THE CONTROLLER OF PATENTS,
PATENT OFFICE, MUMBAI

C. L. A. NO.1 of 2015

IN THE MATTER OF:

Lee Pharma Ltd. ..... **Applicant**

Represented by: Mr. Afzal Hasan and Ms. Vatsala Singh Hasan, both Advocates & Patent Agents of HASAN AND SINGH

VERSUS

AstraZeneca AB ..... **Respondent**

ORDER

1. An application under Section 84(1) of the Patents Act, 1970, as amended (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 Patentee/ 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 2017.

4. SAXAGLIPTIN, as a Dipeptidyl Peptidase-4 (DPP-4) inhibitor, is a drug prescribed for the treatment of Type-II Diabetes Mellitus. Diabetes Mellitus (DM) 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 5/500 mg and 5/1000 mg.

5. The applicant has submitted his willingness to accept the following terms and conditions if compulsory license is granted:

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 of 14 tablets (MRP in Rs.)	Price per Unit tablet (MRP in Rs.)
SAXAGLIPTIN	2.5 mg	378.00	27.00
SAXAGLIPTIN	5 mg	406.00	29.00
		Price per Strip of 7 tablets (MRP in Rs.)	Price per Unit tablet (MRP in Rs.)
SAXAGLIPTIN+ METFORMIN XR	5/500 mg	210.00	30.00
SAXAGLIPTIN+ METFORMIN XR	5/1000 mg	220.50	31.50

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

Notice

6. By the notice dated 12th August 2015, the Applicant was informed that a *prima facie* case has not been made out for making of an order under Section 84 of the Act. By said notice, it was also informed that in accordance with Rule 97(1) of the Patents Rules, 2003, as amended (hereinafter referred to as the Rules), a request for being heard is required be filed within one month from the date of this order failing which the application shall be refused.

Provisions

7. Section 84(1) of the Act 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. "

8. 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. Section 87 of the Act read with the Rule 97, lays down the procedure to be followed while dealing with applications under Section 84 of the Act.

9. 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."

10. The 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."

11. In accordance with the scheme of the Act, the Controller, while considering an application under Section 84 of the Act is also required to take into account the factors mentioned in Sub-section (6) of section 84 of the Act. The said provision is as follows:

"84. Compulsory licences.-

(6) In considering the application filed under this section, the Controller shall take into account, -

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit.

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti- competitive practices adopted by the patentee,but shall not be required to take into account matters subsequent to themaking of the application.

Explanation. -For the purpose of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months."

Hearing

12. In repose to the notice dated 12th August 2015, the Applicant's Counsel requested for the hearing under Rule 97(1) within the prescribed period and accordingly, the hearing was held on 15th December 2015. On behalf of the Applicant, above said Advocates and Patent Agents have attended the hearing and made the submission on

15th December 2015. Further, supplementary submission was filed on 29th December 2015.

Person interested and Capacity of the Applicant

13. 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.

14. 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. The Applicant has submitted that it has a production capability of 10,00,000 tablets of SAXAGLIPTIN and SAXAGLIPTIN + METFORMIN XR per day.

15. 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 the Applicant to procure licence

16. 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.

17. 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/ Respondent on mutually agreeable terms. Despite its queries being answered vide letter dated 22nd November 2014, the Patentee/ 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 Patentee/ 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

18. The Applicant submitted that nearly about 60.1 million people (90% of total 66.84 million diabetic people) in India are suffering from Type-II DM and even if only one million out of 60.1 million Type-II DM patients are prescribed SAXAGLIPTIN, then total number of tablets required for one million patients in one year would be 365,000,000 tablets per year. Whereas as per Form-27 data, the total number of tablets (both ONGLYZA and KOMBIGLYZE) imported for the whole year (2013) was 823,855; which is about 0.23% of the total number of tablets required for a year. Thus, there is more than 99% shortage of SAXAGLIPTIN in the Indian market. Therefore, the reasonable requirements of the public with respect to the patented invention under Section 84(1)(a) have not been satisfied by the Patentee/ Respondent.

19. The Learned Counsel of the Applicant during argument placed insistence on a report by International Diabetes Federation (IDF) that the number of Type-II DM patients in India has gone up to 60.1 million. However, when question was asked whether it is because of reduction/ revision in specified sugar levels for being diabetic or actually more people having higher levels, the Learned Counsel said that he is not aware about it and no specific data is available in this regard. Further, question was asked regarding number of Type-II DM patients taking prescribed medicines vis-à-vis other steps such as life style change, diet control, exercise, etc.; again the Counsel said that

no such data is available. It was also questioned how many Type-II DM patients were prescribed the patented drug and how many of them were unable to get it because of its non-availability; the Counsel said no such data is available. The insistence on IDF report by the Applicant cannot be considered in view of the High Court's observation regarding reliance on third party report in absence of specific survey/ data or any authentic report by Govt. agency (W.P. No. 1323 of 2013).

20. In the matter of '*Bayer Corporation vs. Union of India & Ors*' (Writ Petition No. 1323 of 2013), the Hon'ble Bombay High Court in its judgement ruled that the reasonable requirement of the public has to be considered by the authorities in the context of number of patients requiring the patented drug. However, in the present application, the Applicant has not shown what is the reasonable requirement of the public with respect SAXAGLIPTIN in India in the context of number of Type-II DM patients requiring SAXAGLITPIN. They have also not shown comparative requirements of SAXAGLIPTIN and other Dipeptidyl Peptidase-4 (DPP-4) inhibitors, LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN, which are required for treatment of Type-II DM and are available in the Indian market so that the reasonable requirements of the public in respect to SAXAGLIPTIN could be arrived. Further, they have not shown any authentic data/ statistics on SAXAGLIPTIN prescription by the doctors in India over the DPP-4 inhibitors, LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN. In fact, according to Essential Medicines List of Govt. of NCT of Delhi submitted by the Applicant, SITAGLIPTIN and VILDAGLIPTIN are also listed as Essential Medicines along with SAXAGLIPTIN for the treatment of Type-II DM. As a result, in my opinion, it is not clear from their submission what are the reasonable requirements of the public in the context of number of patients requiring SAXAGLITPIN and the said other DDP-4 inhibitors.

21. At present, said four key drugs, LINAGLIPTIN, SITAGLIPTIN, VILDAGLIPTIN and SAXAGLIPTIN, as DPP-4 inhibitors, are available in India for the treatment of Type-II DM patients and are prescribed by the doctors. The Applicant has assumed that if other three drugs were prescribed to 90% of the patients suffering from Type-II DM and only 10% patients were prescribed SAXAGLIPTIN, still 6 million patients would require SAXAGLIPTIN, and even if only one million patients are prescribed SAXAGLIPTIN, total tablets of ONGLYZA and KOMBIGLYZE supplied by the Patentee/ Respondent (i.e. 823,855 as per Form-27 data) are inadequate to meet the

requirements of public and there is shortage of SAXAGLIPTIN in the Indian market. These are only Applicant's assumptions; however as stated above, in absence of any authentic data/ statistics, I am of the opinion that such assumptions are not sufficient or could not form the basis to prove that the reasonable requirements of the public with respect to the patented drug are not satisfied.

22. The Applicant also submitted that even after 6 years of the grant of patent, in the year 2013, the Patentee/ Respondent could only declare that the public requirements were only adequately met. Whereas, Hon'ble Bombay High Court in the matter of '*Bayer Corporation vs. Union of India & Ors*' has held that in respect of medicines the adequate extent test has to be 100% i.e. to the fullest extent. However, they have not shown any specific data/ evidence with respect to the exact number of patients requiring only SAXAGLIPTIN for the treatment of Type-II DM and therefore, what is the fullest extent of its requirement in India; it is totally unclear from their submission, whether actually one million patients need SAXAGLITIN or not. It is further unclear from their submission why the doctors only prefer SAXAGLIPTIN despite other alternatives, LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN available in the market. They only submitted that each of these drugs has their unique pharmacokinetics and works in their own way and each has some advantages and disadvantages over the others. As a result, the exact quantity of SAXAGLIPTIN required in the context of number of patients and doctors' prescription is not established for arriving at a figure, which could be 100% i.e. to the fullest extent.

23. Further, it is submitted that whether the reasonable requirements of the public with respect to the patented invention as required under Section 84(1)(a) have been satisfied or not, the evaluation should be done only for the patented invention on the basis of statutory provisions provided under Section 83, 84(1) and 84(7) of the Act and in view of the precedents by Hon'ble High Court of Bombay and on no other grounds. Such evaluation should not include any third party or any other product/ patent. However for making such evaluation as envisaged, at the first place, one has to demonstrate the reasonable requirements of the public in respect to SAXAGLIPTIN. But the Applicant's submission has not demonstrated it by way of any authentic data/ concrete evidence. On the face of their submission, there is no way to understand the exact requirements of SAXAGLIPTIN in Indian market and to decide whether or not

the Patentee/ Respondent is meeting the reasonable requirements of the public in respect to patented invention.

24. The Applicant's Counsel argued that out of all DPP-4 inhibitors presently available in India, SAXAGLIPTIN is the latest and the best option for the treatment of Type-II DM while the others have side effects. However, in support of their argument, they neither submitted any comparative study nor submitted any authentic evidence from any statutory authority or the doctors' body to clearly establish that SAXAGLIPTIN is the best option with no or comparatively less side effect/s over the others. Even when they have been asked to submit such study/ evidence by way of their supplementary submission, they failed to do so. In absence of that, it is difficult for me to conclude that SAXAGLIPTIN is the best and the latest option with no or comparatively less side effect/s over the others for the treatment of Type-II DM patients in India.

25. 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

26. The Applicant submitted that about 60.1 million people in India suffering from Type-II DM and about 30% of the total population in India 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 (ONGLYZA and KOMBIGLYZE), 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 in India and due to which it has been submitted that SAXAGLIPTIN is not available to the general public at a reasonably affordable price.

27. In *'Bayer Corporation vs. Union of India & Ors'* (supra.), 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....."

28. As mentioned in Para above, along with SAXAGLIPTIN, other DPP-4 inhibitors, LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN are also available in the Indian market and concurrently used for treatment of Type-II DM by the doctors in India. In fact, as stated/ assumed by the Applicant, these other three drugs were prescribed to 90% of the patients suffering from Type-II DM and only 10% patients were prescribed SAXAGLIPTIN. And if the same is considered as a valid assumption and the prices of these other DPP-4 inhibitors are compared in the Indian Market, it is observed that the prices of these other options despite such large volumes and with side effects, are also in the same range (i.e. Rs. 42 to 58), which are at par with the price of the Patentee's SAXAGLIPTIN (i.e. Rs. 41 to 49). The only exception is tablet ZITAMET (SITAGLIPTIN) by Glenmark, which is priced from Rs. 29 to 32. This observation relating to the prices of SAXAGLIPTIN and other three DPP-4 inhibitors is made on the basis of per day requirements of the medicines presented in the Applicant's submission dated 15th December 2015. The question therefore comes in my mind, if other three DPP-4 inhibitors despite such large volumes, having the same prices/ ranges of prices, are affordable in India, then how one can say that the prices of SAXAGLIPTIN are not affordable in India. As a result, it is difficult for me to believe that the Patentee's tablets ONGLYZA and KOMBIGLYZE are being sold at excessively high prices in the India and that can be termed as a barrier to access of SAXAGLIPTIN. This conclusion is drawn only on the basis of evidences led by the Applicant of their respective prices in the Indian market.

29. Further as stated under Para above, in absence of any comparative study or authentic evidence that SAXAGLIPTIN is the best and the latest option with no or comparatively less side effect/s over others for the treatment of Indian patients, it is likewise difficult for me to believe that due to its excessively high price (Rs. 41 to 49), SAXAGLIPTIN is not available to the general public at a reasonably affordable price when other three options, LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN falling under the same category despite such large volumes are also sold at similar prices (i.e. Rs. 42 to 58) in India.

30. The Applicant also submitted that the cost of importing one tablet of ONGLYZA and KOMBIGLYZE in India by the Patentee/ Respondent is only about Rs. 0.80 and Rs. 0.92 per tablet, respectively. They have based their calculations on the figures submitted by the Patentee/ Respondent in Form-27 dated 10th February 2014. However, the Patentee/ Respondent is selling the two medicines ONGLYZA and KOMBIGLYZE in the range of Rs. 41 to 49 per tablet. Thus, it has been 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 in their application for grant of compulsory license has proposed its own selling price in the range of Rs. 27 to 32 per tablet; clearly this was several times the alleged cost of import and the Applicant's own argument fail. However, after the notice dated 12th August 2015, the Applicant proposed the revised selling prices in the range of Rs. 11 to 16 in the hearing held on 15th December 2015. The details of the proposed revised selling prices are as follows:

Product	Strength	Price per Strip of 14 tablets (MRP in Rs.)	Price per Unit tablet (MRP in Rs.)
SAXAGLIPTIN	2.5 mg	154.00	11.00
SAXAGLIPTIN	5 mg	220.50	15.75
		Price per Strip of 7 tablets (MRP in Rs.)	Price per Unit tablet (MRP in Rs.)
SAXAGLIPTIN+ METFORMIN XR	5/500 mg	112.00	16.00
SAXAGLIPTIN+ METFORMIN XR	5/1000 mg	113.75	16.25

31. The Applicant argued that IPAB has held that submissions made during the hearing to be considered by the Controller and therefore, new rates proposed by the Applicant will make the said drug available to public at affordable price. The Controller shall use his authority in law to bring social justice, and for this reason alone this application shall be allowed. When asked how many poor people in India were prescribed the patented drug but couldn't buy because of affordability issue, the Applicant showed inability to provide any details in this regard.

32. As further submitted by the Applicant, since other two DPP-4 inhibitors SITAGLIPTIN and VILDAGLIPTIN are also listed along with SAXAGLIPTIN in the list of Essential Medicines for treatment of Type-II DM by Govt. of NCT of Delhi and are also sold at comparatively similar prices, it is difficult for me to infer that SAXAGLIPTIN is the only option for patients in India and it is not made available to the general public at a reasonably affordable price. In fact, the Applicant, in their Application or in their submissions, has not furnished the details of the reasonable requirements of the public in respect to SAXAGLIPTIN, the comparative requirements of SAXAGLIPTIN and other DPP-4 inhibitors, LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN, or any authentic data/ statistics on SAXAGLIPTIN prescription by the doctors over the other DPP-4 inhibitors. Therefore, in absence of evaluation of exact quantum of SAXAGLIPTIN required and the number of patients vis-à-vis the Doctors' prescriptions as against the other options existing in the market, the question of its availability and affordability can't be determined. Whether the patented drug is required by 60 million, 6 million, or 1 million patients, nobody knows and these are merely hypothetical figures by the Applicant. Hence, it is not possible to conclude that it is not available to the general public at a reasonably affordable price. It is especially not possible when other options, which fall within the same class (i.e. DPP-4 inhibitor) and used for the treatment by larger number of patients (i.e. 90% as per Applicant's submission) are also available on the relatively same price.

33. In view of the above, 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

34. The Applicant submitted that even after the lapse of a long period of about eight years from the date of grant (30thApril 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 has also submitted that the working of the patented product in the country is hindered by the importation from abroad.

35. In this regard, as is clearly borne out from the judgment of the Hon'ble Bombay High Court in the Bayer case (supra.), to manufacture in India is not a necessary pre-condition in all cases to establish patent's 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. In the present application, since the Applicant has failed to show the exact quantitative requirement of SAXAGLIPTIN in terms of number of patients requiring it or whether it is in shortage, it is very difficult to conclude whether manufacturing in India is necessary or not. No authentic data, report, evidence, or comparative study has been cited by the Applicant, which could clearly establish/ fix the quantitative requirement of SAXAGLIPIN in India and thus, the necessity of its manufacturing in India.

36. Although each ground under Section 84(1) is independently provided in the Act, the Applicant's failure to *prima facie* make out any of the other two grounds has a consequential implication on this ground of manufacturing in India because whether the patented invention is required to be worked in the territory of India would be decided only on the basis of its reasonable requirements at affordable price in India. As mentioned under Clause (a) of section 84(1) above, what is the reasonable requirement of SAXAGLIPTIN in India in the context of number of patients requiring the patented drug has not been clearly shown by the Applicant and thus, the question for necessity of its manufacturing in India cannot be insisted upon. Besides this, by importation, the cost of one tablet of Patentee's medicine (ONGLYZA and KOMBIGLYZE), in the range of Rs. 41 to 49, is in the same range of Rs. 42 to 58, the cost of other three DPP-4 inhibitors LINAGLIPTIN, SITAGLIPTIN and VILDAGLIPTIN in India. Hence, further question for necessity of its manufacturing in India is also difficult as a prerequisite to say whether patent is worked in India.

37. Question whether enough quantity is being imported and whether the requirements justify the investment in facility for manufacturing in India? The Applicant provided the sale figures of SAXAGLIPTIN and its combinations with METFORMIN in the World, US and Europe for the year 2012, 2013, 2014 (Table 1) in their submission dated 15th December 2015, but it did not provide the same in the context of India. The submission further provides the figures of % share of the sales and the diabetic people in India and US with respect to the World figures for the year 2013 (Tables 2 and 3).

The tables show % shares of the US and India with respect of diabetic patients, which are 6.39% and 17.042%, respectively. The tables further show % shares of the US and India with respect to sales of SAXAGLIPTIN, which are 70.1058% and 0.0228%, respectively. It could be therefore easily concluded from the said % shares of the diabetic patients and the sales why the manufacturing of SAXAGLIPTIN in India is not being done, because % share of the sales in India is less despite having large % share of the diabetic patients, as compared to US which has high % share of the sales despite having less % share of diabetic patients. Further, no evidence is led pointing any shortage of the said drug in India because of its importation only. Total volume requirement vis-à-vis quantity imported and availability at reasonable price shall only justify the manufacturing as a necessary pre-condition for patent being worked in India.

38. In view of the above, the Applicant has failed to establish 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

39. As the Applicant has failed to provide evidence along with application or during hearing or by supplementary submission and failed to satisfy the Controller regarding any of the grounds as specified in Section 84(1) of the Act, I am therefore of the view that a *prima facie* case has not been made out for making of an order under Section 84 of the Act. Therefore, the application for grant of compulsory licence by the Applicant is hereby rejected.

Dated this on 19th day of January 2016

(O. P. Gupta)
Controller of Patents