.

34. By virtue of the grant of IN 203937, plaintiff No. 1 under Section 48 has the exclusive right to make use, sell, import and distribute Dasatinib and it is pharmaceutically acceptable, salts irrespective of the form (pro drugs, solvates, isomers).Hence, the aforementioned acts of the defendants are prohibited by Section 48 and amount to infringement of the plaintiffs rights. The said acts of the defendants are in complete contravention and disregard of plaintiffs existing and valid Patent No. 203937 and give rise to an immediate cause of action. It is averred in the plaint that if defendants were permitted to manufacture and market its generic product in contravention of plaintiffs patent. Further, the plaintiffs' would lose out on substantial sales on account of the defendants acts of unfair competition by misappropriating the plaintiffs patent, know-how, technology and confidential information. The plaintiffs' loss of goodwill and reputation would be incalculable and irreparable.

35. Many pleas have been taken by the defendants in both the written statements. However, at the time of hearing, counsel for the defendants have raised the following main points :

> "a) The defendant, BDR Pharmaceuticals Private Limited is a Mumbai based Company engaged in the business of manufacture and sale of pharmaceutical compounds. Defendant Company originally known as MJ Chemphan Private Ltd. formed in 2002 which was changed to BDR Life Sciences Private Limited. BDR Pharmaceuticals and BDR Life Sciences are part of the same group company and are engaged in manufacture of Active Pharmaceutical Ingredients and finished formulations.

b) Credible Challenge in the form of Counter Claim raised by defendant to the effect that Patent invalid as it obvious in view of prior art filed along with the counter claim. The suit patent also lacks utility and hence invalid. Thus, the plaintiffs are not entitled for injunction.

c) The request for voluntary license by the defendant is immaterial, therefore, there is no bar to contest the validity of patent in a suit for infringement. The defendants have not made any admission of validity of patent.

d) The impugned patent is a non-workable. Patentee is not entitled to any injunction;

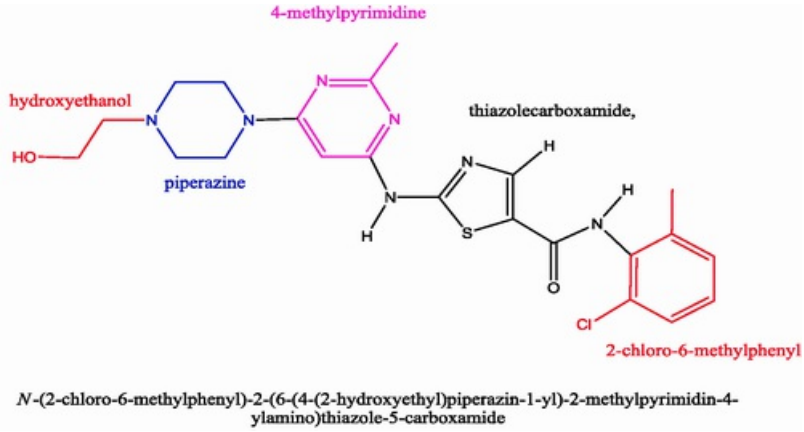
e) The proposed product of the defendant does not infringe suit patent, question of injunction does not arise.

f) Public interest mandates grant of alternative remedy instead of injunction i.e. ongoing royalty;

g) Plaintiff's patent and the claims are obvious in view of existing prior art :

It is argued on behalf of defendants that Dasatinib is covered by Indian Patent No. 203937. Claim No. 7 is drawn to Dasatinib. The chemical name of Dasatinib is N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydrosyethyl)-1-piperazinyl]-2-methl-4-pyrimidinyl] amino]-5-thiazolecarboxamide. The molecule Dasatinib is primarily a thiazolecarboxamide derivative.

The same is illustrated here below:



36. It is submitted by the defendants that the impugned compound Dasatinib is obvious to a person skilled in the art on the following reasons:

"(a) That it has been well known that tyrosine kinase (PTKs) family of enzymes releases substances which cause cancer; therefore, PTKs has always been a subject of study and has been used as a target for development of anti-cancer drugs for a long time. The entire goal is to produce chemical compounds that stop the production of these toxic substances by the enzyme PTKs. The plaintiff also acknowledges this fact in their patent specification.

(b) In this regard, amino-1,3-thiazole derivatives are known in the art for a very long period. Such compounds primarily comprise a thiazole as the basic nucleus. It is also known that such thiazole based compounds can be used

and are capable of inhibiting tyrosine and stopping it from producing substances that cause cancer. The defendants has quoted three examples of EP 0412404, US 5,668,161 and WO 98/28282 to show that thiazole derivative compounds are known as useful for the treatment of the cancer."

37. The defendants have filed the prior art in support of their submission, the details are given as under :--

"i) EP 0412404 (EP '404) - discloses many amino-thiazole compounds for treatment of cancer: Example of a patent which discloses amino thiazole compound is EP '404. The patent discloses thousands of compounds which are represented in shorthand or a Markush format. EP '404 was published around 1991. Claim 9 specifically is drawn to various compounds useful for treatment of tumors. The compounds include amino thiazole based compounds and compounds with chloro phenyl groups.

ii) US 5,668,161 (US '161) - discloses heterocyclic thiazole based compounds with piperazine groups - useful for treatment of cancer: On similar lines is US 5668161, which discloses various thiazole based compounds. The compounds of this patent are also used for treatment of cancer. The compounds contemplated and proposed by the inventors of this patent include the addition of a piperazine group and use of multiple heterocyclic rings. The difference in the compounds covered by the Markush claim of US '161 and Dasatinib is the presence of hydroxyl ethanol group in Dasatinib which is absent in the compounds of US '161.

iii) WO 98/28282 - discloses various thiazole derivatives and some compounds similar to Dasatinib: This patent discloses various compounds which are useful for treatment of various thromboembolic diseases including blood cancer. The compounds in this patent are represented by a Markush Structure. This Markush Structure contemplates compounds similar to Dasatinib. It envisages compounds having all the substituents as Dasatinib. As per this patent, these compounds are also useful in enzyme inhibition and by implication in the treatment of cancer."

38. It is submitted on behalf of the defendants that the patent in the Markush formula discloses several hundred compounds, some of which bear a structure similar to Dasatinib which is claimed in the suit patent which establishes that the claim for Dasatinib in the suit patent obvious. It is submitted that the prior art compounds are derived from Markush and thus there exists a motivation to make Dasatinib: All the prior art cited by defendant disclose various compounds useful for treatment of various diseases including cancer. The prior art cited are broadly worded and include compounds for treatment of cancer. Plaintiff suit patent is also drawn to multitudes of compounds for treatment of various diseases including cancer. Markush formula is a short hand for representing various compounds in a precise manner. Markush formula can otherwise be written as individual compounds and in such a case, each of the compounds disclosed should be read as individual disclosure of each compound i.e. individual disclosure of each of the compounds. Hence each compound would act as prior art and make the claims of the suit patent obvious. In such an event, as per the defendant, the suit patent is obvious to the person skilled in art on account of the depiction of the similarly looking structure in the earlier patents or in Markush formula as well as the knowledge of the thiazole compounds yielding to treatment of the cancer.

As per the defendants, the suit patent can be suffering from the prior art and is

obvious from a reading of the prior art. The suit patent is thus vulnerable. Therefore, the interim orders already granted is liable to be vacated and the plaintiffs be asked to prove its validity in trial.

39. The following decisions have been referred by the learned counsel for the defendants :

> "i) Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries [MANU/SC/0255/1978 : AIR 1982 SC 1444], para 33;
>
> ii) F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd. [MANU/DE/0381/2009 : 2009 (40) PTC 125 (Del.)(DB)], para 78
>
> iii) 3M Innovative Properties Company & Anr. v. Venus Safety & Health Pvt. Ltd. & Anr. [MANU/DE/1389/2014 : 2014 (59) PTC 370 (Del)] - Para 57;
>
> iv) Novartis AG and Anr. v. Mehar Pharma & Anr. [MANU/MH/1058/2004 : 2005 (30) PTC 160 (Bom)] - Para 25;
>
> v) Sandeep Jaidka v. Mukesh Mittal & Anr. MANU/DE/1157/2014 : 2014 (59) PTC 234 (Del) - Para 32;
>
> vi) Glaverbel S.A. v. Dave Rose and Ors. MANU/DE/0205/2010 : 2010 (43) PTC 630 (Del)- Para 85;"

40. I have gone through the submission advanced by the learned counsel for the defendants and have also perused the patents documents EP'404 filed on 31st July, 1990, US'161 filed on 9th July, 1996 and also perused the explanation provided by the defendant's expert in his affidavit in relation WO 98/28282. It is indeed correct that the three patents filed in different years disclose the existence of the Thiazole derivates which are yielding results and/or connecting thiazole derivatives in inhibiting PTK to release toxic substances, also in some references talks about tumors etc. I find that the said information is a part of the common knowledge and for which one need not cite any prior patents like the ones cited by the defendants. It is on the contrary a precursor to the plaintiffs patent itself wherein in the introductory part of the specification, the plaintiffs acknowledges the said position. Therefore, the existence of the information that Thiazole compounds having a role to play in curing tumors and cancer is, I think a bare minimum information for any person skilled in the art to arrive at the plaintiff's patent. This is my prima facie observation by merely having a glance to the patents cited by the defendants to lay the challenge as to obviousness. This is due to the reason that the defendant while citing the said patents filed in Europe and US acknowledges that the said patents were filed in the year 1990 and 1996 using thiazole derivates compounds and also talking at some places about their role to cure cancer and tumors amongst other diseases. If the mere nexus of use of Thiazole Derivatives as compound to inhibit PTK is assumed to be the sole ground to infer obviousness, then it is defendants' own argument and saying that the Thiazole derivates are known since the year 1950 and all these patents using Thiazole derivates and their references towards inhibiting PTK should lead to a presumptive kind of approach that the subsequent patents granted in the years 1990 onwards are all obvious to the person skilled in the art. I think such is not the case and cannot be the case and the said submission ignores the principle operating behind improvements in the patents. It is common in the field of the medicines that the chemical compounds are pre-existing and there are further improvements upon treatment and workings on the compounds so as to increase their efficacy by reacting with chemical compounds and the group of the reactants. Therefore, the commonality of the base compound like thaizole derivatives and its characteristics may be one of

the attending circumstance which can act as a starting point to consider the plea of the obviousness but it cannot be said that the said commonality is the sole basis which yields to inference of the obviousness to the person skilled in the art. Believing this submission of the defendants would raise questions/concerns which are that if the compounds are so obvious then, why did it take years together from 1990 to 1996 to arrive at the different compounds of Thiazole derivatives as per the prior arts/patents quoted by the defendants and why these patents were then not rejected on the ground of prior arts or obviousness if they are simply on the face of it so obvious. Clearly, there is something else to it besides the simple chain of events like commonality of the thiazole derivates and its nexus with curing cancer by inhibiting PTK. The said something else is the process of reactants and the role of other group of reactants and the relevant processes in the patents. Therefore, I prima facie do find myself to be convinced with this simplicitor theory of the presence of Thiazole derivatives leading to obviousness to the person skilled in art which is otherwise easy to understand but miserably ignores the pragmatic approach that the major medicinal patents are chemical compounds which are in the nature of the improvements in the existing state of the art and having higher efficacy than what was present decades ago. Thus, commonality of few integers would not alter the position unless the cause and effect relation between all the integers are present and indicating towards arriving at the subject invention in the suit patent which is missing in the present case.

41. In this context, I had an occasion to examine the obviousness plea in the case of Hoffman La Roche v. Cipla Ltd. (supra), wherein I took the similar view while deciding the case finally and rejected the plea of obviousness due to the failure of the defendant to prove the connecting factors leading to invention or making it obvious. The relevant discussion is reproduced below:

> "The said submissions are neither present in the written-statement nor in the counter claim nor same are deposed in the affidavit of DW1, 2 and 3 towards establishment of the fact that the said working on the compounds is arbitrary and based on trial and error. I find that the said submissions cannot be believed in the abstract in the absence of the any positive evidence coming from the defendant's end showing some tenability of the same clinically as to how the said invention could be arrived at on trial and error method or selection is arbitrary. This could have been done by the defendant by going step by step. Firstly to show the example from the known compound, which the defendant has done, secondly to show as to how the said selection is not far removed not merely by relying upon the structural similarity or generally saying that the ethynyl or methyl could reap the similar results but by clinically showing what is the effect of the said working of ethynyl at the several positions and how it is not far removed from EP'226 and lastly by showing that the entire selection is arbitrary. All this could have been done by the defendant in the affidavit by showing positive evidence. Failure on the part of the defendant to establish the bare minimum material facts would thus lead to inference as to non obviousness.
>
> **84.** In the absence of the positive evidence from defendant to the effect that the selection of the range is arbitrary by non application of mind which CS(OS) No. 89/2008 Page No. 85 of 275 is crucial factor in discerning whether the said impugned patent is obvious or not, It cannot be assumed on a priori basis that the mere fact that there exist some similarities in the structure of ranges, the replacement of the third position with ethynyl may follow and thus the said patent is obvious based on trial and error method.

(Emphasis Supplied)

85. The defendant counsel has argued at length and it has also been deposed that US' 534 along with the other specifications establish the substitution of ethynyl and methyl components are usual.

I find that if the evidence to show the selection is arbitrary is not present on record and even it is established on the record that there is a sort of inspiration taken from EP'226, the existence of the said fact, by itself does not denote obviousness. This is due to the reason that it is seen in the deposition of the PW-3 Nick Thatcher and in the other pleadings also stating that there were certain defects in the medicine GEFTINIB and for the said reason the said medicine was not able to cure the patients properly and consequently was not recommended. Therefore, even if it is shown that the starting point of the invention is EP'226 and there are changes made in the chemical structures cited as example compounds in the said patent by reacting the same with ethynyl later on in relation to selected range, I do not find that such selection can be arbitrary, rather it can be inferred that there may be some further experimentations done in future on the Geftinib compounds which eventually narrowed down the examples cited by the defendant in its submissions, ultimately resulted into the claim No. 1 of the patent. All this rather indicates towards purposeful selection rather than arbitrary one."

(Emphasis Supplied)

42. In the said suit, I am inferring this in view of totality of the circumstances, the plaintiffs are engaging into manufacturing of the drugs, their inventors surely are the persons skilled in the field and are aware of quinazoline derivatives and the compounds therein. Of-course, the inventors cannot change the main compound as the said characteristic of curing the cancer emerges from the said very compound which is a quinazoline derivatives.

The plaintiff's inventor being a conscious person is equally aware of the defects in the pre-existing medicine or compound and its inability to cure the disease properly and therefore would select the range from the point from where the last research ended. Therefore, there is no harm so far as taking the compounds from the previous state of the art is concerned unless it is further backed by the evidence that the said selection and the working thereupon is not far removed from the known range, further that the said selection and the working is arbitrary in nature. On the other hand, it indicates that inventor was conscious about the existing state of art. Accordingly, even if the range from EP'226 is selected by the plaintiffs to conduct the further workings upon the same, unless shown contrary, it cannot be said that the said selection to be an arbitrary one.

(Emphasis Supplied)

From the reading of the above observations and coupled with the discussion done above, I prima facie reject the plea of obviousness on the two prong theory propounded by the defendant which is that the endeavor of every inventor is to find out the compound to inhibit PTK to produce the toxic substance to cause cancer and the commonality of the thiazole derivates both of which are of common knowledge and yet there are different kinds of the improved inventions existing having these common factors. Likewise, applying the dictum of the Roche (supra), the mere some similarity of the structure would not lead to inference as to obviousness unless it is shown that the said selection was arbitrary one without application of mind and

thereafter the working done was also inconsequential result which leads to workshop result and not further new improvement. Even if the defendant intend to show on prima facie basis, some sort of the connectors must be shown to lend prima facie credibility to such defence. Once, this point of obviousness is discussed threadbare and rejected on these lack of connectors towards obviousness, then the Court has now been equipped in evaluating the tenability of the plea at this prima facie stage. Therefore, if it lacks material facts, there is no option but to left this plea open ended to be proven in trial without finding force in the same.

43. In addition to above, so far as the similarity of the structure of the formulae in the suit patent vis-Ã -vis three patents quoted by the defendants are concerned, the counsel for the plaintiff has countered the defendant's challenge by painstakingly able to explain the difference in the figures which were sought to be stated as same by the plaintiffs. The counsel for the plaintiffs has explained as under:

Fig. 1

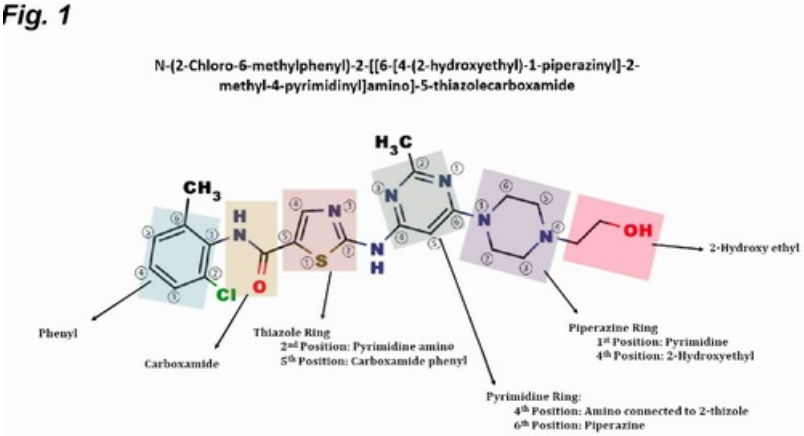


Fig. 1 explained:

i. The above is the chemical structure of Dasatinib as claimed in claim 7 of IN203937.

ii. The Core ring of the compound is a thiazole ring linked/substituted at 2nd position by an amino group and at 5th position by carboxamide group.

iii. Amino group is linked further with [6-[4-(2- hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]; and

iv. carboxamide group is linked further with N-(2-chloro-6- methylphenyl).

Fig. 2

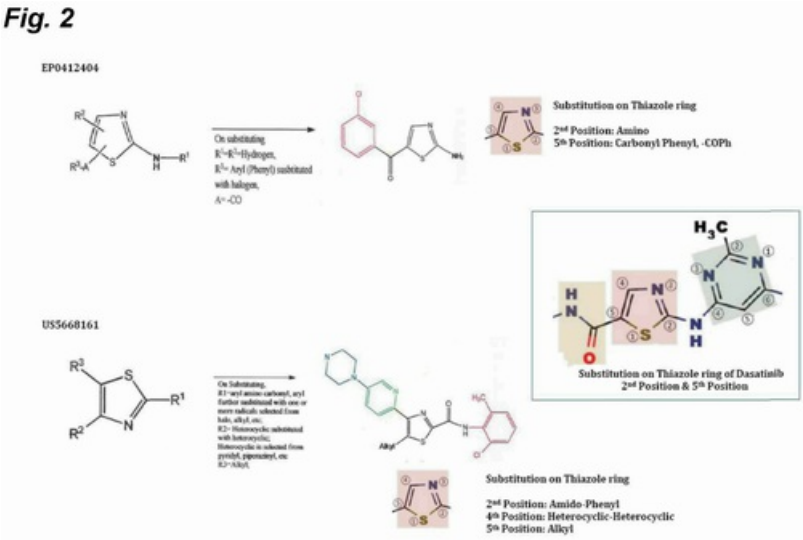


Fig. 2 explained:

i. EP0412404 teaches thiazole ring further substituted at 2nd Position by a amino group and at 5th position by Carbonyl phenyl [-COPh]- therefore at the core structure itself the compound is different.

ii. US5668161 again teaches a different compound at the core structure level. The cited compound of US'161 has thiazole substituted further at:

a. 2nd position: by Amido-phenyl;

b. 4th position: by heterocyclic-heterocyclic; and

c. 5th position: by alkyl

Fig. 3

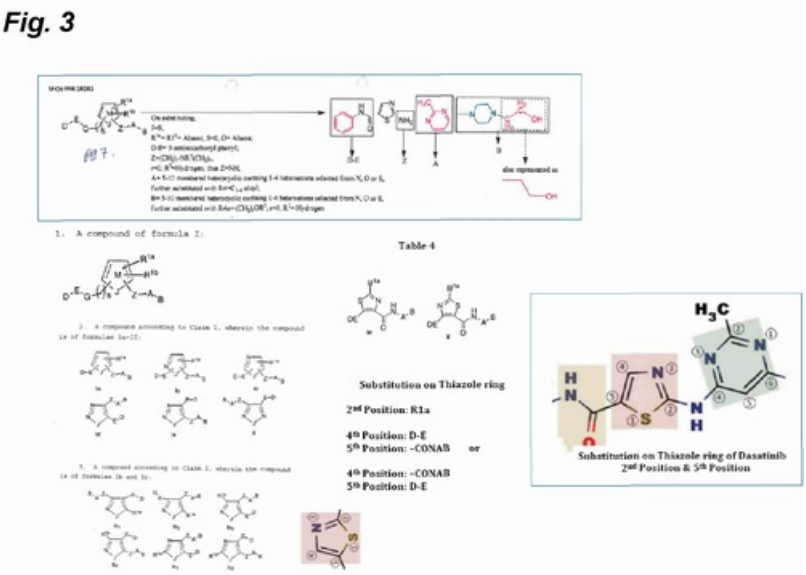


Fig. 3 explained:

i. WO1998/28282 is another irrelevant prior art reference. The thiazole ring of WO'282 teaches the following substitution:

a. Claim 1 teaches wide variety of 5 membered heterocyclic compound.

b. Claim 2 teaches a thiazole substituted with R^{1a}, -Z-A-B and -D-E; which is 3rd compound of first row in the above figure.

c. Claim 3 defines the positions at which said groups are substituted, which are 2nd and 3rd compound of second row in the above figure :

i. R^{1a} at 2nd position

ii. -Z-A-B and -D-E can be substituted at 4th and 5th position i.e.:

- 4th position: -Z-A-B and

- 5th position: -D-E

OR

- 4th position: -D-E and

- 5th position: -Z-A-B"

Thus structures of all the exhibited prior art compounds are not similar. Furthermore, none is an analogous prior art. All the cited patents disclose compounds for treating are not for the same ailments. Therefore, even the hypothetical structures given by BDR fail to establish the ground of obviousness.

In view of the above explanation, I would say that there are two rival stands which are available so far as the similarity of the structure of formula of the compounds are concerned which are that as per plaintiffs there are differences of the formula present in the suit patent with that of the prior patents whereas, the defendants continue to maintain that the examples quoted in the EP 414, WO 098 and US' 161 are same. There is an expert report filed by the defendants in this respect. However, I would not venture into the exercise of the appreciation of the evidence lead by the expert at this prima facie stage when the plaintiff is yet to lead its own expert evidence and the parties are also yet to cross examine the experts in order to find out the truth during the process of trial. Suffice it is to say, that in view of the differences explained by Mr. Anand, learned counsel for the plaintiff, there are two rival stands available on record and the defendant's position that the similarity of the structure exists between the prior patents and that of the one claimed in claim No. 1 and claim No. 7 of the suit patent cannot be readily inferred and neither they are so obvious to believe the stand of the plaintiffs or to brush aside the same at the threshold. Rather, the plaintiffs pointed the differences also need examination as to whether these are workshop substitutions or there lies innovation in the said substitutions of the positions of the chemicals. Therefore, I prima facie consider this aspect of the similarity of the structures of the formula as a disputed question of the fact and do not find the challenge on this count as credible enough to doubt the validity of the patent at this stage on the premise of the similarity of the structure of the formulae in the manner contended by the defendants. It has been thrashed out in trial as to what extent the formulae/structure of the compounds stated to be similar as examples are same/similar to the suit patent Markush claim. The plea of the obviousness raised by the defendants on this ground is thus rejected. Likewise, the judgment of Biswanath Prasad (supra), Gleverdale (supra), 3M (supra) and others relied on by the defendants are factually distinguishable as in those cases the common integers leads to arriving at the inventions were present in order to infer obviousness in the form of attendant circumstances which are missing in the present case for prima facie

purposes.

Lack of Utility and challenge under section 64(1)(g)

44. The second plea raised by the defendants is that the suit patent discloses no utility and is void/invalid and fails for lack of utility. It is submitted that as per the plaint, the compound of the Suit Patent is useful for treatment of chronic myeloid leukaemia and cancer, which is resistant to treatment by Imatinib. The patentee has failed to demonstrate at the date of filing that he had made the invention and knew that all the compounds would be useful against Chronic Myeloid Leukaemia. Under Section 10(4) of the Patents Act clearly states that the specification shall fully describe the invention, its operation or use and the method by which it is to be performed, describe the best method of performing the invention.

The patentee was required to disclose not only the product which is regarded as inventive but also the practical utility of the product otherwise as per Section 64(1)(g) a Patent can be revoked on the ground that the invention as claimed is not useful.

45. It is argued on behalf of the defendants that in the present cases, a plain reading of the suit patent reveals that it simply provides a list of billions of compounds and leaves the "utility" or "evidence of usefulness" to the imagination of a person skilled in the art. There is not a single sentence or whisper as to how the billions of compounds claimed in claim 1 or other claims are useful for treatment of blood cancer or leukaemia. The mode and use of the compounds for Chronic Myeloid Leukaemia is conspicuously missing. In the present case there is no evidence of BCR-ABL inhibition and utility qua CML. The plaintiffs have only made the statement that the compounds are useful for treatment of various diseases including cancer is a self-declaration by the plaintiffs without any evidence; even for the 580 compounds, which are shown in experiments, there is not an iota of data to show whether all of these compounds or even one of these compounds is useful for treatment of all the diseases under the head "utility".

46. It is argued by the defendants that the patentee never knew on 15th April, 1999 i.e. on the priority date of suit patent that the compounds had activity qua CML or were useful against Imatinib which is of resistant cancer as Imatinib was approved by USFDA and launched by Novartis in November 2001. It is therefore inconceivable that in 1999, plaintiffs knew that Imatinib would be approved for treatment of Chronic Myeloid Leukaemia and patients would develop resistance and plaintiffs' compound would be used to treat such resistance in patients - it is for this reason that there is no evidence of utility tests in their patent. The plaintiff's sequel patent for use of Dasatinib against CML and Imatinib resistant cancer was not filed in India as the plaintiffs having realised that their suit patent does not cover "treatment of Chronic Myeloid Leukaemia or Imatinib resistant cancer" and filed a "sequel-patent" in US i.e. US 7125875 which was not been filed in India. This patent covers case of the compounds of suit patent for treatment of CML and Imatinib resistant cancer only.

47. There is also no evidence in the specification for a person skilled in the art to determine which compound is most effective as compared to other compounds. Therefore, a person skilled in the art would have to perform unduly large number of experiments to ascertain which compound is useful for which disease condition. There is no evidence as to which compound is superior - hence, patent is a merely library of compounds, insufficient and vague.

48. It is argued that validity of suit patent is wholly in doubt and under cloud, especially in the light of challenge raised by defendants. It is settled law that grant of patent does not guarantee its validity and there cannot be any presumption in favour

of validity of the patent and when validity of Patent is yet to be tested, and credible challenge is made out, no injunction can be granted.

49. From the mere reading of the aforementioned submissions of the defendants on the aspect of the lack of utility, it can be said that the defendants continue to insist that in order to qualify the test of the utility, the plaintiffs ought to have disclosed numerous aspects as narrated by the defendants above and the same are missing in the patent. The counsel for the defendants also contend that the suit patent contains several compounds which are claimed but does not provide how these compounds can be used to cure the blood cancer or leukaemia. It is further stated that the mode and use of the compounds for chronic myeloid leukaemia is missing. It is further argued that the details as to in vitro or in vivo studies on inhibition of BCR- ABL. Likewise, it is also stated that the utility is assumingly claimed only for treatment of the cancer caused by particular family of tyrosine kinase which SRC family and not by the BCR - ABL family which normally causes Blood cancer or leukaemia.

50. All these so called infirmities are pointed out by the defendants in order to contend that the plaintiffs suit patent lacks utility. Further, it is argued that the plaintiffs deliberately did not provide the statement of utility towards the Leukaemia as in the year 1999 the plaintiffs were themselves not aware that the compounds claimed can cure CML as well. In this context, it has been argued that the plaintiffs also filed sequel patent to cure CML in US but not in India bearing No. US' 7125875. The defendants also relied upon several judgments in this respect which proceed to hold that the patent should describe the practical way of the exploiting it in atleast one field of the industrial activity and it should not be vague and speculative etc.

51. Per contra, Mr. Anand learned counsel for the plaintiff refuted the challenge laid by the defendants on the ground that the patent lacks utility by making following submissions:

> "a. The patent specification has extensively discussed the utility/industrial application of the compounds of IN 203937 as being Protein Tyrosine Kinase Inhibitors and their use in the treatment of cancer. The International Authorities have also recognized the claims of the patent to possess industrial application. The Indian Patent Office during examination of the suit patent recognized the industrial applicability of the IN 203937. It is undisputed fact that the commercial product has been developed from IN 203937 endorses that the compound, Dasatinib has utility and industrial applicability, otherwise why the defendants have sought a voluntary and compulsory license for IN 203937 from time to time even rejected of the prayer of the compulsory licence.
>
> b. On the issue of utility of a patent, the Bombay High Court in Farbewerke Hoechst v. Unichem Laboratories & Ors. [MANU/MH/0064/1969 : AIR 1969 Bom 255] has held:
>
> > "17. ...The first question that arises in regard to the subject of the utility of the plaintiffs' patent is what is the quantum of utility required to support a patent. Reference may be made in that connection to the statement in Patents for Inventions by T.A. Blanco White (the learned Counsel appearing for the plaintiffs in the present case), 3rd edn., at pp. 152-153 to the effect that in the absence of any promise in the specification that a definite degree of advantage would result from the use of the invention, the amount of utility required to support a patent is very small. It is further stated in the

said passage that it is, in particular, not necessary that the invention as described should be commercially useful, unless the specification promises that it would be, and that it is sufficient that that invention should, by reason of the features that distinguish it from earlier proposals, be of some use to the public...

...

20. As stated by Halsbury (3rd Edn.) Vol. 29 p. 59 Para. 123, "not useful" in patent law means that the invention will not work, either in the sense that it will not operate at all or more broadly, that it will not do what the specification promises that it will do. If the invention will give the result promised at all, the objection on the ground of want of utility must fail. It is further stated in the said passage that the practical usefulness or commercial utility of the invention does not matter, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested, and that it is only failure to produce the results promised that will invalidate the patent, not misstatements as to the purposes to which such results might be applied. In Terrell on the Law of Patents, (11th Edn.) p. 98 para 248, quoting from an English case, it is stated that if the patentee claims protection for a process for producing a result and that result cannot be produced by the process, the consideration fails. It is further stated there that objections to patents on such grounds are sometimes treated as objections for want of utility, and when so treated, the well known rule is that the utility of an invention depends upon whether, by following the directions of the patentee, the result which the patentee professed to produce can in fact be produced. Quoting from another English case, the same proposition is stated in another way in Terrell at p. 99, viz. that the protection is purchased by the promise of results, and that it does not, and ought not, to survive "the proved failure" of the promise to produce the results. As already stated above, the only result which the specification (Ex. A) in the present case professed to produce was a new class of chemical compounds having hitherto unsuspected blood sugar lowering property, but without the undesirable side effects of the previously known sulphonamides. As also stated above, the defendants have not been able to prove that a single compound falling within the patent does not possess blood sugar lowering properties to a greater or lesser degree. The position, therefore, is that not only is there no "proved failure" to produce the results promised by the plaintiffs' patent specification (Ex. A), but there is a "proved failure" on the part of the defendants to show that compounds falling within the patent do not have the blood sugar lowering properties promised by that patent. I, therefore, hold that the objection on the ground of want of utility must fail, and with it also the objection that the methods of manufacture are old and known methods and, therefore, there is no inventive step as far as the plaintiffs' patent No. 58716 is concerned. In the result, all the grounds on which the validity of the plaintiffs' patent was challenged stand rejected, and issue No. 3 must be answered in favour of the plaintiffs."

(c) The Division Bench of this Court in Merck v. Glenmark [FAO(OS) 190/2013] (supra) has also held the following on utility of patents:

> "69. On a fair application of the above principles, as explained above, it is concluded that prima facie there is a concrete basis for recognizing that the contribution of the suit patent could lead to practical application in the industry. As long as Sitagliptin is recognized to have a therapeutic effect in humans, it is practically applicable, even if it is not commercially successful due to an ineffective carrier.....The utility here refers to the function alleged to be performed by the compound, which in this case is the inhibition of the DPP-IV enzyme - clearly a beneficial addition to the medical industry that has been used as a fictional ingredient. Justice Blackwell remarked, "happy the inventor whose patent is infringed" for that is the surest sign that he has devised something of utility and worth."

52. By examining the aforementioned rival submissions raised by the parties, it can be said that it is the case of the defendants that the plaintiffs have not sufficiently disclosed the working of the each and every compound contained in the suit patent and there exists a vagueness in the disclosed process/working of the patent which does not allow the person skilled in art to arrive at the compounds contained in the patent. On the contrary, the plaintiffs counter the said plea by negating the position taken by the defendants and by stating that the minimum level of the utility required to be disclosed and the same is present sufficiently in the suit patent. I find that the argument of the sufficiency and inadequacy of the utility raised by the defendants not potent enough to raise any doubts as to the validity of the patent at this prima facie stage. Again, this is a bald defense raised by the defendants at their own whims and understanding of the invention in the suit-patent and its utility. The points which the defendants insist must be present in the suit patent or required to be appropriately described further require an in depth enquiry in to several questions to be examined from various perspective and few of them can be posited as under :

> "• What is the extent of the disclosure so far as the working/operation of the compounds as claimed in the suit patent is concerned?
>
> • Whether such operation of the compound is in consonance with the promises made by the specification or not?
>
> • Whether the workings of the few of the compounds are present in the suit patents as against others or not?
>
> • Whether the absence of the workings of the few compounds in the suit patents would effect the disclosure of the utility relating others which are most relevant and closely connected with the claims or not?
>
> • Whether such absence of the workings or manner to arrive at the few compounds depicted in the suit patent would be fatal to the entire patent when such compounds are merely forming part of the larger whole?"

53. Till the time answers to these concerns/question emerging immediately after hearing the submissions of the parties on lack of the utility are conclusively determined/ascertained by appreciation of facts and in depth analysis of the patent specification, no prima facie opinion to the challenge as to lack of utility of the patent can be formed merely upon the insistence of the defendants that certain elements ought to have been present in the suit patent and the same are missing. Suffice it is to say that there is a statement of the utility contained in the patent specification and the same has to be read along side the other paragraphs of the specification meaningfully in order to analyze the disclosure of the working of the compound,

which is claimed in the suit patent. Prima facie, such disclosure has to be considered for the purposes of considering the plea of the utility. Now, if the defendants' questions the utility on certain facts and insisting that those set of facts must find place in the specification and the plaintiffs dispute the said position by contending to the contrary, the same is again the question which cannot be determined at this stage. Neither, the said question of lack of utility is such which is so clinching enough to immediately arrive at the view that the patent lacks utility. This obviously requires an in-depth enquiry into further facts, the elaboration of which is necessary in advance stage of the proceedings. Therefore, I do not find that the plea of lack of utility such which raises a credible challenge as to the validity of the patent warranting the modification of the interim order already granted on the said ground.

54. It is noteworthy to mention here that the challenges which can be raised under the provisions of the Section 64 of the Patents Act 1970 (as amended in the year 2005) are in the nature of the questions dependent on facts or the mixed question of facts and laws. Where in the case after applying the facts in the form of challenge and legal position, it can be prima facie readily inferred that the good ground for the challenge is made out which raises a credible challenge to the validity of the patent, then such inference can be drawn prima facie to state that the credible challenge to the validity is raised. As against the same, there are certain questions within the challenges which requires the enquiry into more facts or complicated questions on which no opinion by the preference one set of facts over the other can be formed at the prima facie stage till the time those facts are ascertained in the trial as they are disputed question of the facts. Those are merely the defences raised by the defendants though not credible enough to raise prima facie doubts as to validity. Those questions can be deferred to trial for further enquiry into facts as against straightaway presuming that they raise prima facie challenge to the validity when they actually do not. I find that the challenge as to utility is such which cannot be by mere asking of the defendants be assumed to be raising a doubt as to the validity of the patent till the time answers to relevant concerns/questions are provided during the trial. Therefore, I prima facie do not find the plea of the lack of utility as convincing to raise any credible challenge to the validity of the suit patent though it may be a defence, which is yet to be substantiated with more facts during the course of the trial.

Objection under Section 3(d) of Patents Act, 1970

55. Learned counsel for the defendants has raised the objection under Section 3(d) of the Patents Act by contending that the compounds claimed are mere derivatives, and not patentable under Section 3(d) as the plaintiffs, as of the date of filing, never knew that the compounds could be used for treatment of Chronic Myeloid Leukaemia. It is pertinent to note that use of a compound for treatment of Chronic Myeloid Leukaemia is demonstrated by its efficacy against the enzyme BCR-ABL. Use of the compounds for treatment of CML is a new use, not covered by suit patent and not enforceable. The plaintiffs have failed to give any answer as to why the compounds do not fall within 3(d) and are patentable.

56. I have gone through the objection taken by the defendants on the count of applicability of Section 3(d) of the Act. I find that the objection/challenge of the defendants is founded on the premise the suit patent is merely a derivative of thiazole compounds and thus does not enhance the efficacy and is not patentable. I have already given some of my prima facie observations that the defendants have not been able to prima facie explain as to how the commonality of thiazole compounds in the respective prior arts would not lead to one patent being far removed from another and how these patents are valid if the commonality of Thiazole compounds would be

sole reason for obviousness. The said observations atleast indicate that the defendants are not able to lay their challenge properly by explaining each and every integer involved in the suit patents and in prior arts which differ in respective compounds from each other atleast for prima facie purposes.

57. Even assuming that Section 3(d) of the Act is peculiar to Indian law and the observations of mine on obviousness would only be relevant for the said head and Section 3(d) is distinct from the aspect of obviousness, the question still remains that if the suit compound is a mere derivative of known elements/integers, then why the suit patent and claimed compound is so successful in curing the cancer and leukaemia. Further, the connected question still remains unanswered which is that if the suit compounds lacks efficacy in curing the cancer, then why the defendants are proposing to launch the product if it is lacking efficacy. Certainly, it requires a fact finding in the trial. But one cannot adopt the presumptive kind of approach by mere saying of the defendants that the patent lacks efficacy. Therefore, even assuming for the sake that the defendants plea that the suit patent compound is a derivate of the known compound, still Section 3(d) cannot be pressed in to service till the time the compound involved in the patent is efficacious. It is true that the plaintiffs have not proved this position by way in vitro or in vivo tests to show the efficacy, but that is the stage of the evidence to show and prove that the product is indeed efficacious in nature. At this prima facie stage, the wholistic reading of the plaints along side the written statement and the attendant circumstances where in the defendants are also equally inclined to launch this product itself shows that the efficacy is involved in the product in treating the ailment including cancer for prima facie purposes though more elaborate proof of efficacy shall be ascertained in the trial. Therefore, the objection under Section 3(d) of the Act raised by the defendants is also rejected.

Non Compliance of Section 8

58. Learned counsel for the defendants has raised the objection under Section 8 of the Act in the written submissions by contending that the suit patent violates the said provision by not disclosing the following :

"Non-Compliance of Section 8 - Revocation Under Section 64(1)(N) :

- It is submitted that as per Hoffman-La-Roche v. Cipla, the plaintiff is required to disclose to the Controller any patent application which is pending in any country outside India in respect of the same or similar application.

- In the present case, the plaintiff filed further application for Chronic Myeloid Leukaemia in US and Europe, which application is drawn from the present suit patent. However, this is not disclosed to the Patent Office under Form-3 i.e. filing of US 7,125,875 and EP 1610780 not disclosed to Patent Office, same is not refuted by plaintiff.

- The European Patent No. 1610780 stands revoked which is not refuted by plaintiff.

- The Chinese Patent which is corresponding to the suit patent stands withdrawn.

- However, these are not disclosed to the Patent Office and not disputed by plaintiff.

• In view of the above, there is substantial non-compliance of Section 8 and on this ground, the suit patent is liable to be revoked."

I have gone through the objection taken by the defendants as to non compliance of the provisions of Section 8 of the Act. Although, the said plea raised by the defendants is not argued at the time of hearing. Still, I am inclined to deal with it. The provisions of Section 8 are already discussed at great length by the courts as such wherein the Court may or may not revoke the patent depending upon the nature of the information not supplied to the controller, relevance of the information and the conduct of the patentee etc. This objection under Section 8 has been discussed in the counter claim as well as in the written submission which was not argued by the counsel orally before the Court nor the relevance of such patents was brought to the notice of the Court as to how the said patents could have effected or impacted the validity of the suit patent. The mere stray references in the written submissions by enlisting the number of the patents in an itemised manner do not imply that there exists a violation of the provisions of Section 8 of the Act which otherwise lies in the discretion of the Court to accept such challenge or not in the end. Therefore, for prima facie purposes, the said objection of the defendant is also without any substance and is not considered to be vital enough to doubt the validity of the patent. There is no positive details produced by the defendants by raising such plea. The said objection is afterthought. It was not raised in the first written statement specifically.

Insufficiency

Likewise, in the same manner, the defendants counsel has also enlisted the objections as to insufficiency of the patent in the written submissions though no elaborate submissions were canvassed across the bar to explain them. The same are:

"• It is submitted that the claims of the suit patent are very broad and include thousands of compounds, if not millions.

• The plaintiff has provided examples for preparation of around 500 compounds;

• Undue experimentation required to test utility - hence patent invalid for lack of sufficiency : There is nothing in the specification to demonstrate whether all these compounds are useful against all the diseases mentioned under the Section "Utility" or whether some of the compounds are useful or not. There is also no evidence in the specification for a person skilled in the art to determine which compound is most effective as compared to other compounds. Therefore, a person skilled in the art would have to perform unduly large number of experiments to ascertain which compound is useful for which disease condition.

• No evidence as to which compound is superior - hence, patent is a merely library of compounds, insufficient and vague : The Markush claims is drawn to millions of compounds, if not billions. Any person skilled in the art would require more than a life time to actually prepare these compounds. Therefore, these are theoretical compounds for which patent has been granted to the plaintiff. Therefore, on this ground alone, the suit patent is insufficient, vague and liable to be revoked.

• In view of the above, the claims are overly broad, vague and ambiguous rendering the entire patent void for such vagueness."

From the reading of the said objections as to insufficiency of the patent, it can be

said that the said objections are also the kinds of the infirmities pointed out by the defendants. The said objections are akin to the head of the utility as discussed above and raises the several kinds of the concerns and questions, the answers to which are required to be provided in the trial. The defendants are themselves not sure while informing the court as to whether the patent covers thousand compounds or millions as they take different stands at different places and use these terms loosely. If the objections of the defendants are not well founded or not properly laid before the court, the defendants cannot expect the Court to rule on such objections and the Court is left with no option but to reject them as such. In case any such objection exists, the defendants are at liberty to prove it at the time of the trial and final arguments.

Seeking Voluntary licence no bar to challenging the validity

On behalf of the defendants, it is argued that it is a settled position of law that once a patent is granted, any person in the market may seek voluntary licence. Making a request for voluntary license is a bonafide act in everyday's business and such request for license is without prejudice and not an admission of the validity of the patent. In the present case, the communications regarding voluntary license were "without prejudice" meaning thereby that they were without prejudice to the rights and remedies that may be available to the defendant but the plaintiff was not willing to grant any license and therefore, the discussions did not succeed.

59. It is argued by the defendants that the filing of compulsory license application or rejection thereof, was on the ground that appropriate efforts for obtaining voluntary license was not made and hence, the application for compulsory license was rejected. The plaintiff was never willing to grant license and only kept asking for unwanted information and derailed and frustrated the negotiation process. As a result the application of the defendants came to be rejected "for lack of efforts" The application was not rejected on merits. Hence, this factor cannot be held against the defendants. The plaintiffs cannot be allowed to take advantage of his own wrong.

60. I have gone through the submissions raised by the defendants that seeking of the license is no bar to challenge the validity of the patent. Once, I am deciding on the objections on the validity of the patent by returning the prima facie opinion on the same, the said question of seeking a license is no bar to challenge the validity is purely academic in that sense. Therefore, I do not consider necessary to venture into such exercise when the said question is of less relevance in the facts of the present case.

Suppression of Material facts

61. It is submitted by the defendants that the plaintiffs have not disclosed European Patent for Dasatinib for treatment of Chronic Myeloid Leukaemia revoked in February 2013, much prior to the filing of the suit. In the said patent, the use of Dasatinib for treatment of Chronic Myeloid Leukaemia was claimed but such claim was rejected.

62. It is further argued that the plaintiff has not disclosed that the plaintiff's product in the market is a monohydrate. A separate application No. 4309/DELNP/2009 claiming such monohydrate was filed. The same fact was not disclosed in CS (OS) No. 679 of 2009. The withdrawal of the Chinese patent was suppressed and not disclosed to this Court. In view of such suppression, plaintiff is not entitled to any injunction.

63. I have gone through these objections raised by the defendants on the concealments taken by the defendants and prima facie found no merit in any of them.

This is due to the reason that the so far as the revocation of the European patent is concerned, it is to be seen what relevance the European patent would have on the Indian patent. The patent law is always territorial in nature and the rejection, acceptance of the patent depends on several factors which depends on case to case basis. The defendants while raising these objections that the plaintiffs European patent has been revoked and Chinese patent has been withdrawn have not pointed out as to what bearing these patents would have to the facts of the present case and how the same could have the right and entitlement to the injunction of the plaintiffs. Simply by raising the plea that there are patents which has been revoked or withdrawn without discussing under what conditions such happenings took place is totally out of place. Therefore, I do not really find the said objections as concealments till the time it is shown that the same are deliberate in nature and would otherwise if could have shown or explained would be detrimental to the case of the plaintiffs so far as the entitlement of the interim injunction is concerned. Likewise, the plea that the product is monohydrate in nature. Upon this fact being put to Mr. Anand, it has been categorically stated that the salts of the compounds are covered within the ambit of the claims of the patent which is as per claim No. 7 are covered. Monohydrate is one of the salts of the compound. In such an event, the said alleged non disclosure as stated by the defendants would also not disentitle the plaintiffs from the interim injunction when the said product is prima facie appears to be covered within the scope of the patent.

Non working of the patent

64. It is submitted by the defendants that "working" as envisaged under Section 83 must be adequate so as to fulfil the requirement of the public and not mere lipsake. A comparison of the import data/sales in India (as in plaint), the working statement and the total patient base would reveal that the supply of the product by the plaintiff in India is highly inadequate. There is a great demand for the product Dasatinib in the Country and the same can only be fulfilled if there are more than one source of supply of the product. Working of a patent in case of medicines and pharmaceutical products must be interpreted as "local manufacture" keeping in view the "Make in India" slogan of the Government of India. Without local working, it is submitted that technology transfer would never occur. Mere importation and sale of product in India would completely go against the principle of "Make in India" adopted by the Government of India. It is submitted that Non-working Patentee is not entitled to any equitable relief such as injunction, the following decisions are referred :

> "i) Franz Xaver Huemer v. New Yash Engineers, MANU/DE/0015/1997 : AIR 1997 Del 79, paras 16 - 21, 22
>
> ii) Sandeep Jaidka v. Mukesh Mittal & Anr. (supra)"

I have gone through the objection raised by the defendants on working of the patent in India. I find that the said objection is also without any substance in as much as it is the plaintiffs position that the suit patent covers the salts of the compound claimed therein and monohydrate product shall fall in the same though the defendants states to the contrary. It is also known that the plaintiffs have supplied the drugs of millions of rupees as stated in the plaint in India as well. Thus, it really passes human comprehension as to how this plea of the non working of the Indian patent can be sustained at this stage when there is a disputed question of fact which is yet to be determined as to whether the suit patent covers the monohydrate version of the compound or not. Prima facie on the fair reading of the specification and the claim statement, it appears that the salts are covered within the ambit of the suit patent. I find that the said statement in the claims of the patent in this respect is enough for

the prima facie purposes to reject this plea of non-working of the patent and rest is to be proved in trial. Lastly, so far as the non fulfilment of demand and importation of the articles are concerned, the aspects are more of a significance in the application seeking compulsory licence as against in the infringement proceedings. I have already discussed the difference between the scheme of the Compulsory licensing, revocation on the ground of the non working which is a distinct chapter providing independent grounds than that of the infringement proceedings and defences available as grounds of revocation which are altogether different from those mentioned in the compulsory licensing. Therefore, the considerations which are relevant for the compulsory licensing are less of a significance in the defence to the infringement proceedings. Thus, prima facie I do not find merit in the plea of the defendants with respect to non working of the patent.

65. ON THE ISSUE OF PUBLIC INTEREST

It is stressed by the learned counsel for the defendants that the product Dasatinib has now been recommended as first line treatment for Chronic Myeloid Leukaemia therefore, all patients detected with CML may be administered dasatinib 100 mg. People suffering from Chronic Myeloid Leukaemia is more than 20,000 per year and the patient base over the last 5 years may be more than 30-40,000 patients. Most CML patients are diagnosed at the chronic stage. A perusal of the import data, the working statement and the total patient base would show that there is a great demand for the product dasatinib and over the last 5 years plaintiff's is able to fulfilment of hardly 5% of the patient base. It shows that the product is not available and beyond the reach of most of the population in the country. The spread of the disease there is a compelling public interest to make the drug available at reasonable cost, which is only possible through generic competition. The price of plaintiff's product and of defendants' proposed price are set out here below:

Strength of tablet	Proposed Cost of BDR product [per month]	Cost of Plaintiff's product [per month]
100 mg	Rs.8,100	Rs.1,67,000

66. The recommended dosage of the drug is 100 mg and average cost of this therapy per month is about Rs. 1,65,000/-. Even, if a drug is, in fact, existing in the market but beyond the reach of the general population, it would be deemed not 'available' to the public. While the drugs Imatinib, Dasatinib and Nilotinib are used for treatment of CML, only Dasatinib is a product that give a sustain long lasting relief to the patient from CML. Imatinib as is known gives rise to resistance within month and become useless thereafter. Nilotinib cannot be given to patients with hyperglycaemia.

67. It is submitted by Ms. Rajeshwari, learned counsel for the defendants that the plaintiff's charity program of a drug being out of reach of common man and even an existence of the charity program itself is an admission that the price of the plaintiff's product is too high and beyond the reach of a common man in India. It is also an admission that plaintiff is aware that their product is too expensive for an average common man. Therefore, the public interest demands that the injunction granted be vacated immediately.

68. Per contra, Mr. Anand, learned counsel for the plaintiff submitted on the public interests plea by making suitable response to the submissions of the defendants in the following manner:

69. As per the pleadings of the plaintiffs wherein it is stated that ever since the launch of Dasatinib in India, the plaintiffs have addressed the access and affordability needs of the patients by an aggressive commercial Patient Access Program (PAP)

through which prices of the drug is reduced to a fraction of the MRP in order to reduce the cost of drug to patients. BMS's Patient Access Program (PAP) is publicized to all the oncologists of the Country through regular advertisements in medical journals like India Journal of Cancer. The PAP for Dasatinib is termed as the Sprycel Access Programme as mentioned in the affidavit of Mr. Jitendra Tyagi dated 23rd April, 2015. The Sprycel Access Programme is made available through a third party service provider for the self paying patients prescribed Dasatinib by an Oncologist. It is alleged by the plaintiffs that this programme is publicized to all the oncologists of the country through leave behind literature/brochure as well regular advertisements in medical journals like India Journal of Cancer and banners in oncology conferences. The details or the same are filed along with list of documents dated 24th March, 2015. It is the case of the plaintiffs that the service provider, through a centralized call center, delivers the drug to the patients at the door step anywhere in India with no additional delivery cost. In its current form, the effective cost for a months' therapy for the Indian patient is as follows:

"a. 20mg- Rs. 7529 for a month's treatment

b. 50mg - Rs. 15062 for a month's treatment

c. 70mg- Rs. 16110 for a month's treatment"

70. It is stated that in order to avail this service a patient is only required to provide the following documents as mentioned in the affidavit of Mr. Jitendra Tyagi, dated 23rd April, 2015 where the details of declaration is shown:

"a. A prescription for Dasatinib from an Oncologist.

b. Any identification to establish the nationality of the patient as the program is available to only Indian nationals.

c. Declaration to the effect that patient is a self paying or that the Patient's insurance would not cover the MRP of Dasatinib."

71. The details have been produced whereby the plaintiffs have received tremendous appreciation from both patients and doctors for their Patient Access Program. The plaintiffs have given the justification about the current MRP for a month's treatment with 50mg of Dasatinib is Rs. 1,65,680/-. The MRP of the drug reflects the investments made by BMS in the R&D; drug development; clinical trials; pharmaco-vigilance and in addition to that, the MRP of the drug cannot be reduced due to other factors inter alia efflux of parallel exports to other jurisdictions including where governments provide drug access to patients. The plaintiffs through their Sprycel Access Programme have developed an effective mechanism to reduce the price of the drug to 1/11th of the MRP for patients in India while preserving the plaintiffs' right to recover investments in other developed jurisdictions as alleged by them. It is the case of the plaintiffs that Dasatinib is not the only treatment option available to patients suffering from CML. In order to ascertain the demand for Dasatinib, the plaintiffs had sent RTI Queries to 12 top Government Cancer Hospitals across various regions in India enquiring about the treatment protocols in respect of CML. Responses were received from 9 hospitals. The answers to the RTI Applications clearly show that (a) in 95-100% cases Imatinib is the first line treatment; and (b) In the event of failure with Imatinib, the alternatives (without any preference) are (i) Dasatinib; (ii) Nilotinib; (iii) Stem Cell Therapy; and (iii) Bone Marrow Transplant. The RTI responses along with a summary of the same from the 9 Cancer Hospitals have been filed in the present proceedings. Assessing the demand of Dasatinib by regularly filing RTI applications, conducting market surveys and obtaining expert

opinions, the plaintiffs are meeting such demands at an affordable price. The opinion of an Oncologist in India Prof. Dr. Purvish M. Parikh has been filed as Annexure D with the affidavit of Mr. Jitendra Tyagi dated 23rd April 2015.

72. The following are the main reasons given by the plaintiffs to provide the drug to the patients in reasonable price:--

> "(i) BMS, through its Patient Access Program, makes the product available at reasonable prices to non-reimbursed self paying patients. Through the program the product is available for a monthly price of approximately Rs. 15,000/- as opposed to Rs. 1,65,000/-. The PAP is transparent and easily accessible. The said scheme has been appreciated by doctors and patients.
>
> (ii) CML itself is a very rare disorder and the first line treatment option for this disease is Imatinib (several generic versions of the same are available in the market). CML has in fact been declared as an Orphan Disease and Dasatinib an Orphan Drug considering minuscule population of patients which are affected by this disease. Imatinib Mesylate continues to remain the Gold Standard for first-line treatment of Chronic Myeloid Leukemia;
>
> (iii) Dasatinib is predominantly used as a second line of treatment for a handful of patients who develop resistance to Imatinib. There are other second line treatment options available for patients and oncologists including Nilotinib, Bosutinib, Ponatinib; and therapy including Bone Marrow Transplant and Stem Cell Therapy as per Annexure A filed along with the affidavit of Mr. Jitendra Tyagi dated 23rd April, 2015.
>
> (iv) Dasatinib has been approved as a first line treatment only recently and that too for patients who are resistant to Imatinib in the first instance which is about 1% of the total population suffering from CML as filed as Annexure D of affidavit of Mr. Jitendra Tyagi dated 23rd April, 2015 which says as under:--
>
> > "First line therapy" is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment of a given type and stage of cancer. It is also called primary treatment or therapy. "Second-line therapies" are those tried when the first ones do not work adequately. The management of a cancer case requires regular evaluation of treatment to assess their success and adjust as needed."

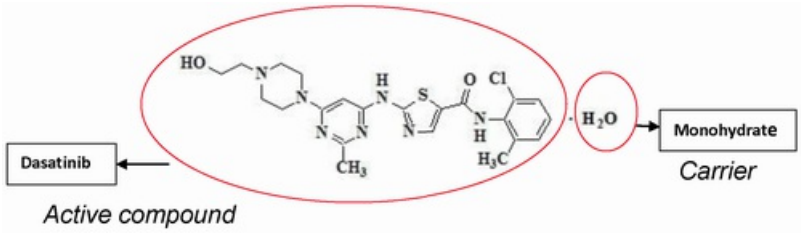
73. I have gone through the submission of the defendants on the public interest requiring the vacation of the injunction. I would say that after examining the material available on record, again there exist the rival stands of the parties in form of the contra material available on record that the plaintiffs are adequately able to meet the demands of the public. No conclusive opinion or prima facie opinion in favour of the either side can be formed by appreciating the said material. At this stage, it could be said that the credibility of the plea of the defendants is yet to be tested in view of the fact that defendants being a proposed competitor of the plaintiffs and is in desperately attempting to launch the product under the same compound and whether such plea of the serving the public interest is genuine or not. In this connection, I have done detailed analysis in the judgment of Novartis v. Cipla (supra) decided on 15th January, 2015 herein I have discussed this plea of public interest often taken by the defendants who intend to do private business by manufacturing the products under the patents and affecting the statutory rights of the patentees. The scheme of the patent Act allows the examination of the plea of public interests towards

allowance of the compulsory licence under the distinct chapter of the compulsory licensing and non working of the patent which is code in itself. The question of the public interests for the purposes of the infringement proceedings in the form of deciding the interim application has to be only seen from the prima facie view of the credibility in the defence of the defendants. I find that the plea of the defendants being non credible in the present case and in case the defendants intend to have a licence from the plaintiffs, the defendants need not inform the term of 2.7 % blanketly but should come out with concrete proposal which should be discussed amongst the parties on the mutually agreed terms or before the competent tribunal which is the compulsory licensing tribunal as provided under the patents Act. This aspect has been discussed by me in detail in Novartis case (supra) at great length and is equally applicable to the facts of the present case. Therefore, prima facie plea of the public interest or setting out the terms of the royalty cannot be accepted at this stage. The defendants are although free to approach the plaintiffs on any terms mutually acceptable to the parties or before the compulsory licensing tribunal in this respect.

Product not covered by the Patent claims

74. Learned counsel for the defendants has raised the plea that the product which the plaintiff No. 1 is using is the monohydrate version of the Dasatinib which is not covered by the suit patent and is the matter of the separate application. It has been argued that once the product is not covered by the patent, thus, the proposed launch of the product by the defendants would also not fall within the ambit of the suit patent

75. In response thereto, plaintiffs submit that the plaintiff No. 1 has also filed applications including a divisional application for the crystalline monohydrate form of Dasatinib and their intermediates which are currently pending before the Patent Office. The chemical structure for Dasatinib Monohydrate is as follows:



76. The active ingredient/molecule of the commercial product is Dasatinib. It is the active ingredient which refers to the chemical that results in the therapeutic effect. It is Dasatinib that has a medical value in managing certain diseases and conditions. Monohydrate is merely a carrier that has no therapeutic value. The Division Bench of this Court in Merck v. Glenmark [FAO(OS) in 190/2013] observed that:

> "50. In this case, from known compounds, prima facie, the Sitagliptin free base is disclosed. As it is a free base, a pure form of an amine, as opposed to a salt form, this naturally does not include particular salts, whether phosphates, hydrochlorides or any other. The elements of the free base - since many alternatives exist - are then also detailed in the above table. Conspicuously - and this is not denied by Glenmark- the free base must be transformed into a salt form before it can be administrated to patients (with the salt acting as the carrier). Unsurprisingly the free base requires a further appropriate reaction to create that salt. The argument that at no point is the free base disclosed (and only salt forms, though still not the phosphate salt form, SPM) lacks prima facie substance. First, Scheme 6, read with the table

above, discloses the free base, which is claimed in Claim 1, and specifically, Claim 19. In each of these specifications, Sitagliptin is found as a free base, without any attached salt. Two, the Court has to look to the invention in this case, and not read the claims literally. The invention in this case is a DPP inhibitor which assists control and prevention of diabetes by regulating insulin production, and specifically, inhibiting the DPP-IV enzyme activity. The claims and disclosures made, should be seen in the light of the invention underlying the patent and sought to be disclosed. In this case, the active therapeutic component is the Sitagliptin free base (which is delivered into the body with an attached salt that wears away once in the system), and not the attaching phosphate, Hcl or other carriers. No doubt such carrier salts are needed to deliver the drug into the body, and the salt must contain certain crucial properties that allow for the drug to be administrated properly (solubility, flow issues, propensity for adhesion, poor filtration, drying etc.) This is recognized in the statement of the inventor, Mr. Robert M. Wenslow FAO (OS) 190/2013 Page 39 Jr, as well in determining the best method for administration (on which Glenmark relies in its written submissions); but there too, the active therapeutic ingredient remains the Sitagliptin free base, and that product is sufficiently disclosed in Form 2 filed by MSD. It seems, that Sitagliptin free base's activity, prima facie, on the DPP enzyme is not naturally affected by the attached salt; those properties remain, though the efficacy of administration is dependent in part upon the carrier. The Sitagliptin free base, previously unknown as a compound that could affect the activity of the DPP enzyme is a new and arguably, a novel addition. It is in that context - and in the shoes of that notional addressee who is working in that field of pharmaceuticals - that the technical contribution has to be seen...

...

65. The description of industrial applicability is of the "active ingredient", i.e. Sitagliptin, instead of any individual compound, for example, a salt. It is contemplated that the active ingredient - which refers to the chemical that results in the therapeutic effect - will be combined with a carrier of some form. The essential focus of the specification therefore is the industrial application of the main therapeutic agent, or simply, the invention. There is also an implicit admission that while it is the active ingredient -Sitagliptin free base - that has a medical value in managing certain diseases and conditions, it will be accompanied by a carrier that has no therapeutic value.

...

79.....a case for the infringement by Glenmark - through its product Zita - is established since it uses the Sitagliptin free base as the active component in its chemical formulation. An argument was advanced by Glenmark during the course of oral hearings that this is not the case since Zita uses SPM, which is manufactured directly without using the Sitagliptin free base. The Court is unimpressed with this submission - not only was no evidence or document adduced to support this plea, but moreover, the written submission and counter-claim do not in any meaningful manner disclose such a case. Indeed, Zita - by account of all documents canvassed before the Court - uses the Sitagliptin free base as the active component i.e. the DPP inhibitor. Glenmark's explanation that it uses a different process to produce the infringing article is facially unconvincing. It appears to this court that the production of Sitagliptin Phosphate would precede use of MSD's patented

article, which entails infringement."

77. To this, the learned counsel for the defendants states that the operation of the order passed by this Court has been stayed and hence the Division Bench judgment cannot be relied upon by the plaintiffs.

78. I do not agree with the counsel for the defendants as Supreme Court in Glenmark v. Merck [SLP (Civil) No. 9220 of 2015] has made the following observation with regard to the order passed by this Court wherein it was held as under :

> "...Going by the prima facie satisfaction recorded by the High Court, we are of the view that the unfinished formulation of Sitagliptin Phosphate Monohydrate which is to be processed in the petitioner's factory/factories will not be undertaken for the present and until the next date fixed..."

79. Even otherwise, the Supreme Court in Shree Chamundi Mopeds Ltd. v. Church of South India Trust Association [MANU/SC/0501/1992 : (1992) 3 SCC 1] has held:

> "11....While considering the effect of an interim order staying the operation of the order under-challenge, a distinction has to be made between quashing of an order and stay of operation of an order. Quashing of an order results in the restoration of the position as it stood on the date of the passing of the order which has been quashed. The stay of operation of an order does not, however, lead to such a result. It only means that the order which has been stayed would not be operative from the date of the passing of the stay order and it does not mean that the said order has been wiped out from existence. This means that if an order passed by the Appellate Authority is quashed and the matter is remanded, the result would be that the appeal which had been disposed of by the said order of the Appellate Authority would be restored and it can be said to be pending before the Appellate Authority after the quashing of the order of the Appellate Authority. The same cannot be said with regard to an order staying the operation of the order of the Appellate Authority because in spite of the said order, the order of the Appellate Authority continues to exist in law and so long as it exists, it cannot be said that the appeal which has been disposed of by the said order has not been disposed of and is still pending."

80. Relying on the above decision, the Calcutta High Court in Pijush Kanti Chowdhury v. State of West Bengal and Ors. [MANU/WB/0077/2007 : (2007) 2 CALLT] has held:

> "13. Therefore, the effect of the order of stay in a pending appeal before the Apex Court does not amount to 'any declaration of law' but is only binding upon the parties to the said proceedings and at the same time, such interim order does not destroy the binding effect of the judgment of the High Court as a precedent because while granting the interim order, the Apex Court had no occasion to lay down any proposition of law inconsistent with the one declared by the High Court which is impugned."

81. In any case, the sum and substance of the plea raised by the defendants when they state that the plaintiff No. 1 has filed another patent for the monohydrate form of Dasatinib is that the monohydrate form of the compound is not covered in the suit patent and the product which is the reproduction of the monohydrate form of DASATINIB would not be infringing the patent. On the contrary, Mr. Anand states and urges that the said monohydrate form contains the essentially the same compounds with some treatment but not able to explain the filing of the separate patent if it is essentially covered in the first one as a broad based claim. This question of the scope

and ambit of the monohydrate version Dasatinib is relevant and necessarily required to be adjudicated once the defendants point out elaborately the differences claimed in the subsequent patent filed by the plaintiffs as claims relating monohydrate form of DASATINIB and relate it with the claims of the suit patent and how they are different from each other and relate all these with alterations in the consequential products and its working. At this stage, where the defendants are yet to launch the product containing DASATINIB in either form after obtaining the license to manufacture the same, the question of distinction of monohydrate form or otherwise lends no support to the plea of the defendants that there lies difference in the nature of the products and their workings and they are not covered with in the ambit of the suit patent. After all, it is the defendants who are raising the plea that the suit patent does not cover the monohydrate version of DASATINIB, therefore, in order to set up this plea, the onus lies upon the defendants to explain the differences by carving out the two patents filed by the plaintiffs and thereafter relating with the products which are available in the market whether of the defendants or other parties in either of the forms suggested by the defendants. It is only then, the onus shall shift to the plaintiffs who shall be called upon to explain the difference in the patents filed by them, the respective forms and the difference in their workings. This requires further fact finding and elaboration that of merely raising the plea. Without the existence of the product, a plea which has been inadequately set up by the defendants purely on academic basis lying a distinction between amorphous and monohydrate nature of DASATINIB is merely a bald defence which is required to be substantiated during the course of the trial. There exists a distinction between the credible nature of the defence affecting the validity of the patent vis-Ã -vis a bald defence of non infringing product to the claim of infringement. The later form is not the question affecting the validity of the patent and thus doubts of the invalidity in such a case cannot be inferred on the suit patent. It is only to escape the charge of the infringement, such a defence is raised. Therefore, the mere fact that the defence as to non infringement is deferred to the trial for further substantiation of facts does not warrant the variation of the interim order till the time the defence raised by the defendants are fully substantiated. At this prima facie stage, I find that in case the defendants maintains the position is that the monohydrate version of the DASATINIB product is not covered in the suit patent and the defendants' product is monohydrate version of the DASATINIB which is yet to be launched, then there was no occasion for the defendants to contest the suit patent so vehemently or challenging its validity on several scores though it is the statutory right of the defendants to challenge the validity. On the contrary, the defendants are doing so which means that there is some more facts which are to be brought into light and the defendants are also unsure as to whether the suit patent covers all forms of the DASATINIB or not. In such event, I would refrain from upsetting the status quo in the form of ad interim injunction which has already been operating merely on the ground that the proposed product to be launched by the defendants which is yet to the see the light of the day is the form of the DASATINIB drug is not covered by the suit patent. If that is so, the status quo as on date does not harm the defendants, but this Court would refrain from commenting anything on the same till the facts are completely brought into light during the voyage of the trial.

82. In view of the above discussion, it is seen that the defences raised by the defendants are prima facie not credible but vague or bald which require more factual foundation. The patent No. IN 203937 is an old patent and has been on the register for 15 years. It is settled law that in the case of old patents there is a kind of presumption of validity in the form of the continuance and perpetuity arises unless controverted with the strong evidence to the contrary.

There has been no pre-grant or post-grant opposition or a revocation that has been

filed against IN 203937.

83. This Court in Strix Limited v. Maharaja Appliances Limited [MANU/DE/2174/2009 : MIPR 2010(1) 0181] has held that:

> "22. ..... In order to raise a credible challenge to the validity of a patent, even at an interlocutory stage, the Defendant will have to place on record some acceptable scientific material, supported or explained by the evidence of an expert, that the Plaintiff's patent is prima facie vulnerable to revocation. The burden on the Defendant here is greater on account of the fact that there was no opposition, pre-grant or post-grant, to the Plaintiff's patent."

84. The Division Bench of this Court in the case of Telemecanique & Controls (I) Limited v. Schneider Electric Industries SA, MANU/DE/1264/2001 : 2002 (24) PTC 632 (Del) (DB), in paras 28, 30 and 31 held as under :

> "28. A further aspect which has to be analysed arose from the subsequent application filed by the appellant IA 6504/2000 alleging that the patents of the respondent had not been worked and since they were not being commercially exploited, no injunction could be granted in favor of the respondent. This plea is sought to be again forcefully contended before us by counsel for the appellant. The Division Bench judgment of this court in Franz Cavern Huemer v. New Yash Engineers MANU/DE/0015/1997 : 1996 PTC (16) 232 has been considered by the learned Single Judge. There can be no doubt about the proposition that since the patents create a monopoly, they must be commercially exploited and the parties are not to only register a patent and sit tight over it. However, Mr. Rohatgi, learned senior counsel for the respondent sought to rely on the statement of working of patents filed in the year 1998-99 to contend that the patents are being exploited and thus the present case would not fall within the parameters laid down in Franz Xaver's case (supra) to categories the patents in the present case as one which are not commercially exploited and thus leading to a conclusion that public was being denied the benefit of such patents by its lack of user. The learned Single Judge accepting this contention concluded that he was not satisfied at this stage that the five patents are not being worked by the respondent in view of the statement produced by the respondent for the year 1998-99.
>
> **30.** It has to be appreciated that undoubtedly patent creates a statutory monopoly protecting the patentee against any unlicensed user of the patented device. Thus once a violation is established in case of a registered patent, subject of course, to the patent being used, it will not be permissible to contend that the said patentee is not entitled to an injunction. A monopoly of the patent is the reward of the inventor. It is also to be appreciated that law of the patent is slightly different from the law of copyright and trademark as the patent is granted only for a period of 14 years. It is also relevant to note that in the agreement of technical services dated 28.11.94 there is no mandate for the appellant to provide technical information to the appellant in respect of the manufacture of any other items but the only requirement is that the same can be done if terms and conditions are agreed upon between the parties. If the respondent would have provided D2 range of products to the appellant it would have been entitled to royalty in terms of Clause 6.4 of the said agreement. It is thus difficult to believe, as stated above, that there could be a license to copy and that is a major factor which has weighed with us in deciding the present appeal. It may also be added that Section 83 of the Patent Act, 1970 falls under Chapter XVI dealing with the working of

patents, compulsory licenses, licenses of right and revocation. Section 83 by its wording refers to the exercise of powers conferred by the said Chapter and thus in view of their being exploitation of the patent in the country by sale of product by the respondent, the public is getting the product and is not deprived of its benefit.

31. We would also like to note that while making submissions in rejoinder Mr. Arun Kathpalia, learned counsel for the appellant, sought to make submissions that in view of Section 83 read with Section 90(d) of the Patents Act, 1970 the patent has to be worked out in India by manufacture and not by import. Mr. Kathpalia sought to rely on the commentary of Terrel on the Law of Patent, 13th edition chapter X para 10.07, 10.09, 10.10, 10.13, 10.14 and 10.17. Mr. Kathpalia submitted that same principles would apply in respect of the Indian law and thus in the absence of definition of commercial scale, natural and ordinary meaning should be given to the expression. He submitted that in terms of the said treaties the general principles set out are that a patentee must manufacture the product in that country and it should not also be mere improvements. We have, however, considered this aspect aforesaid and have come to the conclusion that there is no force in the submission of the appellant."

Quia Timet Action

85. As far as law with regard to Quia Timet Action is concerned, it is settled law that such action is maintainable. If a party fears or apprehends, who may obtain injunction to prevent some threatened act being done which if done, would cause him substantial damage and which money would not be an adequate or sufficient remedy. In a quia timet action, in the absence of evidence if a strong case is made out against the defendants, after valid justification, the interim order may be passed by the Court. Reliance is placed on the following decisions:--

"i) Kuldip Singh versus Subhash Chander Jain & Ors., MANU/SC/0206/2000 : AIR 2000 SC 1410

> "A qui timet action is a bill in equity. It is an action preventive in nature and a specie of precautionary justice intended to prevent apprehended wrong or anticipated mischief and not to undo a wrong or mischief when it has already been done. In such an action the Court, if convinced, may interfere by appointment of receiver or by directing security to be furnished or by issuing an injunction or any other remedial process " (Para 7)

ii) Rohtas Industries Limited v. I.H.P. Co. Ltd., MANU/BH/0169/1954 : AIR 1954 PATNA 492

> "Even proof of an intention to infringe, apart from actual infringement, may justify an injunction to restrain the infringement provided it is established to the satisfaction of the court that the alleged infringer, dealing with what he is doing as a matter of substance, is taking the invention claimed by the patent." (Para 16)

86. Therefore, the suit for quia timet action is maintainable. No further discussions are necessary on this issue.

87. It was observed in the judgment of Roche v. Cipla (supra) cited by the defendants, that the plaintiffs failed to establish prima facie case of infringement and

on the contrary, defendant successfully raised credible challenge to the validity of the patent and the Courts have accepted the plea of the defendants in that case on the basis of defence raised. However, such circumstances are missing in the present case.

88. Prima facie, it appears that the plaintiffs have got the valid patent and the defences raised by the defendants do not enable the court to find out any apparent concerns which can doubt the validity of the patent but are those which require more fact finding and substantiation prior to arriving to any such contrary view. In such event, the plaintiffs have a prima facie case of the valid patent and the alleged apprehension of the infringement where the defendants have already taken the preparatory steps towards the manufacturing of the products by obtaining the license etc.

Irreparable Harm

89. The defendants have not launched the product in the market, no loss or irreparable harm will be caused to BDR if they are restrained from doing activities that they have not yet commenced. On the other hand, grave prejudice will be caused to the plaintiffs if the defendants are allowed to manufacture and market generic Dasatinib in which the patentee has the exclusive rights in IN 203937 under Section 48(a) of the Patents Act, 1970 especially at the time when the defences raised by the defendants are prima facie less credible and does not warrant any alteration of the already existing status quo in the form of the interim injunction.

90. There are cases pending against three other generic companies which have been filed by the plaintiffs for the infringement of IN 203937. Injunctions are operating in two matters.

91. Even otherwise, where the Central Government is of the opinion that a patent granted, which is exercised, is mischievous to the State or generally prejudicial to the public after giving the notice to the patentee, make a declaration under Section 66 of the Patents Act, 1970 to the effect that the patent shall be deemed to be removed. In the present case, no doubt, the defendants have taken the plea of non-availability of product to all patents in India, as the product in question is of first line product which is highly expensive and the issue of public interest. The grounds which are available for the person interested while seeking an application for the compulsory licensing or revocation of the patent on the ground of non working of the patent could be urged before the relevant authority which will consider the matter and cannot be imported as a matter of defence to the suit for infringement as the civil court hearing the suit for infringement cannot transgress within the domain of the authority/controller/Central Government which are distinct functionaries having their powers and considerations specifically defined under the specific provisions of the Act. Even under the World Trade Organization Trip Agreement, Compulsory Licenses are recognized in order to overcome barriers in accessing affordable medicines and on other ground of non-workable of suit patent as per conditions prescribed under Sections 83 and 84 of the Act.

92. Hence, if the patent is valid and the defendant has not been able to establish prima-facie credible defence, the case of infringement is made out. Under the said circumstances, public interest is an exception to the patent, otherwise the rights granted under Section 48 by the Sovereign towards monopoly would be undermined. The plea of public interest may be invoked once the Court would find that prima-facie the case of credible defence is made out. In the present case, the defendants have not made any representation to the Central Government by raising the plea of public

interest, expensive drug and fully non-availability of the drug in question to the patients, nor has the Government exercised its discretion under Section 66 of the Act.

93. The ad-interim injunction has been operating against the defendants since 4th December 2009. It is an admitted position that the defendants have not yet launched the generic version of Dasatinib commercially in the market. No application for vacation has been filed by the defendants for the last more than five years. No request was made by the defendants to the Court during this period to know their interest or intent to launch the product. Proxy war in the Court at this stage cannot be permitted to allow. The conduct of the parties is obviously paramount. Thus, the balance of convenience tilts in favour of the plaintiffs otherwise.

94. The object of the injunction in patent matters is to protect the patentee against the injury by violation of right for which he could not be adequately compensated in damages recoverable in the action if ultimately a decree for damages is passed. There is no rule in the patent matters that a plaintiff must make out a prima-facie case. No doubt, the Court must be satisfied that the claim(s) is not frivolous or vexatious. An interim injunction may be granted if the defendant has applied for a compulsory licence but he infringes the patent. The interim injunction may also be passed in respect of single claim which is valid even though other claims in the specific actions are not prima facie valid.

95. The patent law in India is governed by Patents Act, 1970 as amended in the year 2005. What constitutes infringement of a patent is not denied in the Act. Thus, one has to gather the meaning of infringement from the scope of the monopoly rights conferred on the patentee for infringement is the violation of those rights. Section 48 confers on the patentee, his agents and licensees the exclusive rights to make, use, exercise or distribute invention in India. The rights of the patentee are infringed if anyone makes and supplies or commercially uses and the patentee may be granted interim order, subject to the condition if the patent is valid. It is not incumbent upon the plaintiff in case of infringement to show that the plaintiff has suffered commercial loss.

96. In the present case, as per the conduct of the defendants, prima-facie no credible challenge has been made, rather they have admitted infringement in their pleadings. The defendants in both the matters are connected with others, hence it is immaterial if two companies are different entity. Their main intent is to manufacture and sell the product in question.

97. In view of the above said reasons if defendants would be allowed to commence the infringement in full knowledge of the patentee invention, the plaintiffs would suffer injury and irreparable harm.

98. On the balance of convenience in a quia timet action the House of Lords, in American Cyanamid Company v. Ethicon Limited [1975 FSR (1) 101], held that:

> "Where other factors appear to be evenly balanced it is a counsel of prudence to take such measures as are calculated to preserve the status quo. If the defendant is enjoined temporarily from doing something that he has not done before, the only effect of the interlocutory injunction in the event of his succeeding at the trial is to postpone the date at which he is able to embark upon a course of action which he has not previously found it necessary to undertake; whereas to interrupt him in the conduct of an established enterprise would cause much greater inconvenience to him since he would have to start again to establish it in the event of his succeeding at the trial."

A similar approach has been taken by the Supreme Court in India in the cases of Wander Ltd. & Anr. V. Antox India P. Ltd. [MANU/SC/0595/1990 : (1990) Supp.SCC 727] and Colgate Palmolive (India) Ltd. v. Hindustan Lever Ltd. [MANU/SC/0494/1999 : (1999) 7 SCC 1].

99. For the aforesaid reasons and in view of the facts and circumstances, the interim order passed on 4th December, 2009 in CS(OS) No. 2303 of 2009 shall continue during the trial and the same shall also apply to the parties in CS(OS) No. 679 of 2013. The prayers in both the applications are allowed by disposing of I.A. Nos. 15720/2009 and 5910/2013.

100. However, it is made clear that the defendants no doubt are at liberty to move the fresh application for compulsory license with the Controller of Patents or voluntary license with the plaintiffs as per law as the defendants earlier application was rejected due to non compliance but the liberty granted to the defendants does not tantamount to allow or disallow such application(s) as the defendants have to comply with the due process. Such petition(s)/application(s) cannot be decided as per demand or as per defendants' whims and fancy. The same has to be considered on merit and if so filed it would be decided without any influence of the order passed in these applications. Even otherwise, the findings are tentative and shall have no bearing when the suit would be finally decided by the Court after recording the evidence.