THE CONTROLLER OF PATENTS,
PATENT OFFICE, MUMBAI

IN THE MATTER OF:

AstraZeneca AB	**…….. Petitioner**
Represented by:	Archana Shanker Patent Agent of ANAND AND ANAND

VERSUS

Lee Pharma Ltd.	**..... Respondent & Applicant for C. L. A No. 1 of 2015**

ORDER

1. On 9th November 2015, the Petitioner through their Counsel, ANAND AND ANAND filed a petition seeking intervention in the proceedings of Compulsory Licence, i.e. C. L. A. No. 1 of 2015 by Lee Pharma Limited vs. AstraZeneca AB, with a request that the Petitioner be granted an in-person hearing under Section 80 of the Patents Act, 1970, as amended (hereinafter referred to as the Act) before the final determination regarding a *prima facie* case being made out in the said Compulsory License case. Particularly, the petition is filed in the matter of an application by the Respondent seeking the grant of a Compulsory Licence under Section 84 of the Act for manufacturing and selling the compound SAXAGLIPTIN, which is protected by Indian Patent No. 206543 titled "A cyclopropyl-fused pyrrolidine-based compound" granted on 30th April 2007 to Bristol Myers Squibb Company (BMS). BMS by virtue of an Assignment Deed, transferred/assigned the ownership rights to AstraZeneca AB, the Petitioner/ Patentee in the present petition, of the address SE-151 85, Sodertalje, Sweden. It is submitted that the Petitioner is the owner of the patent, which is the subject-matter of Compulsory License proceedings and under the principles of *audi alteram partem*, and for the benefit of all parties, the Petitioner to be given a hearing in the matter.

Grounds for the intervention at this stage

2. The grounds for making the petition are as follows:

   A. For. that in view of the undertaking given by the Respondent to the Hon'ble High Court of Delhi, which was accepted and recorded by the Hon'ble Court in its order dated 8th October 2015, the further continuation of these Compulsory License proceedings and their maintainability are serious in question. Hence, an early hearing of this preliminary issue of maintainability is necessary in the interest of justice.

B. For that while giving the above said undertaking, no exception was carved out by the Respondent and the suit having been decreed, the consent order dated 8th October 2015 has attained finality. Hence the Respondent has waived and/or given up their right to seek a Compulsory License.

C. For that the Respondent having made a statement before the Hon'ble Court that *"the application for compulsory license has been rejected by the Controller of Patents"* in fact now precluded from taking a contrary stand.

D. For that it may save both the national exchequer and the parties a lot of time, money and efforts if the *prima facie* view is taken by the Learned Controller upon a correct and full appreciation of facts.

E. For that if a *prima facie* view is taken to issue notice of the compulsory license application to the petitioner without the correct appreciation of facts, it may cause a lot of adverse publicity in the press and media leading to a loss of confidence in the Petitioner's investors and shareholders.

F. For that the Petitioner may suffer incalculable harm, loss of market share, a dip in stock prices, etc. if an adverse *prima facie* view is formed by the Learned Controller based on misleading and inaccurate facts presented by the Respondent.

G. For that it may considerably shorten the length of the present proceedings if the Petitioner is given an opportunity to be heard in-person or through its representatives clarifying certain inaccuracies in the compulsory license application before the Learned Controller forms any definite view.

H. For that the Petitioner is not desirous of entering into a long battle wherein a few clarifications may save the Learned Controller the burden of conducting a protracted hearing on the compulsory license application filed by the Respondent.

I. For that grave prejudice would be caused to the Petitioner if it is not allowed to be heard before the Learned Controller gives its *prima facie* finding on the compulsory license application.

J. For that the principles of natural justice, equity and good conscience demand that a party may be given a right to be heard in order to prevent any harm that may unnecessarily befall upon it and can be avoided easily.

K. For that the Learned Controller has the right to hear the Petitioner in excise of its discretionary powers. Moreover, the Learned Controller may make a departure from normal practice and procedure in the interest of natural justice.

Prayer

3. In view of the facts and circumstances stated above, the Petitioner prayed that the Controller may grant an in-person hearing to them before taking a *prima facie* view in C. L.A. No. 1 of 2015; any other orders as the Controller may deem fit.

Provisions

4. Section 87 of the Patents Act read with Rule 97 of the Parents Rules, 2003, as amended (hereinafter referred to as the Rules) lays down the procedure to be followed while dealing with applications for compulsory license under Section 84 of the Act. Whereas Section 80 of the Act, under which the present petition is filed, relates to exercise of discretionary powers by the Controller.

5. Section 87 of the Act states as follows:

"87. Procedure for dealing with applications under sections 84 and 85.

(1) Where the Controller is satisfied, upon consideration of an application under section 84, or section 85, that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the Official Journal.

(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.

(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.

(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and shall give to the applicant and the opponent an opportunity to be heard before deciding the case."

6. Rule 97 states as follows:

"97. When a prima facie case is not made out.-

(1) If, upon consideration of the evidence, the Controller is satisfied that a prima facie case has not been made out for the making of an order under any of the sections referred to in rule 96, he shall notify the applicant accordingly, and unless the applicant requests to be heard in the matter, within one month from the date of such notification, the Controller shall refuse the application.

(2) If the applicant requests for a hearing within the time allowed under sub-rule (1), the Controller shall, after giving the applicant an opportunity of being heard, determine whether the application may be proceeded with or whether it shall be refused."

7. Section 80 of the Act sates as follows:

"80. Exercise of discretionary powers by Controller.

Without prejudice to any provision contained in this Act requiring the Controller to hear any party to the proceedings thereunder or to give any such party an opportunity to be heard, the Controller shall give to any applicant for a patent, or for amendment of a specification (if within the prescribed time the applicant so requires) an opportunity to be heard before exercising adversely to the applicant any discretion vested in the Controller by or under this Act.

Provided that the party desiring a hearing makes the request for such hearing to the Controller at least ten days in advance of the expiry of the time-limit specified in respect of the proceeding.

Hearing

8. In view of above said provisions of Section 87 and Rule 97, there is no provision in the Act or the Rules, which at this stage requires the Patentee to be heard before the conclusion that a *prima facie* case has been made out for the making of an order under Section 84. In the said proceedings of Lee Pharma Limited vs. AstraZeneca AB, the Applicant was informed by a notice dated 12th August 2015 that a *prima facie* case has not been made out for making of an order under Section 84 of the Act and the application shall be refused if no request for hearing is filed within prescribed time. In reply to the said notice, the Applicant has made a request for the hearing under Rule 97(2) and the proceedings whether or not a *prima facie* case has been made out by the Applicant are underway as per the provisions of the Act and the Rules made thereunder.

9. However, since the Petitioner has requested for the hearing under Section 80, a hearing is offered to the Petitioner on 15th December 2015 vide this office letter dated 3rd December 2015 by informing that the hearing has been fixed for deciding the intervention petition. Accordingly, above said Counsel of the Petitioner attended the hearing on 15th December 2015.

10. At the outset, it was asked to the Petitioner's Counsel that how the Petitioner/ Patentee is a party to the proceeding of Compulsory License at this stage and how it is entitled for the intervention when the decision, regarding a *prima facie* case has been made out for the making of an order under Section 84, is yet to be taken. Further, how the Controller is empowered under Section 80 to allow the Petitioner to intervene in the matter of Compulsory License proceedings at the *prima facie* stage.

Petitioner's submissions

11. The submissions by the Petitioner's Counsel are summarized as under:

12. Regarding the question of whether the Petitioner/ Patentee is a party to the Compulsory License proceedings and is entitled for the intervention before a *prima facie* case has been made out for the making of an order under Section 84, it is submitted that the Controller while determining whether a *prima facie* case has been made out for the grant of Compulsory License under the provisions of Section 87 read with Rule 97 is exercising its discretion, which may have adverse consequences for the Petitioner/ Patentee. Therefore, under the provisions of Section 80, the Petitioner/ Patentee has a right to be heard prior to this discretion being exercised and the obligation on the Controller to grant a hearing is mandatory and not directory in nature. Section 80 entitles "any party" to the proceedings to be entitled to a hearing and it is a statutory provision and the rules made there under are merely directory in nature. The Indian patent No. 206543 belongs to the Petitioner and by virtue of the Compulsory License application being made by the Respondent on the Petitioner's patent makes the Petitioner/ Patentee as a necessary and interested party in the Compulsory License proceedings. Further, the proceedings in relation to the Compulsory License application of IN 206543 undoubtedly cover infraction of the property of the Patentee/ Petitioner.

13. Regarding the question of whether the intervention petition is maintainable under Section 80, it is submitted that as the Patentee is a necessary party to the Compulsory License proceedings, if a request is made by said party, the law mandates that the said party be granted a hearing under Section 80. It is stated that once a hearing is requested, the Controller being a *quasi judicial* authority should always exercise his discretion in favour of the grant of a hearing; particularly, when the proceedings may have adverse civil consequences for the Petitioner/ Patentee, such as in the present case, infarction or dilution of the patent rights. The intervention application in order to be heard in the Compulsory License application at a *prima facie* stage is not premature merely because Rule 97(1) does not expressly state that a hearing should be granted to the patentee. There is no statutory bar in the said rule so as to exclude the Petitioner from being granted a hearing. Therefore, under the provisions of Section 80, the Petitioner/ Patentee has a right to be heard once an application is made and the obligation on the Controller to grant a hearing is mandatory and not directory in nature.

14. Further, it is submitted that, as held by the High Court, no *judicial or quasi judicial* authority ordinarily in the absence of a statutory bar can decline to hear a party in respect of proceeding, which would visit a party with civil consequences. The exercise of discretion has an inbuilt element of hearing that Section 80 statutorily recognises. The right of hearing is an inbuilt wherever any discretionary power has to be exercised and this has been recognized by Rule 129. The Petitioner does not become disentitled to a hearing merely because a formal hearing notice was not served on them. The Patentee's right to a hearing under Section 87(4) after the determination of a *prima facie* case is not a statutory bar to the grant of a hearing at a stage prior to such a determination. Further, Section 80 operates without prejudice to

any other provisions contained in the Act and a *prima facie* finding in favour of the Respondent cannot be arrived at without the correct examination of facts. Such facts might not be to the knowledge of the Controller as in the present case wherein the Respondent is clearly playing foul in the present proceedings by making incorrect statements and contrary undertakings to the Delhi High Court and the Indian Patent Office. Further, the rules cannot travel beyond the statutory provisions of law. Under Section 80, if a hearing is requested, in view of the expression "shall", the Controller does not have any discretionary power not to grant a hearing.

Findings

15. In view of the Petitioner's submission, at the outset, let me make it clear that since the Petitioner has requested for an in-person hearing, the hearing was offered to them and they have been asked as to how the Petitioner/ Patentee is a party to the proceedings of Compulsory License at this stage and how it is entitled for the intervention before a *prima facie* case has been made out for the making of an order under Section 84. They have not made any point in their submission, which convinced me as to how the Petitioner is party to the proceedings at this stage. In my considered view, the petition or the Petitioner's submission holds no merits and the petitioner has no *locus standi* at this stage under any provisions of the Act in the Compulsory License proceedings unless there is an order under Section 87(1) that a *prima facie* case has been made out for making of an order under Section 84 and the applicant is directed to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and the application is published in official journal.

16. And if as and when the order as specified above is made, the patentee or any other person desiring to oppose the application for the Compulsory License, within such time as prescribed, can give the notice of opposition. Therefore, there are specific provisions in the Patents Act and Rules for the Patentee or any other person to intervene in the matter at that stage. Thus, in said circumstances, the Petitioner/ Patentee automatically become the party to the proceedings and hence, entitled to intervene.

17. From the above stated provision of Section 80, it is absolutely clear that without prejudice to hear any party to the proceedings under the Act, it is incumbent on the Controller to hear a party, specifically any applicant for a patent or for amendment of a specification before exercising discretion adversely to the applicant. Whereas according to Patents Act, in an application for the Compulsory License under Section 84(1), the patentee is not a party at this stage. The Act does not provide any provision for intervention by the patentee at this stage. The Patentee can only present his case by way of opposition when there is an order under Section 87(1) that a *prima facie* case has been made out for making of an order under Section 84 and the applicant is directed to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the

application is made. In view of the specific provisions for opportunity provided to the patentee or interested party for being heard before any order that may adversely affect their interests is passed, the petitioner's insistence for hearing as an intervener in a *prima facie* determination is misplaced and without sound legal basis.

18. The proceeding of Compulsory License is not related to a grant of patent or to an amendment of specification as envisaged under Section 80. Since it is not related to the grant of patent or to the amendment of specification, it is therefore, proven that the Petitioner has no *locus standi* in the present case. Therefore, the petition seeking intervention under Section 80 is not maintainable.

19. Further, in order dated 8th October 2015, in the matter of *'AstraZeneca AB & others vs. Mr. A V Reddy & others'* [CS(OS)2197/2015 & IA No. 15107/2015], Hon'ble Delhi High Court has not passed any order refraining the Controller from evaluating the Compulsory License application on its merits and passing any order based on the merits under the provisions of Patents Act. In fact, in earlier order dated 29th July 2015, in the same matter, the Hon'ble High Court, clarified that the petition filed by the defendant for Compulsory License shall be decided by the Controller in accordance with law.

20. The Petitioner/ Patentee in their submission relied upon the following two case laws:

i. State of Orissa vs. Dr. (Miss) Binapani (AIR 1967 SC 1269), which ruled that:

(Para 12):- *"It is true that the order is administrative in character, but even an administrative order which involves civil consequences, as already stated, must be made consistent with the rules of natural justice after informing the first respondent of the case of the State, the evidence in support thereof and after giving an opportunity of the first respondent of being heard and meeting or explaining the evidence. No such steps were admittedly taken; the High Court was, in our judgment, right in setting aside the order of the State"*; and

ii. Mrs. Maneka Gandhi vs. Union of India & Anr. (AIR 1978 SC 597), which ruled that:

(Para 221):- *"It is well established that even where there is no specific provision in a statute or rules made thereunder for showing cause against action proposed to be taken against an individual, which affect the rights of that individual, the duty to give reasonable opportunity to be heard will be implied from the nature of the function to be performed by the authority which has the power to take punitive or damaging action"*.

21. In both the cases, the party did not have any opportunity to be heard and therefore, Hon'ble Court has ruled that in the interest of natural justice a hearing shall be given in such cases. Since the Patentee/ Petitioner is provided with the opportunity to oppose any Compulsory License application at appropriate stage, the case laws do not apply in this case.

Conclusion

22. In conclusion, I am therefore of the view that the intervention petition is not maintainable and is hereby rejected.

Dated this on 18th day of January 2016

(O. P. Gupta)
Controller of Patents