Pharma & Healthcare Update

September 03, 2015

PHARMA ALERT

- India may unveil new IPR policy in two months
- Lee Pharma fails to make out prima facie case for grant of compulsory licence over AstraZeneca's diabetes drug
- Eli Lilly denied patent over alcohol de-addition molecule

INDIA MAY UNVEIL NEW IPR POLICY IN TWO MONTHS

The secretary of the Department of Industrial Policy and Promotion (DIPP) has been quoted as saying that India may unveil a new intellectual property rights (IPR) policy in as soon as two months.

This development is significant considering the DIPP is tasked with the formulation of policies relating to IPR in the fields of patents, trade marks, industrial designs and geographical indications of goods and the administration of regulations and rules made under those policies. The news report indicated that the new policy will strive to strike a balance between patent rights and affordable access to medicines.

It will also be interesting to note the treatment given to the provisions on 'ever greening' and 'compulsory license' of patents in the new policy, as these provisions have attracted a lot of debate at international and domestic level in the past few years.

LEE PHARMA FAILS TO MAKE OUT PRIMA FACIE CASE FOR GRANT OF COMPULSORY LICENCE OVER ASTRAZENECA'S DIABETES DRUG

On 29 June 2015, Lee Pharma Ltd filed an application before the Indian Patents Controller to seek a compulsory licence for AstraZeneca AB's patent relating to Saxagliptin. Saxagliptin is a dipeptidyl peptidase-4 (DPP4) inhibitor for the treatment of type II diabetes mellitus.

After considering the evidence produced by Lee Pharma, the Indian Patents Controller issued a notice on 12 August 2015, recording its finding that the application does not make out a prima facie case for the grant of a compulsory licence.

As per the Indian Patent Rules 2003 (framed under the Indian Patents Act 1970), Lee Pharma has one month from the date of the notice to request a hearing before the Patents Controller. It is presently unclear whether Lee Pharma has filed the request or not.

ELI LILLY DENIED PATENT OVER ALCOHOL DE-ADDITION MOLECULE

In June 2010, Eli Lilly and Company applied for a patent over "kappa selective opioid receptor antagonist for treating anxiety disorders selected for panic disorders, obsessive-compulsive disorder, social myopia, and post-traumatic stress disorder and ethanol disorder, in a patient in need thereof". The claim was later amended to "kappa selective use of opioid receptor antagonism activity for the treatment of alcoholic disorder".

In a final order dated 19 August 2015, the Indian Patents Controller rejected Eli Lilly's patent application on the ground that the claim fell under section 3(d) of the Indian Patent Act 1970 and therefore does not qualify as an "invention" worthy of being granted a patent.

Section 3(d) states:

"The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant".

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– Anay Shukla & Khushboo Baxi
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