India: Compulsory license application for "Saxagliptin"

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Introduction

"Saxagliptin", a dipeptidyl peptidase-4 (DPP4) inhibitor which is prescribed for the treatment of Type II diabetes mellitus made headlines recently when an Indian pharmaceutical manufacturer - Lee Pharma Limited — filed a compulsory license application for the drug at the Indian Patent Office. This drug is patented in India by AstraZeneca AB and sold under the brand names "Onglyza" and "Kombiglyze". Given that in India more than 7% of its 1.2 billion people are afflicted with diabetes - the entire pharma community is watching the case keenly.

The story so far

Compulsory licensing in India first caught attention in 2012 when Natco Pharma succeeded in obtaining such a license for Bayer's anticancer drug Nexavar (sorafenib). The following year, another Indian generic, BDR Pharma sought a compulsory license for Bristol-Myers Squibb's (BMS) Sprycel (dasatinib). But, BDR Pharma failed in its attempt for not having met the precondition of making sufficient prior efforts at negotiating a voluntary license. Lee Pharma's application is the third of its kind under Section 84 of the Indian Patents Act. In its application, Lee Pharma has tendered evidence of reasonable efforts made towards negotiating a voluntary license from AstraZeneca. Alleging AstraZeneca's non-responsiveness to its license request, Lee Pharma asserts that:

- Even 8 years after grant, AstraZeneca's patented drug is "not worked" i.e., manufactured locally;
- Reasonable requirements of the public' have not been met because AstraZeneca's drug is sourced entirely from the US and Ireland and upon import, a majority of the drug is re-exported to other countries which has led to more than a 99% shortage in India; and
- The drug is "not available to the public at a reasonably affordable price" because saxagliptin is imported into India at a cost of INR 0.80- 0.92 per tablet but sold at 40 times the price of INR 41-49 per tablet.

After review, the Patent Office has served a preliminary notice to Lee Pharma. While acknowledging that Lee Pharma has made reasonable efforts to obtain a license from the patentee, and has the capacity to "work" the invention in India, the Patent Office is of the opinion that a prima facie case has not been made out.

Particularly, on "working" of the invention, the Patent Office states that manufacture in India is not a mandatory pre-condition to establish working in India and no data was furnished by the applicant to substantiate its position regarding the manufacturing capability of the patentee. With respect to "availability", the Patent Office noted that apart from Saxagliptin, there are 3 other medicines available for treatment of the same disease in India, such as Boehringer's Linagliptin, Merck's Sitagliptin and Novartis' Vildagliptin, and Lee Pharma has failed to furnish any details to evaluate the "market demand" as a result of these substitutes being present in the market. Finally, on "pricing", the Patent Office stated that Lee Pharma's proposed pricing of INR 27-31 per tablet is not a significant discount over AstraZeneca's retail price and also is several times over the cost of import over AstraZeneca's drug. Thus, there is no pricing disadvantage.

The Road Ahead

Lee Pharma is expected to enter a request for a hearing to contest the preliminary findings of the Patent Office. In a related development, infringement suit based on the same patent has been filed by AstraZeneca against Lee Pharma where the latter has deposed through an affidavit that its generic version has not been launched in the Indian market and that it has no intention of launching or exporting the patented drug until the compulsory license application is finally decided.

As the IP fraternity waits for the next chapter — the events which have unfolded so far show that, contrary to majority opinion, India is not rushing to decide matters in favour of its generic players but is ready to adopt a balanced, non-biased approach while not compromising on its public interest principles enshrined in the law.