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