PHARMABIZ.com
india's most comprehensive pharma portal

USPTO official lambasts issuance of compulsory licensing by Indian patent office

Ramesh Shankar, Mumbai
Monday, July 02, 2012, 08:00 Hrs [IST]

The first-ever compulsory licensing (CL) issued by the Indian Patent Controller on March, 9 2012 to an Indian generic company to manufacture generic version of Bayer's cancer drug Nexavar (sorafenib tosylate) has come in for severe criticism by the US Patent and Trademark Office (USPTO).

According to reports, USPTO deputy director Teresa Stanek Rea lambasted the use of compulsory license by Indian Patent Controller in March this year.

"...disappointed in March, when India's patent office ordered Bayer AG to grant an Indian generics maker a compulsory license for the cancer drug Nexavar (sorafenib tosylate), ruling that it was expensive for most people to afford. We are consistent on our efforts ... of trying to stop these compulsory licenses," Rea stated.

"...believes the issuance of the Indian compulsory license was in violation of the Agreement on Trade Related Aspects of Intellectual Property Rights, an international pact administered by the World Trade Organization which sets minimum standards for intellectual property regulation," Rea, who is also the deputy undersecretary of commerce for intellectual property, presented to a US Congressional Committee (House Judiciary Subcommittee on Intellectual Property, Competition and the Internet) on the CL in India. "I was quite dismayed and surprised when they issued that compulsory license," Rea told the committee.

The Indian Patent Controller issued the compulsory license to the Indian generic manufacturer Natco to manufacture generic version of German pharma major Bayer's patented cancer drug Sorafenib Tosylate due to it being unaffordable. The compulsory license allows the Indian company Natco to produce a generic version of the drug that will be priced 97 per cent lower than Bayer's price. Natco will pay six per cent royalty on net sales to Bayer.

Meanwhile, experts in the field have differed with the USPTO official. Compulsory licensing cannot be equated to IP infringement as it is the authorisation given by the government, patent office, judiciary or the competition commission to a third party to produce, market and supply a generic version of a patented drug, without the consent of the patent holder. Under Article 31 of the TRIPS Agreement, CLs are a legally recognised means to overcome barriers in accessing affordable medicines. Generic competition has not only led to significant price reductions but also brings with it benefits of multiple quality suppliers. The CL in India made the oncology drug 31 times cheaper or three per cent of the price that Bayer's charged for sorafenib tosylate in India, experts said.

USPTO is working to stem the tide of IP infringement in foreign countries by the use a host of training programs and educational efforts aimed at foreign officials and judges along with the

placement USPTO overseas IP attaches in Thailand, China, Russia, India, Brazil and Egypt. The government of India, the Indian Patent Office and the Indian judiciary must immediately address this plan to prevent any further CLs from being granted by influencing Indian policy makers, officials, judges through trainings organised by the USPTO IP attache in India, they said.