TRIPS, WTO and IPR: IPA 2005: Potential for Disputes and Litigation

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The World Trade Organization (WTO) was set up in 1995 and has been the custodian of all matters related to implementation of the TRIPS Agreement endorsed by 153 member countries. WTO is therefore the most important body which monitors and influences working of global intellectual property rights protection in all its member countries. This opinion discusses IPA 2005 and its potential for disputes and litigation.

On 4 April 2005, the President of India gave his assent to the Indian Patent (Amendment) Act [IPA] which in spirit and letter was deemed to be consistent with the obligations under the TRIPS Agreement to which (as part of GATT) India was a founder signatory. While exploiting the flexibilities provided under TRIPS, India also included in the amended Patents Act, some provisions which more than others are likely to lead to disputes and even litigations in future. While provisions under TRIPS itself are the minimum prescribed for effective protection of intellectual property and members are free to provide for stronger protection under their national laws, it is a moot point whether they are free to dilute the provisions and make the system less protective for the patent holders. These, as well as some of the amended provisions in IPA 2005 may become contentious in the future and lead to possible disputes and litigations. In practice, it has been the experience in recent times that much of the litigation initiated has ended in out of court settlements considering extremely arduous procedures and expenses involved in the judicial processing of patent disputes.

Disputes and Litigation

IPA 2005 has several sections which could possibly lead to disputes and litigations in the coming years. These relate to issues on novelty, patentability, microorganisms, plants and animals, incomplete or incorrect disclosure of biological sources used, compulsory licenses under various conditions including prescribed terms under the Doha Declaration, non-working of patented inventions, parallel imports, access to drugs, etc. In addition, questions may be raised as to whether Indian Patents Act, 2005 in its present form is TRIPS compliant, an issue if raised by any other Member can be sorted out only at the Dispute Settlement Board of WTO.

The source of many future disputes will come from problems of different interpretations of the vague and arbitrary wording embodied in many sections of the Act as well as the fresh and somewhat unique provisions in IPA 2005, not included in Patent Acts of other Members. As of now, there has been little litigation based on any of the provisions of the IPA 2005, primarily since these are early days and the impact of the most contentious issue of grant of product patents to all inventions regardless of the technology or origin is yet to be felt by the domestic industry and the public. However, while there have been very few litigations in India based on IPA 2005 so far, some leading companies such as Dr Reddy’s, Ranbaxy and others have filed many infringement suits against US based MNCs to increase their generic market share in US Courts along with ANDAs with Para IV certification in the US FDA.

General Issues Leading to Infringement Suits

Patents give the owner, exclusive rights for a limited period to practice the invention and prevent any third party from using it in any form without formal authorization from the patentee. The scope of what the owner is entitled for exclusivity is based on the claims granted for the invention and no more. The problem arises when a third party deliberately or out of ignorance or wrong interpretation trespasses on the claims and exploits the invention leading to a challenge
by the innovator. Issues which lead to litigations are based on disputes on the validity of the patent on the assumption that the application is devoid of novelty, inventiveness or utility. In addition, there could be arguments on the scope of the claims which may be much too broad and does not cover the alleged infringer’s product or process. There are also issues of predictability of use in humans based on animal data on which the application was based. In cases of infringement suits between Eli Lilly and Novopharm (Olanzapine), Apotex v Lundbeck (Escitalopram) and Pfizer v Novopharm (Sildenafil), the Canadian Court ruled that animal data was sufficiently predictive for use in humans.

One of the landmark decisions which had a great impact on the development of the biotechnology sector was the decision of the US Supreme Court in the Diamond v Chakrabarty case (1980), which ruled that man made microorganisms are patentable. The Courts contention was not for distinguishing between animate and inanimate matter, but rather natural versus man made microorganisms. On the patent infringement front, a classic and oft-quoted court decision that of the Hoechst v Haffkine Institute of Bombay in the Tolubutamide case (1968). In spite of the fact that Haffkine claimed to have used a process different from the one claimed in the Hoechst patent, the Court ruled that the Haffkine process infringed the Hoechst patent. This was perhaps the only case in Indian patent history where an infringement suit was decided in favour of the patentee. Haffkine Institute’s licensor Unichem Laboratories was ordered to close down their production of tolubutamide. Of course, India at that time was under the 1911 Patents Act which was amended to disallow product patents for drugs under the IPA, 1970.

**Novelty Issues**

The Indian Patents Act requires absolute novelty in any part of the world to qualify for grant of a patent. Any invention which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of the complete specification is thus novel. While this provision is consistent with the novelty requirements of patent laws in other countries, establishing non – use in any part of the world any time before filing of the application is indeed a very arduous task for the applicant and at present the administrative set up in India is ill-equipped to carry out this task.

**Inventiveness**

This term which is synonymous with non-obviousness, patentability etc, has many ambiguous and hard to prove terms which allow room for differential interpretations. Thus, inventive step is that feature of an invention which involves technical advance as compared to existing knowledge or economic significance or both, making the invention non-obvious to a person equally skilled in the art. Under this provision, terms such as technical advance and economic significance are ambiguous and subject to different interpretations. In addition, the IPA 2005 has enlarged the scope of inventiveness to include economic significance perhaps to indicate that reducing costs of production, particularly of drugs is a desirable objective for new innovations and therefore could constitute a patentable invention.

Article 27 of the TRIPS Agreement clearly mandates that ‘patents shall be available for any invention whether for products or processes in all fields of technology provided they are new, involve an inventive step and are capable of industrial application …’ and in that context, Section 3(d) would appear to be violative of this provision since it dictates a discriminatory provision that ‘the mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy (safety is not mentioned) of that substance - unless such known process results in a new product or employs at least one new reactant.’ However, the explanation which follows stipulates that derivatives of the known substance are not patentable unless ‘they differ significantly in properties with regard to efficacy’ Assuming that there is agreement on the interpretation of the term ‘significantly’, thereby eliminating possible subjective interpretations, this section does not preclude the grant of patents even for products derived from a known substance.

The only question is with regard to the inventive merits of the invention dealing with new derivatives of existing molecules. Once again the decision regarding significance of the improvement is often a subjective decision amenable to different interpretations. The case of Glivec (Novartis) and the protracted litigation around it is a case in point. In the coming days it is reasonable to predict several litigations on patentability or otherwise based on interpretation of Section 3(d).
Compulsory Licences
According to IPA 2005, compulsory licences could be granted when there is a national emergency or urgent need for public non-commercial use or for exports to least developed countries that are in possession of compulsory licences themselves. Section 92 covers all these possibilities and when granted for national use there is no opportunity provided to the patent holder to make his case. In other words, the Controller has overall and absolute rights for such grant. There is also provision for grant of compulsory licences when the practice of the invention requires licence of an earlier related patent (dependent patent). The Controller’s decisions on these issues are subject to diverse disputes.

Pre and Post-grant Opposition
Post-grant opposition is the normal procedure adopted in patent offices around the world. Countries which earlier had provisions for pre-grant opposition have since abandoned this facility in their patent laws. Experience has shown that pre-grant opposition provisions lead to cumbersome processing of such oppositions and considerable delays in their resolution through semi and quasi judicial processes. Post-grant oppositions follow the normal judicial procedures involving the Patent Office, Appellate board and the judicial system right up to the Supreme Court of India.

Bolar Provisions, Burden of Proof, Parallel Imports
IPA 2005 provides for exemptions to practise the invention for experimental work as well as trial production for testing to enable early introduction of the generic version without delay, post patent expiry (Bolar like provisions). In cases of process patents, the burden of proof remains with the defendant in case of alleged infringement. In the case Merck v Apotex, the US court ruled that the supplier of the generic drug to Apotex may have fabricated records to establish non-infringement of the Merck process based on their batch records. On the question of parallel imports, TRIPS Agreement is silent and some countries including India have interpreted as legal the theory of exhaustion of rights permitting parallel imports, even though so far there has been no specific case of such imports.

Conclusion
It is obvious that both due to legislative dictates based on the IPA 2005 and the possibility of differential interpretations of the wording of several sections, the new Act when fully practised and implemented is likely to lead to a large number of disputes and litigations in India. While only specific cases will give an indication of the direction for settling the large number of disputes likely to come up due to the ambiguities and special TRIPS-plus provisions in IPA 2005, it is important to anticipate them, take note of them and evolve satisfactory explanations as footnotes to clarify the Act’s intentions in various sections and rules pertaining to them.