HON'BLE SRI JUSTICE A.RAJASHEKER REDDY

C.M.A.No.879 of 2014

JUDGMENT:

This Civil Miscellaneous Appeal is filed against order dated 26.09.2014 passed in I.A.No.1462 of 2014 in O.S.No.670 of 2014, whereby and whereunder, the Court below dismissed the petition under Order 39 Rules 1 and 2 read with 151 CPC filed by the appellant against the respondent seeking ad-interim order against the respondent/defendant, its directors, employees, officers, servants, agents and others acting for its behalf or from using, selling, advertising, exporting, offering for sale and in any other manner directly or indirectly, dealing in any product that is intended for export to Venezuela or in any other way goes beyond the scope of the agreement dated 17.04.2011 and thereby infringes the subject matter of Indian Patent Nos.210496 and 206217.

2. Facts which are necessary for disposal of this appeal are as under:

Appellant filed O.S.No.670 of 2014 stating that the Bristol-Myers Squibb Holdings Ireland, (for short 'BMS') is a company incorporated under the laws of Ireland having its office at Switzerland. BMS has assigned, transferred and conveyed to the appellant herein its rights and interests in the suit patents by virtue of a Deed of Assignment dated 01.10.2012. Upon filing of Form-16 for recording of the title of the appellant to the suit patents on 07.11.2013, the change in

title of the Patentee of the suit patents has been recorded in the Patent Register by the Indian Patent Office. It is stated that BMS entities have been actively engaged in research and development of Atazanavir, which contains formulation, the processes for preparation of the same and also intermediates used in the preparation of Atazanavir and also the processes for the preparation of the intermediates. Atazanavir is an antiretroviral drug developed by the BMS entities to treat Human Immunodeficiency Virus (HIV), which causes AIDS. The BMS company sells Atazanavir under the brand name Reyataz(R). It is stated that the Atazanavir was approved by the United States Food and Drug Administration on 20.06.2003 and has been approved in approximately 57 countries throughout the world and also included in the list of World Health Organization's list of Essential Medicines. The Atazanavir includes Indian Patent Nos.210496 and 206217 granted by the Indian Patent Office.

3. It is stated that the respondent company, formerly known as Matrix Laboratories Limited, is a registered company under the Companies Act, 1956 in the year 1984, has been rebranded under its present name viz., Mylan Laboratories Ltd., in October, 2011. The respondent was granted immunity against suits for infringement of the appellant's intellectual property *inter alia* IN '496 and IN '217 vide Agreement dated 17.04.2011. It is stated that as per the Appendix 'C' of the Agreement, the territories include 43 countries and submitted that the respondent got immunity in

respect of countries under Schedule-C and denied the immunity particularly export to Venezuela and alleged that the respondent is violating the patent rights of the appellant in respect of export to the Venezuela. The respondent entered into an agreement with the Pan American Health Organization (PAHO) for the purpose of sale and distribution in Venezuela and that PAHO placed purchase order dated 09.06.2014 worth Rs.4.5 cores, in favour of the respondent and the delivery was expected to be made by 28.08.2014. It is stated that the respondent is using the process identified in IN '496 and IN '217 for the manufacture of general Atazanavir and not disclosed an alternative proprietary process or an improved process for the manufacture of the same to the BMS Entities, as per Article 18 of the Agreement. Therefore, the respondent infringed and further intends to infringe the rights of the appellant in IN '496 and IN '217, by manufacturing and supplying generic Atazanavir for the purpose of sale in Venezuela and prayed for granting of permanent injunction on the ground that the petitioner has suffered damages to a tune of Rs.90 crores due to infringement by the respondent, the potential causing loss of at least Rs.180 Crores and also loss of goodwill and reputation.

4. Respondent filed counter affidavit before the Court below denying the averments of the affidavit filed in support of the interlocutory application stating that it is a company having 7 plants in Telangana State alone and total 24 work locations

including plant, research and offices across India and manufacturers of several pharmaceutical products including Atazanavir Sulphate Capsules for supply across the world and contributes significantly both in terms of corporate social responsibility initiatives as well as in taxes, both Central and State Taxes to India. It is stated that the documents filed by the appellant regarding the assignment is inadmissible in evidence and denied the validity of the assignment. The appellant is not entitled to any right to sue against the respondent as per agreement dated 17.04.2011 and that the appellant has not filed any document to show the violation of the patent rights of the appellant by the respondent. It is stated that since the appeal is pending before the United States Court of Appeal, this Court cannot entertain this appeal. It is stated the suit patents IN '496 and IN 217 do not relate to Atazanavir Sulphate and the claim regarding IN '496 will show that it relates to process for preparation of alpho-chloroketones. It is stated that Atazanavir sulphate is not an alpha-Chloroketone and that the patents are immaterial and irrelevant to the impugned actions of the respondent in exporting Atazanavir Sulphate to Venezuela. It is stated that IN '217 relate to a process for preparation of substituted oxobutane through an enzymatic process and that Atazanavir Sulphate is not a substituted oxobutane and the suit patent is immaterial and irrelevant to the impugned action of the respondent in exporting Atazanavir Sulphate product to Venezuela in compliance with contractual obligations undertaken with the International Body i.e.,PAHO/WHO. It is

stated that the practice of the process of IN '217 is apparently useful as precursor compounds in a further process for preparation of an intermediate. On process of IN '217 is apparently converted to another epoxide which is also not Atazanavir Sulphate. It is stated that the epoxide may be further reacted with other material to form Atazanavir Sulphate and the petitioner stated that a patent allegedly relating to a process for preparing a precursor of an intermediate for Atazanavir Sulphate cannot be infringed by the export of Atazanavir Sulphate final product. Therefore, the suit is not maintainable and that the petitioner is not entitled to any interim relief on the ground of absence of cause of action and also contended that the suit is undervalued. It is stated that the appellant's patents are not working in India and that working of a patent is very essential and that the appellant is not entitled for any relief, much less interim relief.

5. Rejoinder is filed by the appellant to the counter affidavit filed by the respondent denying the averments in the counter affidavit stating that the entire burden is on the respondent, as the appellant has discharged the burden in respect of patent suit obtained for the last 14 years and that there is no pre-grant or post-grant opposition against the suit patents under Sections 25(1) and 25(2) of the Patents Act, 1970 (for short 'the Act of 1970') and also no revocation proceedings under Section 64 of the Act of 1970 are pending.

6. When the matter is taken up, both the Senior Counsels Sri D.Prakash Reddy and Sri S.Ravi insisted for disposal of

main CMA stating that arguments in interlocutory application as well as in the main CMA are one and the same.

7. Sri D.Prakash Reddy, learned Senior Counsel appearing for the appellant submits that the trial Court dismissed the interim injunction application solely basing on the decision of the Madras High Court in **FDC Limited & Others v. Sanjeev Khandelwal Ors**[1], wherein the above stated decision was in the context of laying down guidelines for granting *ex parte* interim injunctions in patent infringements suits and the principles laid down in the said judgment are not applicable to the facts of this case, since the impugned order is passed after hearing both sides. He further submits that the trial Court, without going into the merits of the matter, came to the conclusion that there is no *prima facie* material and according to Section 104-A of the Act of 1970, the burden of proof in case of suits concerning infringement lies on the respondent, as the respondent has to prove that the process used by him to obtain the product, identical to the product of the patented process is different from the patented process, since respondent admitted that product manufactured by it i.e., Atazanavir is identical to the product obtained by the patented process.

8. He further submits that the respondent despite being given several opportunities, including during arguments in the present appeal, has failed to provide any explanation as to how its process or its supplier's processes to manufacture the intermediates used in Atazanavir are different from the

patented processes. The respondent has failed to disclose the name of its purported supplier, thereby denying the appellant an opportunity to make any 'reasonable efforts' to determine the processes followed by the respondent or its supplier. He further contends that the respondent is using the patented process for manufacture of the product for sale in 49 countries for which it has entered into Immunity by Suit Agreement and it is unbelievable that an altogether different process is used by respondent for the manufacture of the same product for sale in Venezuela. He further contends that the only inference that can be drawn from the respondent's reluctance to divulge any information, they are indeed using the patented processes for the manufacture of the intermediates in question. In support of his contention, he relied on the judgment reported in **Merck Sharp Dohme v. Teva Pharma B.V and another**[2]. He further contends that the only obligation of the patentee under Section 104-A of the Act of 1970 is to *prima facie* prove that the product used by the respondent is identical to the product manufactured by the patented process and that the appellant has proved the same, since the respondent has admitted that the intermediates in question i.e., Chloroketones and Oxobutanes are used and are integral in the manufacture of the end product i.e., Atazanavir, which cannot be manufactured without the use of Chloroketones and Oxobutanes. He further submits that the respondent entered into the immunity from Suit Agreement dated 17.04.2011 with

the appellant, wherein they sought permission to use the suit patents for the manufacture of Atazanavir and that if the respondent did not want to manufacture Atazanavir using the intermediates in question, there was no need of entering into the Agreement covering the suit patents. He further submits that the correspondence between the respondent's representatives and the appellant would clearly show the respondent had absorbed the technology of manufacturing Atazanavir while it was a sub-licensee and had requested the appellant for separate license for the manufacture and marketing of the same. He further submits that the respondent was well aware that the suit patents are part of this technology and hence were subsequently included in the immunity from Suit Agreement. He further submits that the respondent did not deny that it sought the appellant permission to export generic Atazanavir to Venezuela in addition to the 49 countries covered in Appendix-C of the agreement. He further submits that if the intermediates covered by the suit patents are not being used for the manufacture of Atazanavir there is no need for the respondent to seek the appellant's permission. In support of his contention he relied on the Judgment of Bombay High Court in **Fabwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning a Corporation etc v. Unichem Laboratories and others**[3]**.**

9. He further contends that the appellant cannot make efforts to gain access to the respondent's factory premises to

obtain a sample of the intermediates or in the absence of the respondent disclosing any information, purchase it from the respondent's so called supplier. He further contends that the appellant has established a *prima facie* case for infringement of the suit patents without a challenge to the validity of the suit patents and hence the respondent's reliance on **F.Hoffman-La Roche Ltd. & Anr. v. Cipla Ltd.**[4]**; Natural Remedies Pvt. Ltd. v. Indian Herbs Research & Supply Co. Ltd.; Vringo Infrastructure Inc. v. Indiamart Intermesh Ltd.; and Franz Xaver Huemer v. New Yash Engineers** regarding burden of proof, irreparable harm and balance of convenience is of no use.

In all the cited cases, the defendants therein had raised a credible challenge to the validity of the patents in question and hence an injunction was refused. In the present case, let alone challenging the validity of the suit patents, the respondent has in fact acknowledged their validity by seeking a licence and subsequently entering into Immunity from Suit Agreement with the appellant. The respondent is, therefore, estopped from challenging validity of the suit patents.

10. He further contends that the appellant has enjoyed the suit patents for 14 years without any dispute. There have been no pre-grant oppositions, post-grant-oppositions or revocation proceedings filed against the patents. The suit patents are therefore *prima facie* valid. He further contends that the respondent has gained business in over 49 countries including in India because of the appellant. The appellant has

not received any royalty for the same. The investment of time, effort and money made in Research & Development and coming up with inventions such as the suit patents cannot be compensated in monetary terms alone. In support of his contention he relied on the Judgment in M/s. **National Research Development Corporation of India v. The Delhi Cloth & General Mills Co. Ltd. And others**[5].

11. He further submits that an infringer should not be allowed to continue infringement solely on the basis of its alleged ability to pay damages. If it is allowed, Section 48 of the Act of 1970 which grants the patentee an exclusive right to practice its patents would be rendered otiose. Damages can become a remedy when there is a credible challenge to the validity of the patent, unlike the present case. Section 108 of the Act of 1970 makes it clear that the remedy in a suit for infringement of patent includes an injunction and damages and hence one cannot be in lieu for another. He further submits that the respondent deliberately participated in the WHO tender 'at risk' knowing full well that the supply of the product to Venezuela will result in the infringement of the suit patents. He further submits that the Courts in India can only look into the aspect of public interest in our country, and that grant of an injunction will not have any harm to the public interest in Venezuela either. The Government of Venezuela has a policy of providing HIV/AIDS treatment including access to Atazanavir to patients in Venezuela for free.

12. He further contends that Atazanavir is patented including

the processes for the manufacture of the intermediates used therein i.e., Chloroketones and Oxobutanes. He further contends that the contention of the respondent that it purchases the intermediates in question from a third party supplier is not correct, as it has not given any details of its suppliers for manufacture of Atazanavir and this shows that the respondent is employing the patented process for the manufacture of the intermediates for which it also requested for a license and entered into an agreement with the appellant. He further contends that though the affidavit of Mr.Ramesh Dandala states that he has assessed the process followed by its supplier, it is clear that the process is in his knowledge but he refuses to disclose the name of the supplier or what is the process followed by its supplier and that if the supplier is indeed manufacturing the intermediates in question, the respondent ought to have filed the affidavit of its supplier and not an affidavit of its employee and that at any rate, the affidavit filed by the employee of the respondent cannot be relied since the same is biased. In support of his contention, he relied on the judgment reported in **M/s.TVS Motor Co. Ltd., v. Bajaj Auto Ltd.,** [6].

13. It is also contended that Section 48(b) of the Act of 1970 is not restricted to the use of the patented process but also includes the use of the product obtained by the patented process which would amount to infringement of the exclusive right of the patentee. In support of his contention, he relied on the judgment reported in **Saccharin Corporation v. Anglo**

Continental Chemical Works & Another[7]. He further argues that the 'Patents and patent applications' in Venezuela have been explicitly described in Appendix A of the Agreement, therefore, the respondent will not be immune from a suit for infringement of the suit patents if it manufactures Atazanavir in India for the purpose of export to Venezuela. He contends that as per Article 3.1.b of the Agreement, apart from the countries mentioned in Appendix C, the respondent will be permitted to export the product to any country where there are no pending patents or patent applications i.e., any country that has not been explicitly mentioned in Appendix A and that Venezuela has been explicitly mentioned in Appendix A. He further contends that the cause of action in the suit filed before the US District Court is not the same cause of action in the present suit, as contented by the respondent, and that the present suit is for infringement of the patents and placed reliance only upon the Agreement to describe the activities of the respondent, which go beyond the scope of agreement, which amounts to infringement of patents. He further argues that the appellant is not trying to enforce the agreement but is merely relying upon it to prove its case for infringement in exercise of its statutory rights provided under the Act. In support of his contention, he relied on the judgment reported in **Mother Dairy Fruits & Vegetables Pvt. Ltd., v. Maa Baisnavi Enterprises & Others**[8]. He further contends that the US District Court has held that the appellant can seek remedies under the relevant patent laws thereby clearly distinguishing

the cause of action in the present case and that the *prima facie* case, balance of convenience are in favour of the appellant and that if injunction is not granted, appellant would suffer irreparable loss.

14. On the other hand, Sri S.Ravi, learned Senior Counsel contends that the appellant does not have the product patent or process patent in India or in Venezuela in respect of Atazanavir, as such, no injunction can be granted against export of Atazanavir. He further contends that the appellant should have sought for injunction against the process restricting the use of process patent but not in respect of Atazanavir. He further submits that the respondent is using the improved process in respect of manufacture of Atazanavir; that the respondent never manufactured intermediates i.e., Chloroketones and Oxobutanes, but they have received supplies from the suppliers and that the respondent has not used the patent process in respect of which petitioner is alleging infringement for manufacturing Atazanavir.

15. He further contends that a patent right is strictly limited to the country where it is granted, which allows the patentee to stop others from making, using, selling, offering for sale or importing the invention in the country that granted the patent.
A process patent is a narrow right, which stops others from making/using etc, only the specific process granted in the process patent to make a product, which means that third parties can use alternative processes to make the product

and that will not be a patent infringement. He further contends that in order to enforce a process patent, the appellant must *prima facie* prove not only ownership, but also *prima facie* that the impugned product is directly obtained by that process, as envisaged under Section 48(b) of the Act of 1970. He further contends that a patent for a process for making a starting material does not afford protection against manufacture of the final product, particularly where there are multiple intermediate products, and multiple discrete chemical processes involved in between. He further contends that the appellant has not discharged their burden of proof as provided under Section 104-A of the Act, which mandates that a patentee claiming protection in respect of a process patent must first show that the impugned product is identical to the product obtained by the patented process and also that it has taken reasonable efforts to determine the process used by the respondent/defendant. He further contends that the appellant has failed to determine the respondent's process through reasonable efforts before instituting suit and relying on reversal of burden of proof onto respondent and that filing of a suit is not a reasonable effort. He further contends that there is an established body of precedent in India wherein several Courts have held that interim injunction in patent matters, particularly in the field of pharmaceuticals must be the exception rather than the rule. The precedents also establish that there is an onerous burden on an appellant in a patent infringement to *prima facie* prove infringement through independent technical affidavit evidence and that the

requirement to file affidavit evidence in support of an averment of infringement is essential to establish a *prima facie* case. In support of his contention he relied on the judgment reported in **FDC Limited, v. Sanjeev Khandelwal (supra)**. He further contends that interim injunction cannot be granted in case of pharmaceutical patents relating to life saving drugs, particularly when the damages are quantifiable. In support of his contention he relied on the judgment reported in **F.Hoffman La Roche v. Cipla, High Court of Delhi (Division Bench) (supra).**

16. He further contends that the respondent had entered into an agreement dated 17.04.2011 with a US company called Bristol Myers Squibb Company (BMS Co.) *inter alia,* providing it immunity from any legal action for any sales in certain territories and not prohibiting Mylan from selling to a jurisdiction where BMS Co. does not have a patent or pending valid patent application and that the scope of the agreement was limited to *inter alia* Atazanavir, and did not include any intermediate or precursor involved in the process of preparation of Atazanavir. He further contends that BMS Co. sued the respondent in the US District Court of New York for breach of contract, wherein the said suit was decided in favour of this respondent stating that BMS Co. failed to establish a claim for breach of contract, despite applying liberal construction of the contract. He further contends that BMS Co. filed an appeal before the United States Court of Appeals for the Second Circuit, wherein the said Appeal was

decided on 07.10.2014, and that the appellate Court not interfered with the finding of the lower Court and that the respondent is entitled to export to Venezuela under the agreement and as such present suit by appellant for relief is not maintainable.

17. Both patents also admit that the products themselves are not new, that there are no patent for the respective products and that both patents relate to and claim only processes. He further contends that the appellant has failed to furnish any affidavit which is required to establish and discharge the burden under Section 104A of the Act of 1970 and that the only evidence relied on by the appellant is an affidavit of Mr.Ulhas Dhokate, who claims to be an Associate Director of BMS Co. of USA and an e-mail purportedly sent by an officer of respondent in 2008 to BMS Co. of USA and both of them show that the product in question referred to is Atazanavir final product and not Chloroketone or substituted oxobutanes.

18. He further contends that the appellant has not at all established *prima facie* case of infringement, irreparable loss to it which cannot be compensated in terms of money and balance of convenience in its favour, which are essential to for grant of an injunction order in a suit for infringement of patent. Both the precursors i.e., Chloroketones and substituted oxobutanes can be prepared by many different processes and that these are alternative starting material for preparing epoxide compounds through separate processes,

but they cannot be used simultaneously. He further contends that mere signing of an agreement with BMS Co. is not evidence of patent infringement and that it is a technical issue which requires scientific proof. There is no iota of evidence to show that any technology protected by the suit patents covering preparation of chloroketone and substituted oxobutane was provided to respondent. The appellant has failed to prove that the respondent is using either of the processes of the two suit patents to prepare the precursors which are then converted into the epoxide intermediate which is then converted into Atazanavir. He further submits that the respondent does not manufacture either the substituted oxobutane or chloroketone by any process and also does not obtain these products from any party and that respondent obtains the epoxide intermediate from a third party. He further contends that Section 48(b) of the Act of 1970 expressly stipulates that a process patent is infringed only if the product is 'directly obtained' by the claimed process. He further contends that the respondent is not using, making, selling or offering for sale either of the precursors or intermediate that are 'directly obtained' by the process of either of the two suit patents. He submits that a non-working entity is not entitled to an interim relief of either injunction or even *status quo*. In support of his contention he relied on the judgment reported in **Franz Xaver Huemer v. New Yash Engineers**[9],. He further contends that if an injunction is granted to the appellant, the respondent would suffer irreparable harm as respondent has invested huge amounts of money in development and

manufacture of Atazanavir and that it will suffer the loss of goodwill and reputation due to failure to meet a contractual obligation. He further contends that an Appellate Court will not interfere with reasoned order passed by a lower court, even if it is of the view that it would have arrived at a different conclusion based on the facts and prayed to dismiss the appeal.

19. In view of the above rival contentions of the parties, the points that arise for consideration in this appeal are:

1) Whether the rights of petitioner in respect of suit patents in Indian Patent No. 210496 and 206217 are violated by respondent? If so,

2) whether petitioner is entitled for injunction?

20. Before discussing the factual aspects, it will be useful to have glance at the relevant provisions of the Act of 1970 for the purpose of disposal of this case.

> **Section 2(m)**: "Patent" means a patent granted under this Act"
>
> **Section 2(ab)**: "assignee" includes an assignee of the assignee and the legal representative of a deceased assignee and references to the assignee of any person include references to the assignee of the legal representative or assignee of that person;

Section 48: **Rights of patentees:**

(a)….

(b) Where the subject matter of the patent is a process the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India".

Section 104-A: Burden of proof in case of suits concerning infringement:

(1) In any suit for infringement of a patent, where the subject matter of patent is a process for obtaining a product, the court may direct the defendant to prove that the process used by him to obtain the product, identical to the product of the patented process, is different from the patented process if,-

(a) the subject matter of the patent is a process for obtaining a new product; or

(b) there is a substantial likelihood that the identical product is made by the process, and the patentee or a person deriving title or interest in the patent from him, has been unable through reasonable efforts to determine the process actually used:

Provided that the patentee or a person deriving title or interest in the patent from him, first proves that the product is identical to the product directly obtained by the patented process.

(2) In considering whether a party has discharged the burden imposed upon him by sub-section (1), the court shall not require him to disclose any manufacturing or commercial secrets, if it appears to the court that it would be unreasonable to do so.

Section 108: **Reliefs in suits for infringement:**

[(1) The reliefs which a court may grant in any suit for infringement include an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the plaintiff either damages or an account of profits].

[(2) The court may also order that the goods which are found to be infringing and materials and implement, the predominant use of which is in the creation of infringing goods shall be seized, forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation].

21. A reading of Section 104-A of the Act of 1970 makes it clear that in a suit for infringement of a process, if the patentee proves that the product of the respondent is identical to the product of the patented process, then the burden of proving that the process used by the respondent in obtaining his product is different from the patented process

lies on the respondent. Therefore, the condition precedent for application of the provisions is that the product of the appellant and respondent should be identical and if the products are not identical, a suit for infringement of a patent of the process would not lie and Section 104-A of the Act of 1970 is not attracted. Once the plaintiff proves that his product and the product of the defendant are identical, then the Court may direct the defendant to prove that the process used by the defendant to obtain the product is different from the patented process. Therefore, in the event of the product of both the plaintiff and the defendant being identical, the burden shifts on the defendant to prove that the process adopted by him to obtain the product is totally different from the process adopted by the plaintiff in obtaining his product. The word used is identical and not similar. The definition of 'identical' in Oxford Dictionary is, similar in every detail 'exactly alike'. Therefore, the meaning of the word 'identical' means being the same, exactly equal and alike having such a close similarity or resemblance as to be essentially equal or interchangeable, matching, equal, twin, equivalent, synonymous, coinciding, exactly when superimposed. Two things are identical if one can be substituted for the other without affecting the truth. However, the definition of 'similar' in Oxford Dictionary means, having a resemblance in appearance, character, or quantity, without being identical. Showing resemblance in qualities, characteristics or appearance; alike but not identical. Resembling or similar, having the same or some of the same characteristics often

used in combination, expressing closely related meanings. Meaning the same or nearly the same. Therefore, the word used in Section 104-A is identical and not similar and that unless the two products are identical, Section 104-A is not attracted. The products being identical is *sine quo non* for applicability of Section 104-A of the Act. Only when the court comes to the conclusion that there is an identical product manufactured by the defendant similar to that of the plaintiff, then the Court can call upon the defendant to produce the particulars of the process by which his product is manufactured. It is only then, if the defendant refuses to furnish the particulars of the process, the Court may draw adverse inference and invoke Section 104-A. If the Court comes to the conclusion that the plaintiff's patent is valid and the product of the defendant is identical with that of the plaintiff the Court may call upon the defendant to disclose the process by which his product is manufactured and the defendant must be ready and willing to place the process before the Court subject to the Court protecting the trade secret of the defendant. [Judgment of Karnataka High Court in Natural Remedies Private Limited v. Indian Herbs Research & Supply Co. Ltd., in O.S.No.1 of 2004, dated 09.12.2011]

22. The object of interlocutory injunction is to protect the appellant against the injury by reason of violation of his right and relief by way of interlocutory injunction is granted to mitigate the risk of injustice to the appellant during the period

before the uncertainty could be resolved. The interlocutory remedy by way of a grant of an order of injunction is intended to preserve the rights of the parties in *status quo* (**Wander Ltd., v. Antox India (P) Ltd.,** [10]). Now, in the present case on hand, it has to be seen whether the appellant is entitled to grant of injunction. This Court has to appreciate the rival contentions and pleadings of the parties and whether the Court below is right in refusing the grant of injunction in favour of the appellant while considering the above referred provisions of law, which are relevant for the purpose of deciding this case. For grant of injunction, petitioner must establish a) *prima facie* case b) Irreparable Loss which cannot be compensated in monetary terms c) Balance of convenience in its favour (**Colgate Palmolive (India) Ltd., v. Hindustan Lever Ltd.,** [11] and **Franz Xaver Huemer v. New Yash Engineers (supra**)

23. On behalf of the appellant, Exs.P1 to P17 are marked as evidence. Exs.R1 to R5 were marked on behalf of the respondent.

24. The patented invention is directed to an improved process for the preparation of alpha-N-acyl-alpha chloroketones by the action of sulfur ylide on aryl esters to generate a keto yilde that is in turn treated with a source of chloride and an organic acid and that the present invention is further directed to an improved process for the preparation of corresponding epoxide compounds that are intermediates in the synthesis of Atazanavir. The advantages of the patented

invention over the prior art are *inter alia* that it enables the large scale production of alpha chloroketones without the production of any toxic by-product. The Indian Patent No.206217 relates to a 'Steroselective process for the preparation of substituted oxobutanes. The IN '217 is directed to a novel process for the preparation of (3S, 2R)-1-halo-2-hydroxy-3-(protected)amino-4-substituted butanes by stereoselective reduction of the corresponding oxo compounds. The substituted butanes produced in accordance with the process of the inventions are precursors of hydroxyethylamine isostere sub-units present in many molecules therapeutically useful as inhibitors of angiotensin converting enzyme, rennin and HIV-protease, including Atazanavir.

25. As per Exhibit Nos.P1 to P5 and assertion made in paragraphs 13, 16, 17, 19 and 20 of the affidavit in interlocutory application, it is *prima facie* found that the petitioner is assigned rights for Patent Nos. 210496 and 206217 by BMS which are patent process for manufacture of intermediates i.e., chloroketones and oxobutanes, which are used for preparation of Atazanavir, which is a final product, but not the product of Atazanavir.

26. The Patent No.210496 is related to process for the preparation of N-acyl-a chloroketones. The Patent No.206217 relates to a Steroselective process for the preparation of substituted oxobutanes.

27. It is pertinent to note that the appellant has not produced any evidence to show that any technology protected by the suit patents covering preparation of alpha-chloroketone and substituted oxobutane was provided to the respondent. The appellant has not produced any scientific evidence to show that the process used by the respondent is same as that of the appellant in manufacturing of Atazanavir. Unless some scientific evidence affidavit of any expert in the relevant field, is filed and proved, as held in the judgment reported in **FDC Limited & others v. Sanjeev Khandelwal (supra),** the appellant is not entitled for injunction. The Court below by mainly relying on the aforesaid decision came to the conclusion that no such evidence is produced by expert, and dismissed the injunction application of the appellant.

28. It is the case of the respondent that it is not infringing either of the two suit patents and does not manufacture alpha-chloroketones or substituted oxobutanes precursors or epoxide intermediates using either of these two patents process in India. It is stated that the respondent obtains epoxide intermediate from a third party. Therefore, at this stage, it cannot be said that the respondent has infringed the patent process right of the appellant. Hence Point No.1 is answered against the appellant.

29. Section 48(b) of the Act states where the subject matter of the patent is a process the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale,

selling or importing for those purposes the product obtained directly by that process in India. But in the present case on hand, the allegation of the appellant that it has been granted process patent in respect of chloroketones and oxobutanes, but admittedly they are intermediate products for the manufacture of Atazanavir and Atazanavir is not directly obtained from the process patented. Atazanavir is manufactured by using the intermediate products. Moreover, the suit patents does not claim drug Atazanavir or any process for preparation of Atazanavir. It is also not the case of the appellant that respondent is manufacturing choloroketones or oxobutanes.

30. As per the chart produced by the learned counsel for the respondent, three processes are involved after intermediates are produced i.e., chloroketones and oxobutanes, which are alternative starting material for preparing epoxide compounds through separate processes.

The epoxide compound is converted into an hydroxyethylamine through a separate complex chemical process and the hydroxyethylamine is then converted into Atazanavir through a separate chemical process. As such, Atazanavir is not the direct product for which, no patent is granted in favour of the appellant and that after the use of intermediates and after completion of several processes, Atazanavir compound is produced. Therefore, the appellant has failed to discharge its burden of showing that the respondent is actually using either of the process of the two

suit patents to prepare the precursors which are then converted into the epoxide intermediate intermediate which is then converted into Atazanavir. P*rima facie,* Section 48 of the Act of 1970 cannot come to the rescue of the appellant at this stage, since the respondent has taken such a plea.

31. No doubt, the principle laid down by Madras High Court in **FDC Limited & others v. Sanjeev Khandelwal (supra)** is for grant of *ex parte* injunction, but even otherwise, I am of the opinion that appellant should have produced some independent evidence in the facts and circumstances of the case. The fact that the appellant is having patent in respect of intermediates is not in dispute since the patents are admittedly granted, as discussed above and that the same is not subject to any pre-grant or post grant as envisaged under Sections 25(1) and 25(2) of the Act of 1970 respectively. It is also stated that no revocation proceedings are pending under Section 64 of the Act of 1970 and also the fact that the respondent is manufacturing Atazanavir is also not in dispute.

32. The respondent has clearly explained from the chart that after several intermediate processes, which involved for the manufacture of Atazanavir, with the intermediates Chloroketones and Oxobutanes in respect of which the appellant has patent, that it is not infringing the patent right of the appellant by using the intermediates Chloroketones and Oxobutanes, as such, *prima facie* case is not made out for invoking Section 48(b) of the Act of 1970. Therefore,

appellant's rights are not violated. Though the appellant is able to prove that it has obtained process patents, but at this stage, it is not clearly proved that there is an infringement by the respondent. In such circumstances, refusal of injunction at this stage, without production of scientific evidence, as held by the trial Court, cannot be faulted. In view of the aforesaid decisions referred supra, injunction can be granted only when *prima facie,* appellant is able to prove his case that his patented process is being infringed by the respondent, the balance of convenience lies in its favour and that irreparable loss would be caused to the appellant, if injunction is not granted in its favour.

33. The respondent has not disclosed the name of its supplier of intermediates for manufacture of Atazanavir, which aspect has to be considered in the trial and which factor necessitates the respondent to give sufficient security for export of Atazanavir.

34. In the present case, appellant has alternatively claimed damages. Section 108 of the Act of 1970, provides for grant of damages also. A perusal of the material available on record, it cannot also be said that the appellant has no case at all, but unless he discharges his onus clearly establishing the case, injunction cannot be granted. In the judgment reported in **F.Hoffman La Rache v. Cipla Ltd. Delhi High Court**[12], it is observed as under:

> "85. (vii). The question of general public access in our country to life saving drugs assumes great significance and the adverse impact on such access which the grant of

injunction in a case like the instant one is likely to have, would have to be accounted for. This Court finds no ground to differ with the reasoning or the conclusions arrived at by the learned Single Judge on this aspect."

In **Best Sellers Retail (India) Pvt. Ltd., v. Aditya Birla Nuvo Ltd., and others**[13], it is observed as under:

"14. Yet, the settled principle of law is that even where *prima facie* case is in favour of the plaintiff, the Court will refuse temporary injunction if the injury suffered by the plaintiff on account of refusal of temporary injunction was not irreparable. In *Dalpat Kumar and another v. Prahlad Singh and others, (1992) 1 SCC 719 = AIR 1993 SC 276=1992 AIR SCW 3128, this Court held:*

"Satisfaction that there is a prima facie case by itself is not sufficient to grant injunction. The Court further has to satisfy that non-interference by the Court would result in 'irreparable injury' to the party seeking relief and that there is no other remedy available to the party except one to grant injunction and he needs protection from the consequences of apprehended injury or dispossession. Irreparable injury, however, does not mean that there must be no physical possibility of repairing the injury, but means only that the injury must be a material one, namely, one that cannot be adequately compensated by way of damages...."

35. When once goods are exported and in case the appellant is able to satisfy in the suit that the respondent has infringed the patent rights of the appellant, respondent can be asked to furnish security at the time of export of product for safeguarding the interest of appellant. While granting interim order in CRP No.2724 of 2014, this Court has permitted to export the drug Atazanavir to Venezuela, on production of Bank Guarantee to protect the interest of the appellant.

36. The trial Court, after considering the evidence of appellant marked by way of Exs.P1 to P17 and also exhibits

marked on behalf of the respondent by way of Exs.R1 to R5 and after considering the pleadings of both parties, dismissed the injunction petition holding that the petitioner has not placed any prima facie convincing material regarding the infringement of the process patent under Exs.P1 and P3, except relying on Exs.P1 to P17 and that a scientific investigation is required regarding the violation as per the decision of the Madras High Court in **FDC Limited & Ors v. Sanjeev Khandelwal & others (supra).** The trial Court has held that since there is no *prima facie* material, the decision regarding the balance of convenience and irreparable loss does not arise at this stage, without the proof of the facts with material evidence for exercising the discretionary power for granting equitable relief. The trial Court has taken a view that temporary injunction cannot be granted and I do not see any reason to interfere with the same in view of above facts and circumstances. In view of above discussion, other decisions relied on by both sides, may not be relevant at this stage.

37. It is needless to mention that the respondent has to render separate account regarding the export of Atazanavir drug to Venezuela for safeguarding rights of appellant in case it succeeds in the suit and furnish bank guarantee for export of the product. (**Sandeep Jaidki v. Mukesh Mittal & another**[14]).

38. In view of the above facts and circumstances, in view of the principles laid down in the aforesaid decisions, I do not see any ground to interfere with the order passed by the Court below. However, it is made it clear that the

observations made herein are only for the purpose of deciding the appeal arising out of interlocutory application and that the trial Court shall dispose of the suit uninfluenced by any of the observations made in this case. Respondent is directed to maintain a separate account in respect of export of Atazanavir to Venezuela and produce before the trial Court at the time of trial. Respondent is also directed to furnish Bank Guarantee before the Court below to the extent of 5% of the cost of Atazanavir to be supplied to Venezuela every time. The Bank Guarantee already furnished will be kept alive till the disposal of suit.

Accordingly, the Civil Miscellaneous Appeal is dismissed. As a sequel thereto, miscellaneous petitions, if any, pending in this CMA, shall stand dismissed.

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A.RAJASHEKER REDDY, J

Date: 05.12.2014

kvs

HON'BLE SRI JUSTICE A.RAJASHEKER REDDY

C.M.A.No.879 of 2014

Date: 05.12.2014

kvs

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[1] 2007 (35) PTC 436 (Mad.)

[2] [2012]EWHC627(Pat) High Court of Justice, Chancery Division (UK).

[3] (AIR 1969 Bombay 255)

[4] 159 (2009) DLT 243 = ILR (2009) Supp.(2)Delhi551, MIPR 2009(2)1, 2009(40)PTC 125 (Del)

[5] AIR 1980 Delhi 132

[6] ORA/1/2007/PT/MUM

[7] [(1900) 17 RPC 307]

[8] [172 (2010) DLT 229]

[9] AIR 1997 DELHI 79

[10] 1990 Supp Supreme Court Cases 727

[11] 1999 (7) SCC 1

[12] 2009 (40) PTC 125 (Del)

[13] 2012 (5) ALD 140 (SC)

[14] 211 (2014)DLT 401