

## Indo-US IPR Conundrum

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The much hyped 'stand off' between US and India on India's current IPR regime and concerns expressed that India is not fully compliant with TRIPS Agreement is more a myth than a reality. The differences are relatively minor and even though India is in the Priority Watch List of USTR, it is more of an internal alert system within US with no relevance to India or her position in the global trading community or the WTO. In fact, U.S. has no pending serious disputes with India in WTO's Dispute Settlement Body, unlike against China and many other Countries including ones in Europe, Latin American countries and Japan.

The Indian Prime Minister's visit to the U.S and bilateral discussions on a variety of trade and economic issues came just a few months after India refused to sign the Trade Facilitating Agreement drafted at the Inter-ministerial WTO Meeting of member countries at Bali in December 2013. India's contention that any Agreement which can possibly jeopardise India's right to ensure food security through the much needed subsidy system is not acceptable. Even though the Indian stand was not received well by most of the developed countries including the U.S.A, till recently, it appears that now there is a tentative bilateral agreement that the issue will not be a bottleneck for finalising the Trade Facilitating Agreement which was at the heart of the Bali Round. Even then, there are still several other areas of concern, such as, the poor standards of implementation of the TRIPS Agreement in India, Section 3(d), terms for provisions for compulsory licenses and pre-grant opposition in the Indian Patents Act 2005, lack of provisions for Data Protection, all affecting the U.S. pharmaceutical sector. Some of these issues would have come up during the Modi-Obama meetings in Washington. Presumably as a follow up of these discussions, Washington and Delhi are reviewing all pending issues between the two countries related to trade, tariffs, subsidies, market access, IPR protection etc.

At the meeting of the Indo-US Trade Policy Forum which met in Delhi in November 2014, co-chaired by India's Commerce Minister, Mrs. Nirmala Seetharaman and the US Trade Representative Michel Froman, it was agreed that in the matter of IPR, interests of 'creative

industries' such as, the Pharmaceutical industry will be protected while ensuring enhanced access to quality health and affordable medicines. The details of modalities to achieve these twin objectives were reportedly not discussed. It is believed that these issues were discussed further during President Obama's visit to India in January 2015.

### **USTR Annual Report 2014**

The Annual Report of the Office of US Trade Representative (USTR) extensively deals with the current status of implementation of IPR protection systems among its trading partners. The US had included India along with Algeria, Argentina, Chile, China, Indonesia, Pakistan, Russia, Thailand and Venezuela in the Priority Watch List announced in the Special 301 Report published in April 2014 by the Office of the USTR. In addition, of the 95 countries reviewed by the US Trade Office, 26 countries are in the Watch List. Further, the Indian case will come up under the contentious 'out-of-cycle-review' by the U.S. Trade Office. The reasons for inclusion of India in these Watch or Priority Watch lists as well as for 'out-of-cycle-review' are stated to be non-compliance with the provisions of the TRIPS Agreement either due to inadequacy of legislative support or lack of proper endorsement of IPR, thereby denying exclusive market access for parties who rely on their Intellectual Property to improve trade.

### **The U.S. Stand and WTO**

While the U.S. in its internal law talks of possible retaliatory action against members who violate

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International treaties and US's trade interests, including WTO Agreement, no member of WTO can unilaterally take such action without the sanction of the WTO's Dispute Settlement Body. The U.S. feels that utilization of the flexibilities available under the TRIPS to members is adequate to protect their national interests. So too, in a recent change in mindset, U.S. now proclaims full endorsement of the two most important Articles affecting developing countries under the DOHA Declaration of November 2001, even though the Round has not been finalised even after 13 years. Thus, the U.S. respects members' rights to protect public health and promote access to medicines for all (Para 4) and the rights to grant compulsory licenses in a manner consistent with TRIPS and the DOHA Declaration, including the right to export patented drugs to other members (Para 6) who lack technology skills to produce them.

### Section 3(d) of Indian Patents Act 2005

The Section 3(d) in the Indian Patents Act 2005 which has attracted major criticisms in recent years is the Section dealing with standards of patentability of new inventions required for granting exclusive rights through the patent system. The Section says that inventions which are mere discovery of a new form of a known substance (some examples are quoted) and do not result in increased efficacy of that substance are not patentable. What is implied here is that merely providing a new form of a known substance which has no improved activity (strangely better safety has been left out in the statement) or new therapeutic profile is not a patentable invention. It does not in any way mean that, if a new form, however simple it is to produce, has better activity than the known molecule, is not patentable. In fact even without resort to Section 3(d), the patent examiner can very well judge an invention as non-inventive (obvious) if he feels that the reported improvement is not significant enough to be termed 'inventive'. TRIPS is totally silent on the matter and hence does not prescribe any specific standards for determining patentability. In the Indian Patents Act, under Section 2(ja), inventive step is defined as "any invention that involves technical advance over existing knowledge". Unfortunately, the prolonged case on *Gleevec* lasting over 5 years and the wide publicity that followed the judgment, which denied grant of the patent to Novartis, gave rise to unnecessary concerns about the introduction of Section 3(d) in the amended IPA (2005) and its impact on grant of patents.

Regarding non-compliance with Article 27 of TRIPS, which mandates that all fields of technology are eligible

for grant of patent rights, the TRIPS Agreement itself provides exceptions for example in the case of microorganisms, software and new plant varieties. In all these cases differential treatment is permitted.

### Section 84 of Indian Patents Act (1970)

Provision for grant of Compulsory Licenses is part of the Patent Acts of many countries and there have been many cases of issue of Compulsory Licenses in those countries. Under the Indian Patents Act, Compulsory Licenses may be issued in cases where the needs for the patented product has not been met and in cases where the country needs the drug to meet national emergencies and urgent medical needs. Like all the other countries, India has also invoked this provision in very few cases, in fact only in one case during the last ten years.

### The Imitanibmesylate (*Gleevec*) and Sorafenibtosylate (*Nexavar*) Cases

Two major irritants to R&D based Pharma companies have been India's recent decisions on patents and patent applications on two important anti-cancer drugs, *Gleevec* (Novartis) and *Nexavar* (Bayer). In the first case, the Indian Patent Office rejected Novartis's Application for grant of product patent on the question of lack of inventiveness as defined under Section 3(d) of IPA 2005 and in the second case, a compulsory license was granted to the Indian company NatcoPharma since the patent holder had not met the demand for the drug in India and the costs of treatment made it totally unaffordable to the patients who needed them. Against a treatment cost of Rs. 280,000 per month, the Supreme Court directed Natco Pharma to sell the drug at Rs 8800 and pay Bayer a royalty of 7% of sales turnover. Even though the TRIPS Agreement does not take into account the economic factors such as, high costs of treatment while considering patentability of an invention, invoking the provisions under DOHA Declaration would justify the grant of Compulsory Licenses if they improve access to medicines at affordable prices. Both the cases, initially decided by the patent office went through the process of appeals to the Appellate office, the High Court and ultimately, the Supreme Court of India, which gave the final judgment.

The Case of Gilead's anti-Hepatitis C drug, *Sofusbuvir* (Sovaldi), which has been priced at \$ 84000 per course of treatment in the U.S, is yet another case of newer biologicals being unaffordable to patients. However, unlike in the cases of *Gleevec* and *Nexavar*, the Innovator Company Gilead has been negotiating with

Indian Companies, offering voluntary licenses for manufacture and sale of this drug to Indian manufacturers to produce the drug under license (with royalty payment). Considering the large market that India provides, this indeed is a more prudent strategy on the part of the innovator companies to voluntarily offer licenses to Indian companies to manufacture and sell the drug in the event the innovator company has commercial or strategic reasons for not making the drug available and accessible in India. It is obvious that these new developments are no cause for concern for the R&D based Pharma Companies of U.S., Western Europe and Japan, since they offer viable opportunities to expand markets and gain economic benefits. In other words, the new model could very well be making new drugs available through the licensing route to developing countries, at lower prices but much higher volume of sales.

### **Other Issues**

A few other issues which need resolution are related to provision of Data Protection under Trade Secrets or other new legislative measures and the question of parallel imports based on the principle of exhaustion of rights. The data protection issue has been under consideration of the Government of India and already it has been granted for five years in the pesticide sector. On the latter, the matter is being deliberated among many other WTO members and no consensus has emerged. Strengthening of the procedures and operational systems of the Indian Patent Offices and awareness creation of the challenges and opportunities that IPR protection offers to the innovating community are important. Protection of Geographical Indications (GIs), one of the ill-structured and ill-defined IP instruments in TRIPS and its impact on trade in GI protected commodities in global markets is another area of ambiguity. Even though India has registered over 200 GIs, it is still not clear as to how these registrations are to be used for market gains and improving global trade.

### **What Does the US Want?**

Among all the member countries of WTO, the U.S. is the most innovation driven, inventor friendly and IPR savvy country. The fact is in evidence when you see the large number of US patents granted and new products coming out, based on scientific and technological innovations due to the efforts of scientists and technologists. From the US perspective, at least the major economies including the emerging ones, among which India is one of the leaders, should further strengthen their IPR regimes through

additional systems of protection beyond the requirements under TRIPS (TRIPS PLUS). The TRIPS Agreement states that

the 'members may, but shall not be obliged to implement in their law more exhaustive protection than is required under this Agreement'.

The U.S. also believes that joining the League of Nations which have TRIPS PLUS provisions in their National Patent Laws, is beneficial to promote an innovative climate in India. U.S. also argues that a stronger IPR protection system is advantageous to India in view of its dominance in Software and Movie industries, where copyright piracy across the World is a major problem.

### **Where India Needs TRIPS PLUS Provisions**

There are, however, areas, for example, protection of Biodiversity and Traditional Medicines, where India should possibly consider additional protection systems in the TRIPS PLUS mode which will be beneficial to Indian interests. In spite of various attempts to develop an equitable protection system for traditional systems of knowledge and products based on them, so far there have been no breakthroughs on that front. While Convention on Biodiversity held in Rio de Janeiro in 1992 has led to legislative support (outside TRIPS) to protect bio-resources from unauthorized exploitation by third parties, in most members of WTO, implementation has been tardy as of now. There are issues of ownership of Bio-resources, rights for their utilization and systems which will ensure proper rewards to the owners whether they are individuals, communities or even nation states. As of now, proper systems are not available or are practiced in any of the signatory countries. Clarity on procedures is important since bio-resources are important elements for the discovery of newer healthcare and agricultural products.

India has no reason to consider any changes to the prevailing IPR protection system since, in letter and spirit, the Indian IPR System is in full compliance with the TRIPS Agreement. India is putting in place a robust IPR operational system to implement IP Laws in the country and the coming decade will ensure effective enforcement of all the provisions in the Indian Patents Act 2005, regardless of the origin of the application, subject matter or the nature of the invention. India has in place, a fair and impartial judicial system which handles issues and litigations related to IPR legislations in a highly professional and equitable manner.