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TRIPS and India: An Analysis

Dr. Hilal Ahmad, Reader Department of Economics, D.S.N. (P.G) College, Unnao

Recent changes in India's patent policy indicate a paradigm shift in seeking greater protection of intellectual property rights. On one hand, this has given rise to fears being expressed over the impending collapse of local firms; on the other, there is optimism amidst expectation of a large increase in patent activity of domestic actors. This paper analyses the development of Trade Related Intellectual Property Rights (TRIPS) and how India is responding to it. India does not have many options as it is committed to implement the agreement on TRIPS of WTO. All India can do is buy time and implement IPRS in phased manner so that it can safeguard the Indian interest and give some time to Indian industries to invest and develop its research and development work.

Key Words: TRIPS, WTO, R&D, IPRS, Patents Act, WIPO

Introduction

Agreement on Trade Related Intellectual Property Rights of GATT/WTO has been one of the most contentious issues between developing and developed countries. Developing countries, due to lack of R&D (Research and Development) in their respective countries want **flexibility** in Patent Laws. On the other hand developed countries want the **harmonisation** i.e. one size fits all the international patent system, with minimum or no flexibilities. The first major attempt to develop international patent agreement across the countries was Paris Convention for the Protection of Industrial Property in 1883. These agreements have been amended several times the most recent of these being the Stockholm. WIPO (World Intellectual Property Organisation) was established by United Nations in 1974, with the purpose of monitoring international treaties on intellectual property. In the first half of 1980s the efforts were made by WIPO to harmonise the Patent Law between the members of Paris Convention. In 1986, at Uruguay round of negotiations of GATT the issue of Intellectual Property Rights (IPRs) was taken up on the initiative taken by the industrial countries to promote effective and adequate protection of intellectual property rights. Developing countries opposed the inclusion of IPRs under the GATT, as there are special agencies like WIPO and UNCTAD. The developing countries failed to force their views in GATT, in 1994 harmonisation of intellectual property law was taken up and agreement on TRIPs was an outcome of Uruguay Round agreements.

The agreement between member countries of WTO (1 Jan, 1995 GATT was replaced by WTO) on TRIPs was to set minimum standard for patent protection across all countries. TRIPS has tried to take into consideration all major conventions for the protection of IPRs. The agreement covers

all the obligations that members have towards each other under the Paris Convention, Berne Convention, Rome Convention, etc. The WTO and WIPO have also entered into an agreement in 1996, one of the objectives of this agreement "desires to establish a mutually supportive relationship between them and with a view to establish appropriate arrangements for cooperation between them". USA was not in favour of substantive harmonisation of patent laws till 1990s as initiated by WIPO, and them a new approach was adopted for promoting harmonization of Patent laws i.e., one that focuses entirely on the formality of the national and regional patent application. This forms the basis for the negotiations and the adoption of the PLT (Patent Law Treaty) in 2000. In PLT negotiations WIPO members and participating organization made it clear that substantive harmonisation of patent laws had to be eventual outcome and that the PLT was the initial step.

The adoption of the PLT in 2000 thus pave the way for deep harmonisation of number of issues relating to the grant of patent rights as well as the validity of patents through the negotiations and for the adoption of SPLT (Substantive Patent Law Treaty). These issues in SPLT Draft include definition of prior art, novelty, inventive step (non-obvious) and industrial applicability (utility) sufficiency of disclosure and interpretation of claims. The approach was in fact consistent with the recommendations of the US that WIPOs patent law harmonization efforts concentrate on deep harmonisation of those concerned with the drafting, filing and examination of patent's application. The interesting dimension of the SPLT negotiations is firstly, it received the backing of all the developed countries including the US. Secondly, the 1991 patent harmonisation treaty was brought back on the agenda of WIPO, which may be seen as beginning of adoption of an international patent system.

It will take some time before the blue print of international patent system can be prepared by SPLT. Due to reservation o developed countries like EU and US this would make negotiation of the SPLT a difficult process. Concerns of developed countries, which led to the failure of the Hague diplomatic conference on the Patent harmonization treaty in 1991, remain unsolved. Industry and intellectual property community are keen to push ahead with patent law harmonization. The Biotechnology Industry Organisation (BIO) has stated that "true harmonisation" can take place only through "a treaty that imposes identical standards on substantive patenting among all treaty signatories rather than a treaty that accommodates a range of options." According to BIO, "Patent system based on such a treaty should capture the best element of the US, Europeans and Japanese patent system". The above mentioned positions of the interest groups in the US indicated that SPLT negotiations could result in the harmonization of patent laws along the lines that exist in developed countries.

Areas of Contention between Developed and Developing Countries:

The stand taken by WIPO shows that SPLT is more concerned about developed countries. Developed countries on the other hand are influenced by their industry and intellectual property community. The reason being, developed countries and NGOs representing corporations and patent lawyers interests dominate that PLT and SPLT negotiations. This is ironical that most affected by these patent laws will be developing countries and they are not effectively engaged within the WIPO in setting the intellectual property agenda. SPLT negotiations have been considering several issues relating to grant of patents. The following issues arevery important for national patent laws.

1. Setting standards in respect of conditions of patent-ability.
2. Sufficiency of disclosure in the invention for which the patent is sought
3. The definition of prior art.

The SPLT draft the conditions of patenting has two substantive parts (1) define the subject matter eligible for patent protection, (2) it formulates alternative standards regarding the three criteria used for assessing whether or not inventions are eligible for patenting and the criteria of patenting are (i) novelty (ii) non-obvious or inventive step and iii) industrial application or usefulness. These conditions are in departure from the framework that the agreement on TRIPS has introduced. The areas of conflict arise primarily because the SPLT is aimed at expanding the scope of protection available to inventors well beyond that currently provided by TRIPS, this could have adverse implications on countries like India. SPLT states that patentable subject matter shall include products and processes that can be used in any field of activity. SPLT also seeks to define the three criteria for patenting viz. novelty, inventive step and industrial applicability. These provisions are different from the framework provided in the agreement on TRIPS. TRIPS provides patents for any inventions, whether products or processes in all fields of technology if they are new, involve an inventive step and are capable of industrial application. Its departure from WIPO is that it provides some exception. TRIPs provides for exclusions from patenting when it is necessary to prevent commercial exploitation of certain inventions necessary to protect 'morality' or are essential for the protection of human, animal or plant life or health or to avoid serious prejudice to the environment. More significant exclusions are (a) diagnostic, therapeutic and surgical methods for the treatment of plant (b) plants and animals and (c) essentially biological processes for the production of plants and animals. While SPLT exceptions are limited to mere discoveries, abstract ideas, laws of nature etc. These flexibilities of TRIPS would, however, not be available under the proposed SPLT Draft.

The SPLT draft seems to expand the TRIPS subject matter limitation through the removal of the phrase ‘fields of technology’ to ‘any field of activity’. This has been supported by US with objective to incorporate the patenting of software, business methods and research tools, which are not considered patentable today under the laws of many countries, including that of India. This would place greater control and rights in favour of the patent holder and nullify public

interest benefits, such as ‘fair use’ that is available under copyright laws. In India software is currently protected under copyright laws. The term "in all fields of technology" in SPLT draft is also opposed by European Community.

The harmonisation of the Patent law of member countries of SPLT is something beyond the TRIPS agreement. TRIPS merely states that inventions on which patent rights are claimed must meet the three criteria i.e. novelty, inventive step or non-obviousness and industrial applicability or utility. The Agreement on TRIPS grants freedom to the patent granting authorities in the member countries to define each of these requirements. Thus TRIPS recognises the widely varying approaches adopted by countries while applying the above-mentioned three criteria used for examining patent applications. Definition of ‘industrial application' adopted in different countries led to different national laws on patent. Countries in the developing world have taken hesitant steps towards expanding the scope of patentable subject matter while fulfilling their obligations under the TRIPS agreement and enacted patent Laws suited to their developmental activities. Thus process of harmonisation of patent laws is difficult in near future so developing countries including India should use this time and advocate their position forcefully in next rounds of SPLT/ TRIPS negotiations. Other contentious issue in SPLT Draft is ‘prior art’. The applicant generally uses the term Prior Art to refer to the entire body of knowledge that is available to the public before filing it for patent.

The TRIPS agreement is silent on the definition and explanation of how 'Prior Art’ is to be determined while examining a patent application. The SPLT on the other hand defines ‘prior art’ as information or knowledge available to the public anywhere in the world in any form. Harmonisation of prior art standards is contentious issue, since this would eliminate the flexibilities that patent offices in different countries have been exercising while examining patent claims. For instance, in the US, an isolated and purified form of a natural product eg. pre-existing biological resource unknown to public at large is patentable. Under the Indian Patent Act, 1970 (as amended in 2002) the discovery of any living thing or non-living substance occurring in nature is excluded from the purview of patenting. This flexibility under Indian Patent Act will go if SPLT comes into effect in its current form. Since in SPLT emphasis is not on discovery but on whether there was ‘prior art’ available on the concerned subject matter or not.

The prior art as defined presently in SPLT is nullified by the silence of TRIPS have proved beneficial for country like India, where the traditional knowledge associated with much of our biological resources exists in oral form. This was the reason why India challenged the patent of wound healing properties of turmeric and won (in US it requires its printed form, oral knowledge is no evidence).

Another point of contention between developing and developed countries has been invention that utilises biological resources or traditional knowledge. This controversy aroused when

Convention on Biological Diversity (CBD) recognised the rights of states over their genetic resources as well as those of traditional communities over their knowledge. The Patent laws of most countries are inconsistent with the agreement on TRIPS do not take CBD recommendations into consideration. Several developing countries including India submitted a paper to the TRIPS council in June 2002 with recommendations that members shall require an applicant, for a patent relating to biological materials or to traditional knowledge, to provide following information as a condition to acquiring patent rights:

i) Disclosure of the source and country of origin of the biological resource and the traditional knowledge used in the invention;

ii) Evidence of prior informed consent through approval of authorities under the relevant national regions and;

iii) Evidence of fair and equitable benefit sharing the national regimes of the country of origin.

Developing countries ask this information to prevent bio-piracy and misappropriation. The controversial aspect of SPLT, in this matter, is that the member countries cannot impose any additional conditions on patent applicants other than those envisaged in the SPLT. Thus the SPLT draft is in direct conflict with the proposals made by developing countries to the TRIPS council regarding the disclosure of the origin of biological and genetic material. The developing countries agreed that the SPLT should emphasis on the source and the country of origin of a biological or genetic resource and the associated traditional knowledge used in patent claim. The developed countries have held the view that this issue should be taken to the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional knowledge and Folklore (IGC established in 2000 not SPLT).

Another important development in the ‘disclosure norm’ has been that Switzerland has also joined hands with developing countries. Switzerland proposed that the Patent Cooperation Treaty (PCT) could be amended to include the explicit requirement to disclose the source and country of origin of genetic resources as well as traditional knowledge used in an invention for which patent rights are sought. This proposal will affect the SPLT draft, as well as there is a provision in the Draft SPLT that any amendment to the PCT would be binding on the contracting parties of SPLT. The implication of this amendment will be that it will apply only if patent applicant is submitting an international patent application. Thus the scope of application of the condition on patent applicant would be narrow, since the PCT is applicable only to the international applications and not to all.

Here it will be important to see the definition of ‘source' as proposed by SPLT. The term not only includes origin, geographical origin or country of origin of genetic resources, but also any other source such as publication in scientific journals or books, databases on traditional

knowledge etc. Thus the definition of source appears quite comprehensive but it does not include an important term i.e., oral tradition, which is very important for the country like India.

In India the concept of Patent translated into legislation in 1970. It was a loosely enacted act, which was definitely not in favour of patentee. But with the emergence of New World Order an international pressure has seriously affected the Patent Act, 1970. Being a member of WTO has to accept a TRIPS agreement and make changes according to the dictates of TRIPS agreement. Why India has never taken any pains to represent its point forcefully in the WTO as far as intellectual property rights are concerned is unexplainable. Fortunately for developing countries like India, no consensus has reached, between developed countries on many issues for e.g. prior art, disclosure, etc. so deliberation is going on in WIPO/WTO as we have seen in the foregoing discussions. Here it will be prudent to mention that there is a kind of agreement between WIPO and Agreement on TRIPS regarding harmonisation of Patent Law between member countries. Harmonization is 'one size fits all' international system. This sounds very simple but on the basis of the analysis it is not as simple as it sounds. The kind of development going on in WIPO and WTO clearly suggests that the draft is tilted in favour of developed countries. Many NGO's representing interest of the industry especially of US is trying that the best elements (read favouring developed countries) of the US, European and Japanese patent system should be adopted. This will have serious repercussion on the developing economies like India.

Presently, the position is that agreement on TRIPS is in vogue, which has granted flexibilities to the National Patent Act in many areas. These flexibilities are best suited to developing countries like India especially in the field of pharmaceutical industry and prior art norms.

India and Patent Law:

India is committed to implement the Agreement on TRIPS of WTO and has accordingly modified its Patent Act of 1970. The first amendment was introduced in 1999 This amendment introduced the mechanism for accepting product patent applications covering pharmaceutical and agriculture chemicals from Jan 1, 1995 (better known as mailbox provisions). The second amendment was introduced in 2002 to bring Indian Patents Act in conformity with the provisions of the TRIPS Agreement relating to patents barring few exceptions viz. introduction of product patents in the area of chemicals, pharmaceuticals, agriculture chemicals and food. The exceptions provided in 2nd amendment became the principal subject of third Amendment. The deadline for these changes in India Patent Act 1970 is Jan 1, 2005

The NDA Govt, brought the Patents (Amendment) Bill, 2003 in the 13th Lok Sabha, the Lok Sabha was dissolved and bill lapsed. UPA government in order to meet the deadline decided to refer the bill that the NDA government had presented, to a group of ministers for consideration before it is reintroduced in the Parliament.

Two factors were main consideration in amending the Patents Law, 1970; first, the commitment of the country under the TRIPS Agreement to introduce product regime in the area of pharmaceuticals in place of process regime. The second factor is growing concern in India about the access to medicines at prices that citizens could afford. This concern of the developing countries was adopted at the 4th ministerial conference of the organisation held in Doha on TRIPS Agreement and Public health, 2001.It was held in Doha Declaration that the "TRIPS agreement does not and should not prevent members from taking measures to protect public health." It further stated "the agreement can and should be interpreted and implemented in a manner supportive of WTO members right to protect public health and in particular to promote access to medicines for all." It was emphasised that the WTO members have the right to use, to the full, the provisions in TRIPS that provide flexibility for this purpose

The TRIPS Agreement requires that WTO members must ensure that the laws relating to all forms of intellectual property rights covered by the agreement give due consideration to issues like protection of public health and nutrition and conducive to social and economic welfare as well as a balance of rights and obligations. Both these issues are of immense important for India.

The other issue discussed in Doha declaration, which is of great importance for India is that of Compulsory licenses. Its importance lies in the fact that over the past few decades India has developed a strong pharmaceutical industry, which manufactured 'generic medicines' at very low prices even lower than those available in most countries. These low cost generic medicines have also been supplied to several developed and developing countries. Thus the future of the pharmaceutical industry in India rests on the ability of the producers to license out technologies from the owners of the technologies. Here the compulsory licenses will be of crucial importance for prevention of the abuse of patent. This includes the refusal of the patent holder to commercially exploit the patent in the country granting the rights of monopoly. This right of countries granting patents to use the compulsory licensing system has been clearly enunciated in Doha declaration. It states that every WTO member has "the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." So the TRIPS has given the right to member country to enact legislation for the grant of compulsory licenses in public interest like medicines.

Thus it is clear that the TRIPS consistent patent laws should consider the interest of the public at large but should also grant patent rights on invention that represents 'advances in technology'. Some of the developed Countries using these later prevision i.e.. advance in technologies in granting patent rights on claims that can be termed as frivolous This has led to situation of 'ever greening' of pharmaceutical patents, which are a cause of concern specially when countries like US are doing it. This apprehension is not theoretical- almost 85 % of the patents granted in US are Incrementally Modified Drugs (IMD) i.e. they include new formulations, new combinations of active ingredients of new salts or esters of approved compounds. These IMDS have

contributed substantially to the rising prices; development of IMDS is safer, faster and cost effective for producers rather than an original product.

This is an uphill task for the India to deal with IMDS. India should ensure that the IMDS should not get patent rights and it can do so by narrowing the scope of patenting. Towards this end five amendments have been introduced, if we have close look to these amendments we may conclude that the words defined in the third amendment such as 'inventive step', 'economic significance' 'pharmaceutical substance's', 'technical advance' will open the door for frivolous claims in this area. Thus more clarity is required in defining these terms in the Act.

The other area of concerned in the third amendment draft is that of 'reasonable royalty' and 'substantive investments' which are open to interpretation. The draft provides that the generic producers will have to cease production once the product patent applications in the 'mail box' are granted to such pharmaceutical products under the new dispensation. The generic producers in this case will have to pay 'reasonable royalty' to the patent holder from such enterprises, which have made 'significant investment' and were producing and marketing the concerned product before Jan. 1. 2005. It further provides that no infringement proceedings shall be instituted against such generic producers.

The Act provides that the remuneration would take into consideration the perspective of the patentee, which includes the expenditure incurred by the patentee for making and developing the invention and for obtaining and keeping the patent in force. It may be argued that these considerations for determining the royalty and other remuneration would enhance the already superior bargaining position of the patentee and that these would need to be tempered with public interest considerations as well.

The Patent Act, 1970's third amendment provides the right of 'opposition to the grant of patents. This provision was in the Act only for pre-grant opposition, but in 3rd amendment post-grant opposition is also provided. This Act currently provides that pre-grant opposition can be launched within four months from the date of advertisement of complete acceptance. The grant of patent can be opposed on the grounds that include (i) the invention for which patent has been claimed was publicly known or publicly used in India (ii) the invention is obvious and does not involve the inventive step (ii) the invention is not patent able under the Patent Act, 1970, (iv) the complete specification wrongly mentions the source or geographical origin of biological material used in the invention and (v) the invention on which the patent is claimed forms part of the traditional knowledge whether in India or elsewhere (oral or otherwise available in third amendment)

The third amendment proposes change in the 1970 Act one, the pre-grant opposition to be changed to pre-grant representation second, and the pre-grant opposition to be replaced by post grant opposition.

Post grant opposition allows any interested person to oppose the grant of a patent before the expiry of one year from the date of grant of patent. The grounds for post grant opposition are same as that of pre-grant opposition. The reason for this change has been given that it will reduce the time period for the grant of patients in India. On the other hand pre-grant opposition may check number of patent applications. India is perhaps the only country which will have provisions of pre as well as post grant opposition.

The third amendment to India's Patent Act aimed to establish balance between the rights of the patent holders and interest of the public at large in the light of the agreement on TRIPS. The 'Global Community' took a major step towards bringing about a balance between the two through the Doha declaration on TRIPS Agreement and Public Health. In Doha declaration it was held that member countries should take measures to protect public health and promote access to medicines for all. It has given an instrument to developing countries like India, producing generic medicines, of compulsory licenses in a more effective manner. The Third Amendment fails to reflect the spirit of Doha deceleration although it has made provision of compulsory licensing but there are certain provisions in the draft, which need proper redress, e.g. compulsory license is available only after 3 years from the date of grant of the patent. Secondly, clear effective grounds for issuance of a compulsory license have not been given in the draft e.g.; how can a compulsory license be issued if patentee refuses to issue a license on reasonable commercial terms? No time frame has been mentioned within which the process of compulsory license process should be completed. Then no ceiling on remuneration payable to the patent holder is mentioned in the draft.

There are issues of 'significant investment' and 'reasonable royalty'. Pre grant representation, Post grant opposition, needs more clarification. The most important thing is time frame that is not mentioned anywhere in the draft barring few exceptions like that of Pre-grant and Post grant conditions in awarding the patent ET. Al.

Conclusion:

I feel an important issue is that of competence of Patent office that will be enforcing the provisions of draft. It is likely that there will be flood of applications, resulting in poorly examined and legally invalid patents. The Patent office in India does not have the infrastructure for research, access to information and capacity to face the challenges that the new Act will bring. The bill that has been brought to enact the critical third Amendment of the Patents Act, 1970 has

a number of issues that would need close scrutiny before it is finalised. India should take time in enacting the law and careful assessment is required before it is passed in parliament.

In the end, I would like to say that India should utilise time before the 'harmonisation of Patents Act' comes in vogue under the umbrella of TRIPS/WIPO. India should make full use of flexibilities provided in TRIPS and make forceful presentation in advocating/guarding its interests in future deliberations of WTO/WIPO. Indian industries and NGOS should also come forward and guard their interest on the world forum as Indian Govt, is fighting for their cause. The absence of Indian Industries and NGOS at world forum is conspicuous.

REFERENCES:

1. A confusing Patent Law for India. Economic and Political Weekly, April 16, 2005
2. Bishwajit Dhar and C.Niranjan Rao. Economic and Political Weekly, April9, 2005
3. Bishwajit Dhar and C.Niranjan Rao Economic and Political Weekly. Dec 25, 2004
4. Bishwajit Dhar and R.V.Anuradha Economic And Political Weekly, March 26.2005
5. Carlos Correa and Sisule Mussungu, The WIPO Patent Agenda: The Risk for Developing Countries.
6. Indian Patent Act of 1970
7. K.M.Gopa Kumar And Tahir Amin Economic And Political Weekly, April 9,2005
8. National Institute of Health Care Management, Changing Patterns of Pharmaceutical Innovation: A Research Report. May 2002.