CII Conference on Intellectual Property Rights: Challenges and the way Forward for the Pharmaceutical Industry.
December 15, 2010, Chennai, India

Session II: Impact of 'Trips Plus' Rules on Pharmaceutical patenting
Chairman's speech

January 1, 1995 ushered in a new era, when the agreement of the World Trade Organization (WTO) on Trade-Related Aspects of Intellectual Property Rights (TRIPS), became effective for its member countries. This Agreement significantly changed the international Intellectual Property (IP) regime with the introduction of the principle of minimum intellectual property standards.

This would, therefore, mean that any IP related agreement that will negotiated subsequent to TRIPS between WTO members can only create higher than the specified minimum standards.

The 'TRIPS-plus' concept usually would encompass all those activities, which are aimed at increasing the level of IP protection for the right holders beyond what is stipulated in the TRIPS Agreement.

Some section of the civil society nurtures a view that 'TRIPS Plus' provisions could significantly jeopardize the ability, especially, of developing countries to protect the 'public interest'.

Common examples of 'TRIPS plus' provisions could include:

- Extension of the patent term beyond usual twenty-year period
- Introduction of provisions, which could restrict the use of compulsory licenses (CL)
- Delaying the entry of generics

The raging debate around protecting regulatory data as indicated under Article 39.3 is perhaps unique in terms of its impact on the generic industry and very recently on the Government of India.

Be that as it may, the moot question is, even if these provisions are 'TRIPS Plus', are these good for India?

Key arguments in favor of: 'RDP is not good for the country'

1. Extends Patent life and Promotes Evergreening:

   However, there is hardly any evidence that RDP does not get over well before the patent expires. Thus RDP does extend the patent term of a product and hence is not 'Evergreening'.

2. Will delay the launch of generic:

   A robust 'Data Exclusivity (DE)' regime is effective in the USA since over decades. Despite DE, we witness quickest generic launch of generic in the country. Though the generic players of India, by and large, are up in arms against RDP (protection against disclosure and unfair commercial

use of the test data) in India, highest number of ANDAs are being filed by the Indian companies, just next to the USA, in that country despite a stringent DE provisions being in force there.

Despite very stringent IPR regulations there, Generic prescriptions are quite popular in the USA. Around 62% of the total prescriptions in that country are for generic pharmaceuticals.

Key arguments in favor of RDP:

The Government of India appointed 'Satwant Reddy Committee' report (2007) highlights the arguments on the subject. The report categorically recommends that RDP is good for the country and should be introduced in a calibrated way.

The committee examined two industries:

- Pharmaceuticals
- Agrochemicals

Currently a 3 year RDP for Agrochemicals is in place in the country, vindicating the fact that even if section 39.3 of TRIPS Agreement is considered 'TRIPS Plus', this is definitely good for the country, as the Government has accepted the recommendation, at least, for the Agrochemical industry.

Thus the points to ponder: is Section 39.3 'TRIPS Plus' at all?

Be that as it may, our country needs to decide now, whether the terminology 'TRIPS Plus' should be a taboo in India, despite its relevance for the country or 'TRIPS Plus' provisions do not matter, as long as it is good for the people of India. Distinguished speakers in the panel, I am sure, will dwell on this topic in the next one hour or so. Thereafter, we shall have a Q&A session, before we break for lunch.

Thank you.

By Tapan Ray