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Intellectual Dialogue: Need of the Hour for India US Trade Relation

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Abstract:

There is a requirement of progressing from the jurisprudence of IPR from an individualistic perception to utilitarian analysis and now to IPR-Human rights ideology. The victims of counterfeiting drugs are patients or consumers rather than IPR holders and therefore the issue requires to be addressed from an entirely different premise. On this premise the only laudable argument is to prevent the manufacturing of such spurious drugs that would affect the health of people. This may be done by some miscreants either by deceiving the public about the contents or by presenting the drug as being of such brand, which it is not. This would prevent the consumers from being deceived and promote health in any nation. On this premise, the production of generic drugs in India in the regulated manner does not undermine any public health argument and therefore cannot be treated at par with a counterfeit drug. Thus, it is rather the premise that has to be changed before putting forth any argument in favour or against the compulsory licensing in India to address the real problem faced by millions around the globe.

Keywords: *jurisprudence, Human rights, foreign policy*

India-US Relations:

The foreign policy of India and US towards each other has been very fragile with the beginning of their relationship after Independence of India, in cold war circumstances. Despite that, the countries developed a strategic alliance, especially during the Kennedy Administration. But even today the past relationship of India with Soviet Union and the recent close alliance of US with Pakistan have always stalled the development of complete trust between the countries. Trade is said to break those barriers where even diplomatic dialogues fail against strong walls of political disturbances. Thus, the international relations between the countries took a diversion in the interest of their economic development. But the beginning of this journey was also not smooth, especially at the time when India agreed to devalue its currency for the want of increased foreign aid from US and others during the time when she was in huge deficit. The US has also always perceived Indian economy as a protective economy and therefore pressed India more for liberalizing its markets and found an occasion during food shortage in

India in 1960s.[1] However, when India did not receive much aid and help after devaluation of its currency, it refused to liberalize its economy and re-introduced import substitution.[2] This is perceived by many as a strong economic and political message that a country like India would not bring such drastic changes merely out of international pressure.[3]

Finally India liberalized its economy in the 1990s and this was further assured by India's participation in the Uruguay Rounds leading to the WTO GATT mechanism by 1995. The diplomatic relations grew further with strengthening of trade relations between the nations. However, in spite of the growing trade between the nations, many trade issues are culminating that are again leading to situations of deadlock on its continuance.

There are many such examples and the latest trigger is the allegations of the US against India on violations of Intellectual Property Rights standards and the former's threat to include India in the Priority List denying India of certain trade benefits for which it is currently eligible based on the report of USTR, under its Trades Act 1974. USTR is one of the US federal agencies that engage in identifying the foreign countries that offer weak IPR protection or do not give fair market access to US citizens. Such information may be derived from different industry sources but primarily from other US federal agencies like USPTO. The USPTO has special IP attaché programme in which it designates certain US officials in foreign countries to monitor the IP protection therein and in turn advice the US government on its policies as well as the business relating to IP in the US and at the same time organizes training to the officials in the host country and advises them on IP Protection system in the United States. The personnel for this IP attaché task have been deployed in different countries like Egypt, China, India, Thailand, Russia and Brazil but recently a more detailed examination of the IP laws in China, Thailand and India had in the past been conducted leading to the conclusion that IP laws as well as the enforcement of the existing laws is quite weak as compared to the standards of the US IP laws. This led the USTR to place them under the priority list under its Special 301 functions. In fact, as per the latest 2014 Special 301 report ten countries have been put on this list including India, again.[4]

1. Major Issues alleged in Special 301 Report.

The April 2014 report of USTR covers a wider spectrum of issue than its previous reports. Not only has the coverage of the countries increased but also the level of allegations. Throughout its reports China and India have been constantly referred and more recently another SAARC country has been added along with India, i.e. Pakistan. The major allegations against India have been:

- Copyright Piracy over the internet
- Compulsory licensing of patented technologies
- Trademark counterfeiting and large scale counterfeit products.
- More particularly, the counterfeiting problem in the pharmaceutical industry
- Trade-restrictive measures impeding access to healthcare.

1.1 Copyright piracy is understood to mean any unlawful use or reproduction of a material that enjoys the copyright protection. This could be books or songs or anything that may be available even in electronic format. An infringement relating to software would fall under copyright violation and not patent violation as is generally misconstrued. These days information is so rampantly available in electronic form that its reproduction, legally or illegally, can be done quite easily. Thus, any protection of copyright has gained more significance in the context of any use and reproduction in the internet of a protected item. As they say that technology gets transmitted across boundaries faster than adoption of laws based on international standards, the issue of copyright violation over the internet became an agenda to be addressed at international fora. In India also, the use of technology and internet has significantly transformed the access to copyrighted material.

At present India is asserted to be one of the top seven countries with most number of publishing being done and most of them being in English.[5] That the issue of copyright piracy is not new in India is apparent form the report sponsored by the Government of India in 1997 itself where estimates about total illegal application of software in India was calculated to be about Rupees 1063 crores, which was said to be 44% of the total domestic software market(Rs 2410 crores).[6] The issue of software piracy is, however, not akin to developing countries like India. A real life example of the extent of software piracy is showcased in the website of SIIA[7] where the infringer had purchased a software and copied it to the other system and the same was detected only when an employee contacted the software provider for non-performance of the software when it was detected that the same was illegal version and such similar investigated cases of software piracy in the US have been illustrated there.[8]

Other new forms of copyright infringement have developed with more access to internet, like in the case of illegal downloading of MP3 songs and pirated movies, which until then was done by purchase of pirated movies in CDs and this is the reason why the 2014 report makes a special focus on this.

AS stated above, the phenomena is global and needs to be addressed by all countries alike due to the continuance of violations despite

laws. It is a matter of concern for India too not merely from the point of view of foreign investments but because of the loss of to its own economy. Piracy and counterfeiting with respect to consumable goods or cosmetics could lead to more deteriorating effects than just economic loss to the nation. This is precisely, the next line of argument advanced by the US.

1.2 Trademark counterfeiting and large scale counterfeited products with special focus on pharmaceutical products: Counterfeiting with respect to medicines is one of the major challenges faced by many countries and is seen as a major IP violation when wrong medicines are sold in the brand name of another actual medicine, that is known as trademark counterfeiting, or by selling the medicine with a different brand name but with the claim that the formula is rather the same. Black's Law Dictionary defines 'counterfeit drug' as a drug made by someone other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceive or defraud, and then marketing the copied or forged drug as the original.[9] The latter phenomenon of selling of counterfeit medicines is also equally perceived as loss to the IP holder of the genuine branded variety. The literal meaning of counterfeiting may however differ from country to country and it is to be seen if the Indian IP laws actually permit drug counterfeiting as is asserted by the US reports. The particular instance is that of grant of compulsory licensing whilst the patent still exists.

1.3 Compulsory Licensing: Compulsory Licensing is perhaps the core arena of dispute between the two countries and is rather perceived as a tool by India to promote protectionism in its infant pharmaceutical industry that survived all these years through the science of genetic engineering that was encountered through WTO by forcing India to provide product patent. On the other hand, compulsory licensing is perceived by even other countries as a mechanism that helps maintain a balance between the inventor's interests and the public purpose in granting the patent. This balance could even be successfully secured in WTO TRIPS also in its Article31. Thus, having secured the validity or acceptance of such a concept, the parameters for its validity in Indian IPR remain on its adherence to the WTO form and conditions and that of allowing the same while the patent is still subsisting. The second argument flows from US' assertions of allowing licenses for production of generic drugs only when the patent period has expired. But US still has another allegation even with respect to the period of patent or rather the extension of patent upon modification being made to this existing protected patent. The same is not permitted under section 3(d) of the Patent Act, 1970.

1.4 Enhancement not equivalent to Invention: under the Indian Patent Act, there can be a patent for mere enhancement in the existing product as invention requires something more than mere addition to its expediency. There may be betterment to the product but invention requires higher parameters to qualify for a patent. This way, unnecessary extensions to the patent period for the same product is prevented. Thus, even as per the US laws, production of generic drugs or any enhancements to it by third persons after the expiry of the initial patent period would still not be permitted. This extension of patent period because of mere modifications to the existing product is not permitted under the Indian laws.

No doubt, the Indian laws are different from the US laws, although both are obliged to maintain the minimum standards of TRIPS. Before analyzing the Indian laws, especially its patent laws, a brief sociological approach may be adopted to make an evolutionary study of the IPRs and its laws.

2. India and Intellectual Property:

When India enacted it Patent and Designs Act[10], it contained the provisions of both product patent and process patent. But it were the foreigners who had benefited under the Act rather than the native people and nor did it promote the new researches in science and development in the industrial sector. This Act was, however, modified after the recommendations of a committee under Justice (Dr) Bakshi Tek Chand which was formed in 1949 to examine if the existing patent law promoted innovativeness nor not. But the committee's recommendations of granting compulsory licensing could not be implemented due to the Bill getting lapsed. It was rather the Ayyangar Report that highlighted that in no other country patents for food and medicine was unrestricted and absolute. It was emphasized that for such crucial sectors there should be not product patents and by doing so competition and innovation would better prevail in the market. This is how The Patent Act, 1970 came to be enacted. But the Act came into force in 1972 by replacing the 1911 Act.

2.1 India's previous WTO Disputes on IPR:

India is one of the founding members of WTO institution. Yet, there were many Agreements with respect to which India had disagreements. But owing to the compulsory adoption of TRIPS India had to bring different changes to its IPR regime. Ever since that, the Intellectual Property Laws in India have undergone drastic changes, especially its Patent Laws and introduced a sui generis model legislation of Protection of Plant Varieties and Farmers' Rights Act. the change in the Indian IPR Regime is mostly as a result of the TRIPS obligation. Rather it was due to the

two prominent cases that were resolved through the WTO DSU forum that India introduced a system in compliance with TRIPS minimum standards[11] for granting of marketing rights and thereafter the grant of product patents.

2.1.a Case 1: United States of America against India[12]

This case initiated by the United States on 2nd July 1996 requesting for consultations with India on the issue of India's non-compliance of TRIPS obligations on patents for pharmaceutical and agricultural chemical products. The allegation was that the provisions of Articles 27, 65 and 70.8 were not complied by India. Article 27 mandates grant of patents and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced when the eligibility conditions are met. The section carries certain exceptions also. Article 65 deals with transitional arrangement whereby the implementation of the TRIPS standards within one year of its coming into force may be postponed by the developing countries. Article 70 provides protection of TRIPS Agreement to such existing subject matter after the Agreement comes into force and the previous subject matter is to continue protection under earlier conventions like Berne or Paris Convention. But in case Article 27 is not complied by any member country with respect to pharmaceutical and agricultural chemical products, then the same should be protected through some means through which applications for patents for such inventions can be filed irrespective of the rights contained in Part VI including the transitional arrangement rights under Article 65.

Accordingly, a panel was established to reach a conclusion on the matter. It concluded that India had mot complied with its obligations under Article 70.8(a) or 63 of the Agreement. India appealed against this to the Appellate Body. The appellate body also concluded that India failed to comply with Article 70 requirements with the modification that invoking of Article 63 herein was not within the panel's terms of reference.

As a result of this, India assured the implementation of the decision by introducing a new legislation on this aspect. The *Patents (Amendment) Ordinance, 1999* was promulgated by India to implement the rulings and recommendations of the DSB.

2.1.c Case 2: European Communities against India[13]

Another similar case was filed by European Communities on 28th April 1997 in which US claimed its third party interests. This case was also filed for negotiations on the aspect of Product Patents for Pharmaceutical products and agricultural chemical inventions as well as the establishment of proper means for filing for patents and their marketing rights. Again, the panel concluded in

favour of the European Communities. In its final report, India represented that it had enacted legislation on this aspect as part of implementation of the earlier case. Thus, thereafter, India enacted different legislations like the Farmers' Act, Geographical Indications Act and introduced product patents along with other amendments to the Patents Act to make it TRIPS compliant.

3. Product Patent- A genuine requirement?

It is seen how the patent protection was purposefully removed from the Indian Patent Act and thereby allowed reverse engineering to take place for the production of similar drugs even during the prevalence of patent rights over that particular drug. The process being different, despite the product being the same, there would be no infringement of any rights. The benefits to India were many as most of the patents over the earlier version of the product were based outside India and rather became an alternative to import substitution. This process of genetic engineering requires little input cost and this was much cheaper as drug development and research put into its development need not be undertaken by the producer. In the contrast, the original patent holder has to invest not only huge capital but also in the manpower and in the number of years of hard-work. The fruits of the benefit are however denied due to subsequent production of the same product by a different procedure, which is nothing but merely reverse engineering.

Therefore, the apprehension of the patent holders seems legitimate in the light of the fact that their share of profits cannot be compromised due to production of generic drugs while their right is still subsisting. The whole issue of process patent and product patent holds little importance to the consumers of the generic drugs. These generic drugs are absolutely as effective as the original branded drug and required to pass through the required regulatory standards.[14] At the same time, the branded ones are so expensive as compared to the generic ones that they are often unaffordable by the people in not only developing countries but also developed ones. When Novartis was able to get exclusive marketing drugs in India over the generic drug producers in India it fixed the price of the drug at US 2666 per month per patient whereas the local generic producers were charging about a few hundred US dollars for the same. As these medicines do not have to incur expenditure on promoting their brands, their cost price becomes lesser by that margin.

4. Access to medicines and Patents

Access to medicines is a critical issue in India and in its neighbouring countries. More surprising is the finding of the World Bank that such huge cost of medicines may be a contributing factor in pushing about

2% of such population into poverty.[15] As per the WHO, the cost of medicines accounts to 25-70 % of overall health care expenditure as compared to less than 10% in most high income countries.[16] In rural India, about 79% of the total medical expenditure is that of the cost of medicines.[17] One month of combination treatment for coronary heart disease cost 18.4 days' wages in Malawi, 6.1 days' wages in Nepal, 5.4 in Pakistan and 5.1 in Brazil; in Bangladesh the cost was 1.6 days' wages and in Sri Lanka it was 1.5. The cost of one month of combination treatment for asthma ranged from 1.3 days' wages in Bangladesh to 9.2 days' wages in Malawi. [18] Thus, where it is said that medical treatment is a factor of poverty, the major reason is the cost of medicines alone. As per the last WTO survey on access to medicines in Pakistan, the cost of medicines is a concern for many even though the country has tried to combat it through several pricing measures like exemption of drugs from general sales tax. This is mainly due to proliferation of originator brands and wide price.[19]

5. What about ever-greening of Patents?

Even if the making of affordable medicines of a new discovery is delayed for some rough period of twenty odd years in the lines of countries like the US, the issue is yet confronted with another technique devised by such companies by making certain enhancements to the existing product and thereby leading to ever-greening of patents. Ever-greening of patent leads to retaining of right to exclusivity over a patented technology for years even after the expiry of the initial patent term. This issue is not as simple as that of extending the patent period for the original drug but that about targeting the unoriginal technologies based on the original one by adopting various techniques merely to enjoy further exclusivity.

Thus, in the Indian Patent Act section 3 (d) was inserted while allowing product patents so as to prevent such minor additions to the existing technologies without resulting in any enhancement to the known efficacy of the substance or does not employ at least one new reactant or doesn't give rise to a new product. This criterion is in addition to the inventive step required for patent eligibility. This is perhaps also a mechanism of preventing such ever-greening of patents and thereby a matter of concern for the US pharma industry that claims patents on such additional development made to the existing patented products marketed in India. The legal issue involved in the debate between the countries is whether such requirements like that envisaged in section 3 (d) of the Patents Act as being in addition to the requirement of 'inventive step' is valid or not. This was also the issue in Novartis AG v UOI[20], where Novartis impugned the constitutional validity of section 3(d) because of which it could not get patent rights for beta crystalline form of chemical

compound called Imatinib Mesylate. The court interpreted section 3(d) as one of the conditions for fulfilling the criteria of invention under section 2 (f) rather than as a condition over-looking and over-riding the eligibility criteria of invention having been met by the claimant.

6. Conclusion: Suggestions on the 'Intellectual' Dialogue

The trade relations between India and US exhibit some apprehensions from both the sides. Where US perceives India as still a protectionist economy, India fears the ruthless intrusion of the US into not just Indian markets but also into the socio-welfare objectives that it has. Both the apprehensions need to be cleared for engaging into free dialogue without any influences. No doubt, diplomatic relations are not free from internal and external politics but getting succumbed to such pressure is not called for, especially for countries like India and the US.

India should acknowledge the apprehensions of the US about the proper implementation of the IPR laws in India so as to prevent any copyright violations or the trademark counterfeiting. Counterfeiting of medicines is far more challenging task that has to be kept check upon. No wonder, where we have certain cities in India that are called as software hubs, we equally have places famous for selling pirated software. For this not merely stringent laws are required but also effective implementation and persons skilled in the discipline to adjudicate upon the disputes.

There is a requirement of progressing from the jurisprudence of IPR from an individualistic perception to utilitarian analysis and now to IPR-Human rights ideology. The victims of counterfeiting drugs are patients or consumers rather than IPR holders and therefore the issue requires to be addressed from an entirely different premise. On this premise the only laudable argument is to prevent the manufacturing of such spurious drugs that would affect the health of people. This may be done by some miscreants either by deceiving the public about the contents or by presenting the drug as being of such brand, which it is not. This would prevent the consumers from being deceived and promote health in any nation. On this premise, the production of generic drugs in India in the regulated manner does not undermine any public health argument and therefore cannot be treated at par with a counterfeit drug. Thus, it is rather the premise that has to be changed before putting forth any argument in favour or against the compulsory licensing in India to address the real problem faced by millions around the globe. Even from a strict legal point of view, it has been seen how the Patent laws are in strict compliance with TRIPS Agreement. However, despite that the pharmaceutical lobby in the US continued to pressurize India about its patents law and is now rather

trying to impose TRIPS plus conditions. Also, India reserves its sovereign right of determining its own standards of laws like the fulfillment of the inventive step criteria, the same being different in different countries.

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