THE CONTROLLER OF PATENTS,
PATENT OFFICE, MUMBAI.

C.L.A. No. 1 of 2015

IN THE MATTER OF:

Lee Pharma Ltd.

..... Applicant

VERSUS

AstraZeneca AB

..... Respondent

N O T I C E

1. An application under Section 84 (1) of the Patents Act, 1970 (hereinafter referred to as the Act) has been filed by the Applicant on 29th June 2015, seeking the grant of a compulsory licence for manufacturing and selling the compound SAXAGLIPTIN which is protected by Patent number 206543 titled "A CYCLOPROPYL-FUSED PYRROLIDINE-BASED COMPOUND" granted on 30th April 2007 to Bristol Myers Squibb Company (BMS). The grounds for making the application are as follows:

   (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied; and

   (b) that the patented invention is not available to the public at a reasonably affordable price; and

   (c) that the patented invention is not worked in the territory of India.

2. By virtue of an Assignment Deed, BMS transferred/ assigned the ownership rights in the Indian Patent No. 206543 to AstraZeneca AB, the Respondent, of the address SE-151 85, Sodertalje, Sweden.

3. A time period of 3 years from the date of grant of patent, that is a mandatory prerequisite for initiating any proceeding under sub-section (1) of section 84 of the Act, has expired. Renewal fee in respect of the patent has been paid till 5th March 2016.

4. SAXAGLIPTIN is a drug prescribed for the treatment of Type-II Diabetes Mellitus. Diabetes Mellitus occurs when the pancreas don't produce enough insulin (Type-I DM) or when the body does not effectively utilize the insulin produced by pancreas (Type-II DM), leading to increased concentration of glucose in the blood. SAXAGLIPTIN is used in the treatment of Type-II DM and is sold under the brand name ONGLYZA in dosages of 2.5 mg and 5 mg. It is also sold in combination with Metformin under brand name KOMBIGLYZE XR in dosage 5/500mg and 5/1000 mg.

5. The applicant has submitted his willingness to accept the following terms and conditions:

a) The right to manufacture and sell SAXAGLIPTIN shall be limited to the territory of India. The Applicant shall not use the licence for sale to other countries and will take all necessary steps to ensure that the product is sold and available only within the territory of India.

b) The Applicant will pay the royalties to the Patentee at the rate fixed by the Controller of Patents.

c) The patented product will be made available to the public at the most reasonable and affordable price as follows:

PRODUCT	**STRENGTH**	**PRICE PER STRIP (14 TABLETS)**	**PRICE / UNIT TABLET (MRP)**
SAXAGLIPTIN	2.5 mg	Rs. 378	Rs. 27
SAXAGLIPTIN	5 mg	Rs. 406	Rs. 29

		PRICE PER STRIP (7 TABLETS)	PRICE / UNIT TABLET (MRP)
SAXAGLIPTIN + METFORMIN XR	5/500 mg	Rs. 210	Rs. 30
SAXAGLIPTIN + METFORMIN XR	5/1000 mg	Rs. 220.50	Rs. 31.50

d) The Applicant also agrees to be bound by other terms and conditions as imposed by the Controller of Patents.

6. Section 84(1) of the Patents Act, 1970 states as follows:

"84. Compulsory licences.

(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India."

7. It is alleged by the Applicant that all the aforementioned three grounds of sub section (1) of section 84 of the Act are applicable in the case of patent number 206543.

Person interested and Capacity of the Applicant

8. The Applicant has filed a request dated 13th May 2015 for grant of a Drug Licence for manufacturing SAXAGLIPTIN. Earlier, the Applicant had also filed request with the Respondent for a licence to manufacture and sell SAXAGLIPTIN.

9. The Applicant has stated that for more than 17 years, it has been involved in research and development, production, distribution, sales, marketing and export of pharmaceutical products, pharmaceutical formulations, intermediates and APIs. Its products are sold in India and exported to more than 48 countries worldwide. Applicant has submitted that it has a production capability of 10,00,000 tablets of SAXAGLIPTIN and SAXAGLIPTIN + METFORMIN XR per day.

10. It is *prima facie* borne out that the Applicant is a person interested and has the capacity to undertake the risk in providing capital and working the invention, if the application is granted.

Efforts by Applicant to procure licence

11. The Applicant made a request for a licence to the Respondent, who is the assignee in respect of Patent No. 206543, by letter dated 2nd May 2014. By email dated 2nd June 2014, the Respondent replied to this letter. In this letter, the Respondent sought certain clarifications while disagreeing with the Applicant that SAXAGLIPTIN is not available to the general public or that the reasonable requirements of the general public are not being met or that SAXAGLIPTIN is not available at a reasonably affordable price. It has been submitted that due to some reason, this reply which was sent by an email, could not be received by the Applicant. The Applicant has not clarified why it was not received at their end. As the Applicant was under an impression that the Respondents have not replied, they sent a reminder dated 31st October 2014. The Counsel of the Respondent in response to the Applicant's reminder dated 31st October 2014, replied vide letter dated 7th November 2014. In turn, the Applicant replied on 22nd November 2014 and an acknowledgement was provided by the Counsel of the Respondent by an email dated 2nd January 2015. Thereafter, the Applicant sent a reminder dated 17th January 2015 but did not receive any reply. The Applicant sent an email dated 2nd March 2015 but again did not receive any reply from them. The Applicant has therefore

approached the Controller of Patents as more than one year has already lapsed in the process.

12. A reading of the queries raised by the Respondent vide its email dated 2nd June 2014, and the replies submitted thereof by the Applicant vide its letter dated 22nd November 2014 shows *prima facie* that the Applicant has made efforts to obtain a licence from the patentee on mutually agreeable terms. Despite its queries being answered vide letter dated 22nd November 2014, the Respondent failed to take any substantive steps for over 7 months before filing of this application. Also, the first request for licence was made by the Applicant to the Respondent more than 13 months prior to the filing of this application. Thus, a reasonable period as envisaged under clause (iv) of section 84(6) of the Act has elapsed without the efforts being successful.

Clause (a) of sub-section (1) of section 84 of the Act

13. The Applicant has submitted that as per the available statistics, about 60.1 million people (90% of total 66.84 million diabetic people) in India are suffering from Type-II Diabetes Mellitus and that there is more than 99% shortage of SAXAGLIPTIN in the market. Four key medicines currently available in the Indian market for treatment of Type-II Diabetes Mellitus are LINAGLIPTIN, SITAGLIPTIN, VILDAGLIPTIN and SAXAGLIPTIN. The Applicant has assumed that if other three medicines were prescribed to 90% of the patients suffering from Type-II Diabetes Mellitus and only 10% patients were prescribed SAXAGLIPTIN, still 6 million people would require SAXAGLIPTIN. The Applicant has further presumed that even if only 1 million patients are prescribed SAXAGLIPTIN, the total number of tablets required comes out to be 365,000,000 tablets/ year. It has been submitted that as per the data submitted in Form-27, a total number of 823,855 tablets (both ONGLYZA and KOMBIGLYZE) were imported during the whole year (2013) by the Respondent/ Patentee, which is about 0.23% of the total number of tablets required for a year.

Therefore, according to the Applicant, there is more than 99% shortage of SAXAGLIPTIN in the Indian market.

14. The Applicant has not shown any difference in terms of treatment by any one of the 4 drugs, namely LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN (hereinafter referred to as the 'Substitutes') and SAXAGLIPTIN. If SAXAGLIPTIN can be substituted by the Substitutes, then in the absence of any kind of detail regarding the quantum of these Substitutes, it is not possible to arrive at any conclusion regarding the demand for SAXAGLIPTIN. This demand cannot be viewed in isolation given the fact, as stated in the application, that Substitutes are available in the Indian market. Accordingly, on this ground, I am of the view that a *prima facie* case has not been made out by the Applicant to the effect that the reasonable requirements of the public with respect to the patented invention are not being satisfied, and thus no case is made out in terms of Clause (a) of sub-section (1) of section 84 of the Act.

Clause (b) of sub-section (1) of section 84 of the Act

15. The Applicant submits that about 30% of the total population lives below poverty line and earns less than Rs 32 per day in rural areas and Rs 47 per day in urban areas. The cost of one tablet of Patentee's medicine, in the range of Rs 41 to 49, is therefore more than their whole day's earning. Excessive high price has been attributed as a barrier to access of SAXAGLIPTIN for the poor patients of India due to which it has been submitted that SAXAGLIPTIN is not available to the general public at a reasonably affordable price.

16. Further, the Applicant has submitted that the cost of importing one tablet of ONGLYZA and KOMBIGLYZE in India by the Respondent/ Patentee is only about Rs 0.80 and 0.92 per tablet, respectively. It has based its calculations on the figures submitted by the Respondent/ Patentee in Form-27 dated 10th February 2014. However, the

Respondent/ Patentee is selling the two medicines ONGLYZA and KOMBIGLYZE in the range of Rs 41 to 49 per tablet. Thus, the Applicant has alleged that this clearly demonstrates the monopoly of the patentee and high price of the tablet despite a small amount of cost incurred in manufacturing/ importing a single tablet. Paradoxically however, even the Applicant has proposed its own selling price in the range of Rs 27 to 31.50 per tablet; clearly, this is several times the alleged cost of import and the Applicant's own argument goes against itself.

17. In this regard, in the matter of 'Bayer Corporation v. Union of India & Ors' (Writ Petition No. 1323 of 2013), the Hon'ble Bombay High Court ruled as follows:

"We are of the view that the Act itself does not bestow any powers of investigation with regard to the reasonably affordable price and therefore, the authorities do not have the wherewithal / personnel to carry out the above exercise. Thus, the same has to be arrived at on the basis of the evidence led by the parties before it of their respective prices. The obligation of the authorities under the Act is with regard to grant, control and revocation of patent and not price determination of the patented invention. It is for this reason that Section 90(1) (iii) of the Act on which reliance is being placed does not direct the Controller to fix the reasonably affordable price but only directs the Controller to endeavor to ensure/ secure the patented article is available at reasonably affordable prices…… Therefore, the evidence led by the parties and impeached by the other side would form the basis of determining reasonably affordable prices. This reasonably affordable price has to be determined on the basis of the relative price being offered by the patent holder and the applicant after hearing other interested parties opposing the application. Therefore, in the present case the price at which the petitioner is selling the patented drug is at about Rs. 2,84,000/- per month of therapy and the applicant was offering the same at Rs. 8,800/- per month of therapy. In

such a case, the reasonably affordable price has to necessarily be the price of the applicant as it by itself establishes that the price of the petitioner is not a reasonably affordable price."

18. A comparison of the price at which the Respondent is making the drug available to the public and the price at which the Applicant is willing to make the drug available to the public is as follows:

PRODUCT	**STRENGTH**	**PRICE / STRIP OF 14 TABLETS**		**PRICE / UNIT TABLET**	
		AstraZeneca AB	**Lee Pharma Limited**	**AstraZeneca AB**	**Lee Pharma Limited**
SAXAGLIPTIN	2.5 mg	Rs. 605	Rs. 378	Rs. 43.21	Rs. 27
SAXAGLIPTIN	5 mg	Rs. 581	Rs. 406	Rs. 41.50	Rs. 29
		PRICE / STRIP OF 7 TABLETS		**PRICE / UNIT TABLET**	
SAXAGLIPTIN + METFORMIN XR	5/500 mg	Rs. 343	Rs. 210	Rs. 49	Rs. 30
SAXAGLIPTIN + METFORMIN XR	5/1000 mg	Rs. 343	Rs. 220.50	Rs. 49	Rs. 31.50

19. A comparison of the pricing adopted by the Respondent and the pricing offered by the Applicant demonstrates that the Applicant has failed to *prima facie* show that the patented invention is not available to the public at a reasonably affordable price, and thus no case is made out in terms of Clause (b) of sub-section (1) of section 84 of the Act.

Clause (c) of sub-section (1) of section 84 of the Act

20. The Applicant submits that even after the lapse of a long period of about eight years from the date of grant (30th April 2007), the Patentee has not taken adequate steps to manufacture SAXAGLIPTIN in India

and make full use of the invention in India to an adequate extent that is reasonably practicable. It is also submitted that the working of the patented product in the country is hindered by the importation from abroad.

21. In this regard, as is clearly borne out from the judgment of the Hon. Bombay High Court in the Bayer case (supra.) as also the judgment of the Hon. IPAB in the same case, manufacture in India is not a necessary pre-condition in all cases to establish working in India. The patent holder is however required to establish the reasons which make it impossible / prohibitive to manufacture the patented drug in India, particularly when the Patentee has manufacturing facilities within the country.

22. However, in the present application, the Applicant has not submitted any data relating to manufacturing facilities of the Respondent within India. The Applicant has failed to *prima facie* show that the patented invention is not worked in the territory of India, and thus no case is made out in terms of Clause (c) of sub-section (1) of section 84 of the Act.

Conclusion

23. In conclusion, I am therefore of the view that a *prima facie* case has not been made out for the making of an order under Section 84 of the Act. If the Applicant wishes to be heard in this matter in accordance with the provisions of Rule 97(1) of the Patents Rules 2003, a request for being heard should be filed within one month from the date of this order, failing which the application dated 29th June 2015 shall be refused.

12/08/2015

(Rajiv Aggarwal)
Controller of Patents