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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

+ **CS(COMM) 197/2016**

% ***Judgment dated 18th October, 2016***

BRISTOL MYERS SQUIBB HOLDINGS

IRELAND & ANR

..... Plaintiffs

Through : Mr.Praveen Anand, Mr.Nischal Anand
and Mr.Aman Taneja, Advs.

versus

SANJAY JAIN & ANR

..... Defendants

Through

CORAM:

HON'BLE MR. JUSTICE G.S.SISTANI

G.S.SISTANI, J (ORAL)

1. Plaintiffs have filed the present suit for permanent injunction restraining the infringement of their patent registered under no. 203937, delivery up, damages etc. against the defendants.
2. Learned counsel for the plaintiff submits that summons in the suit and notice in the application for stay were directed to be issued vide order dated 8.10.2015, when an *ex parte ad interim injunction* was passed in favour of the plaintiffs and against the defendants. Counsel further submits that in the order dated 14.3.2016, the learned Joint Registrar had noticed that the defendants have been duly served, however, since the written statement was not filed, their right to file the same was closed. Since none was present on behalf of the defendants even on 9.5.2016, they were proceeded *ex parte*. Counsel contends that having regard to the fact that neither any appearance has been entered by the defendants nor have they filed any written statement and in fact they

were proceeded *ex parte* vide order dated 9.5.2016, the present suit be decreed under the provisions of Order VIII Rule 10 CPC in favour of the plaintiff and against the defendants. The plaintiffs have also filed the *ex parte* evidence of one, Mr.Jitender Tyagi, PW-1.

3. The brief facts of the case are that the Plaintiff No.1, Bristol-Myers Squibb Holdings Ireland is an unlimited liability company incorporated in Ireland with company registration number 360880, with its head office at Hinterbergstrasse 16, 6312 Steinhausen, Switzerland.
4. 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
5. As per plaint, plaintiffs are the subsidiaries of Bristol-Myers Squibb Co., which was 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 & John Ripley Myers and Squibb Corporation founded by Edward Robinson Squibb in 1858.
6. Bristol-Myers Squibb Co. along with its subsidiaries (hereinafter “BMS group”) is a leading bio-pharmaceutical company dedicated to discovering, developing and delivering innovative medicines that help patients prevail over serious diseases. The BMS group has a strong presence in various therapeutic areas including cancer, cardiovascular disease, hepatitis, HIV/AIDS, and rheumatoid arthritis.
7. As per the plaint, plaintiff No. 1 is the exclusive owner of DASATINIB and its pharmaceutically acceptable salts, solvates, isomers and prodrugs which are covered by the claims of IN 203937 in India, which is valid and subsisting. Plaintiffs enjoy patent protection for DASATINIB in over 30 other countries including the United States

of America, Australia, New Zealand, Japan, etc. Plaintiff no. 1 is stated to have acquired ownership of IN 203937 by virtue of a Deed of Assignment in its favour by Bristol-Myers Squibb Co. and the said Assignment has been duly recorded on the Register of Patents by the Indian Patent Office. The details of the registration of IN 203937 are as follows:-

Patent application number	IN/PCT/2001/1138/MUM
Patent Title	A COMPOUND 2-AMINO-THIAZOLE-5-CARBOXAMIDE
Date of filing in India	September 19, 2001
International application No.	PTC/US00/09753
International filing date	April 12, 2000
Date of priority	April 15, 1999
Section 11A publication	March 4, 2005
Date of grant	November 16, 2006
Notification of grant under Section 43 Patent Act	May 18, 2007

8. According to the plaintiffs, DASATINIB, which is the International Non-proprietary Name (INN) 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) and also for treating patients 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. Recently, DASATINIB has also been approved as a first line treatment for CML.

9. As per complaint, Chronic Myeloid Leukemia (CML) is a form of leukemia which 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.
10. The plaintiffs' 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.
11. 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.
12. As per the complaint, 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-ymidinyl]amino]-5-

thiazolecarboxamide) is covered by claims 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 on pages 155-157 of the patent specification. IN 203937 is stated to have valid and subsisting on the register for over 15 years and is therefore an “established patent.” Further it is averred that there is no challenge to the validity of the said patent in the form of a pre-grant opposition (pursuant to the Section 11A publication made on 4th March 2005), post grant opposition (pursuant to the publication under Section 43(2) on 18th May 2007) or in a revocation proceedings before the Intellectual Property Appellate Board (IPAB).

13. 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. 6567/DELNP/2014 as and when granted.
14. As per the plaintiffs, DASATINIB was approved by the US Food and Drug Administration on 28th June, 2006, and 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”) on August 30, 2006, in favour of plaintiff no. 2 and since then plaintiff no. 2 has been marketing DASATINIB under the brand name “SPRYCEL” across India. In order to make SPRYCEL[®] more accessible and available to patients across India, the plaintiffs have incurred huge amounts, details of which have been extracted in para 18 of the plaint. Having regard to their social responsibility, the plaintiffs have actively participated in various programs and during the past five years, BMS group has donated nearly \$260 million of medical products, valued at wholesale, to support partner programs throughout the world.

15. It has also been averred that the Sprycel Access Program is made available through a third party service provider for the self-paying patients prescribed DASATINIB by an oncologist. This program 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 plaintiffs’ third party 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.
16. The plaintiffs are stated to have received tremendous appreciation from both patients and doctors for their Patient Access Program. Copies of letters in this regard have been filed in the present proceedings. The plaintiffs also remain committed to working closely with governments, charitable organizations, NGOs and others to help patients who face access barriers to medicines and health care. In the past, the plaintiffs

have been active in taking action against the parties, who had intended to infringe upon the patent of the plaintiffs.

17. It is averred in the plaint that the defendant No.1 is a Chief Executive Officer(CEO) of the defendant No.2 and the proprietor of M/s Cyno Medicaments. The defendant No.2, Cyno Pharmaceutical Limited, is a public limited company incorporated under the Companies Act.
18. According to the plaintiffs, as per the information available on defendants' websites <http://cyno.net.in/> and <http://www.cynoindia.com/en/>, the defendants are involved in the field of manufacturing, selling and offering for sale various generic pharmaceutical products including oncology products.
19. It is averred in the plaint that on 3rd October, 2015, the Plaintiffs learnt that the defendants may launch a generic version of DASATINIB in complete disregard of the plaintiffs' existing and valid patent. Upon further inquiries, the plaintiff got to know that the defendants are planning to launch a generic version of DASATINIB under the brand name DASACY.
20. The plaintiffs contend that the defendants have already approached the distribution network with test batches however the product had not been commercially launched. The defendants are planning to launch the product within one or two weeks and are already accepting advance orders.
21. It is alleged that the defendants have collectively taken a policy decision to infringe the Plaintiff's Indian Patent No. 203937 by using, manufacturing, selling, exporting, advertising and/or offering for sale the generic version of DASATINIB.
22. The defendants are targeting customers, consumers, hospitals, clinics, patients, doctors and other medical practitioners across India including

in New Delhi and, thus, they are causing immense harm and damage to the plaintiffs.

23. I have heard learned counsel for the plaintiffs and examined the plaint, documents placed on record and also the affidavits by way of evidence of PW-1, who has deposed on the lines of the plaint. The documents exhibited are as follows:

- Power of Attorney dated 1 September, 2015 issued by the plaintiff has been exhibited as Exhibit PW-1/1;
- Board Resolution dated 7th July 2014 passed by the plaintiff No.2 has been exhibited as Exhibit PW-1/2;
- Copy of patent certificate issued for Indian Patent No.203937 has been exhibited as Exhibit PW-1/3;
- Specification and claims of Indian Patent No.203937 has been exhibited as Exhibit PW-1/4;
- Patent office Journal dated 18/05/2007 has been exhibited as Exhibit PW-1/5;
- Deed of assignment in favour of Plaintiff No.1 has been exhibited as Exhibit PW-1/6;
- E-register of patent for Indian Patent No. 203937 has been exhibited as Exhibit PW-1/7;
- Extracts from WHO Drug Information has been exhibited as Exhibit PW-1/8;
- Copy of product insert for the plaintiffs patented product Sprycel has been exhibited as Exhibit PW-1/9;
- Marketing approval for Sprycel issued by the DCGI has been exhibited as Exhibit PW-1/10;
- Form 27 for the years 2008 to 2015 filed in the patent office to show sales has been exhibited as Exhibit PW-1/11(colly);

- Promotional material for BMS's PAP has been exhibited as Exhibit PW-1/12(colly);
 - Declaration for the PAP has been exhibited as Exhibit PW-1/13;
 - Letters of appreciation from patients and doctors has been exhibited as Exhibit PW-1/14(colly);
 - Orders restraining infringement of IN 203937 has been exhibited as Exhibit PW-1/15(colly);
 - Photograph of the product DASACY has been exhibited as Exhibit PW-1/16;
 - Printouts from the Defendants website www.Cyno.net.in has been exhibited as Exhibit PW-1/17;
 - Printouts from the Defendant's website has been exhibited as Exhibit PW-1/18;
 - LinkedIn profile of Sanjay Jain has been exhibited as Exhibit PW-1/19;
 - Reports of the defendant nefarious activities has been exhibited as Exhibit PW-1/20;
24. The plaintiffs have filed the present suit on the basis of the threat or apprehension that the actions of the defendants are likely to cause prejudice to the plaintiff. They have apprehension that the defendants are going to launch the generic product which would infringe the IN 203937 and they may violate the exclusive rights of the plaintiffs granted under Section 48 of the Indian Patents Act, 1970. Therefore, the present suit is the nature of a *quia timet* action against the defendants for the infringement of their patent IN 203937.
25. With regard to a *quia timet* action, the Supreme Court in the case of ***Kuldip Singh v. Subhash Chander Jain*, (2004) 4 SCC 50** has held:

“7. 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.”

26. As per Section 48 of the Patents Act, 1970 plaintiffs have 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.
27. Since the averments of the plaint are uncontroverted, I have no reason but to believe that the defendants, with a dishonest intention knowing plaintiffs' existing and valid patent, they were launching their own product under the brand name 'DASACY' containing the patented salt 'DASATINIB' and have also obtained manufacturing licenses for their drug from the relevant government authorities. The defendants activities of launching test batches of the infringing product at the distributor level thereby encouraging third parties to infringe the plaintiffs exclusive right.
28. Thus, accordingly, the plaintiffs have made out a case for sustaining the present *quia timet* action as the aforementioned acts of the defendants clearly establish their intention to infringe the patent of the plaintiffs in the patented salt 'DASATINIB'.

Punitive damages

29. With regard to the relief of damages as claimed by the plaintiffs in para 46 (c) of the plaint, the plaintiffs relied in ***Time Incorporated v. Lokesh Srivastava & Anr.*, 2005 (30) PTC 3 (Del): 2005 (116) DLT 599**, while awarding punitive damages of Rs. 5 lakhs in addition to

compensatory damages also of Rs. 5 lakhs, Justice R.C. Chopra observed as under:

“8. This Court has no hesitation on saying that the time has come when the Courts dealing actions for infringement of trade marks, copy rights, patents etc. should not only grant compensatory damages but award punitive damages also with a view to discourage and dishearten law-breakers who indulge in violations with impunity out of lust for money so that they realise that in case they are caught, they would be liable not only to reimburse the aggrieved party but would be liable to pay punitive damages also, which may spell financial disaster for them. In Mathias v. Accor Economy Lodging Inc., 347 F.3d 672 (7th Cir. 2003) the factors underlying the grant of punitive damages were discussed and it was observed that one function of punitive damages is to relieve the pressure on an overloaded system of criminal justice by providing a civil alternative to criminal prosecution of minor crimes. It was further observed that the award of punitive damages serves the additional purpose of limiting the defendant's ability to profit from its fraud by escaping detection and prosecution. If a torfeasor is caught only half the time he commits torts, then when he is caught he should be punished twice as heavily in order to make up for the times he gets away. This Court feels that this approach is necessitated further for the reason that it is very difficult for a plaintiff to give proof of actual damages suffered by him as the defendants who indulge in such activities never maintain proper accounts of their transactions since they know that the same are objectionable and unlawful. In the present case, the claim of punitive damages is of Rs. 5 lacs only which can be safely awarded. Had it been higher even, this Court would not have hesitated in awarding the same. This Court is of the view that the punitive damages should be really punitive and not flea bite and quantum thereof should depend upon the flagrancy of infringement.”

(Emphasis Supplied)

30. This Court in the case of **Microsoft Corporation v. Rajendra Pawar & Anr.**, reported at 2008 (36) PTC 697 (Del.), has held:

“22. Perhaps it has now become a trend of sorts, especially in matters pertaining to passing off, for the defending party to evade Court proceedings in a systematic attempt to jettison the relief

sought by the Plaintiff. Such flagrancy of the Defendant's conduct is strictly deprecatory, and those who recklessly indulge in such shenanigans must do so at their peril, for it is now an inherited wisdom that evasion of Court proceedings does not de facto tantamount to escape from liability. Judicial Process has its own way of bringing to task such erring parties whilst at the same time ensuring that the aggrieved party who has knocked the doors of the Court in anticipation of justice is afforded with adequate relief, both in law and in equity. It is here that the concept of awarding punitive damages comes into perspective.

23. Punitive damages are a manifestation of equitable relief granted to an aggrieved party, which, owing to its inability to prove actual damages, etc., could not be adequately compensated by the Court. Theoretically as well as practically, the practice of awarding of punitive damages may be rationalized as preventing under-compensation of the aggrieved party, allowing redress for undetectable torts and taking some strain away from the criminal justice system. Where the conduct of the erring party is found to be egregiously invidious and calculated to mint profits for his own self, awarding punitive damages prevents the erring party from taking advantage of its own wrong by escaping prosecution or detection.”

(Emphasis Supplied)

31. This Court in the case of *The Heels v. Mr. V.K Abrol and Anr.*, CS(OS) NO.1385 of 2005 decided on 29.03.2006 has held:

“11. This court has taken a view that where a defendant deliberately stays away from the proceedings with the result that an enquiry into the accounts of the defendant for determination of damages cannot take place, the plaintiff cannot be deprived of the claim for damages as that would amount to a premium on the conduct of such defendant. The result would be that parties who appear before the court and contest the matter would be liable to damages while the parties who choose to stay away from the court after having infringed the right of the plaintiff, would go scotfree. This position cannot be acceptable.

12. No doubt it is not possible to give an exact figure of damages on the basis of actual loss, but certain token amounts on the basis of the sales of the plaintiff can certainly be made. The plaintiff is unnecessarily dragged into litigation and the defendants must bear consequences thereof. In fact in such a case both

compensatory and punitive damages ought to be granted apart from the costs incurred by the plaintiff on such litigation. In view of the given sales figure of the plaintiff, I consider it appropriate to grant a decree of damages in favor of the plaintiff and against the defendants for a sum of Rs 3 lakh apart from costs of the suit.”

32. In view of the facts of the present case, Rs. 2 lakhs as punitive damages be granted in favour of the plaintiff and against the defendant in terms of para 46(c) of the plaint.
33. The present suit is decreed in terms of the paragraphs 46 (a) and (b) of the plaint with damages of Rs. 2 lakhs.
34. Let a decree sheet be drawn accordingly.

OCTOBER 17, 2016

//msr

G.S.SISTANI, J

