IP protection post-2004: A review

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Intellectual property related Acts have undergone more amendments in India (or even elsewhere) during the last five to ten years, than ever during the last one century. It would have been extremely difficult to keep track of these frequent, sometimes drastic, often minute, changes to the IP laws, even for routine IP practitioner. It is therefore intended to deal with them in general with emphasis on patent laws and their enforcement prospects in India in coming years.

India's obligation for TRIPs (Trade Related Intellectual Property Rights) compliance is what prompted us to come out with a plethora of amendments. Some were welcome to most, while a few where unpalatable to some. Since there are many contentious issues yet to be sorted out and solutions to be arrived at [including review of TRIPs, especially Art. 27(3)(b)], more amendments are probably on the way.

Pharma industry is most widely and traditionally using trade mark protection. The Trade Marks Act, 1958 has been amended in 1999 incorporating new provisions for Services Marks, Well known marks, Appellate Board etc. The period of registration and renewal has been increased from 7 years to 10 years with substantial increase in fees with faster grant accompanied by e-register. Enforcement of trademarks will continue to be smooth. Coupled with stronger supervision and regulations by FDA and revenue agencies, the quantum and spread of spurious drugs in India has substantially come down in recent times.

The Designs Act has also been amended in 2000. The Copyright Act has been amended a few times, the last one in 1999, effective 15-01-2000. Biodiversity Act and Rules 2003 has already come into effect, though the implementation is delayed. In its present form, the CBD enforcement in India could adversely impact patent application procedures in India. Unlike the Biodiversity Act, the Medicinal Plants Board has become effective and functional. The Plant Variety Protection and Farmers Right Act, 2001 is yet to become effective. The Geographical Indications Act, 1999, the IC Layout-Design Act 2000, The Information Technology Act, 2000 are few others to be noted. It is, however, very dismaying that awareness of various WTO provisions specially relating to technical areas like Technical Barriers to Trade (including various Non-tariff Barriers), Rules of Origin, Sanitary and Phytosanitary Measures are neglected by one and all. These are increasingly becoming important in present times of bilateral Free Trade Agreements.

Even though, the Expert Committee headed by Dr Mashelkar, Dr Madhav Menon, Dr Govardhan Mehta and others are yet to finalise their report on "Patentability" criteria, one must admit that "turbulent" times of patent amendments have now come to settle down. Even though there are a few aberrations and some ground for improvements, the Patent

Act, 1970 and the Rules as amended upto 2005 have now become effective and functional. After a gap of nearly 5 to 6 months, patents have started flowing out, albeit, few and far between. The much awaited Appellate Board for patents is yet to take off (though the Trade Mark Board has become effective).

Patents Act provisions are much more stringent in India than elsewhere especially with regard to "Patentability Criteria". New use (Swiss claims), method of treatment, biological materials and since 2005, patenting of new physical forms of known materials (except with substantially enhanced therapeutic efficacy) are not patentable in India. The introduction of "inventive step" for patentability has also made patenting more difficult. With the latest amendments and the guidelines emanating from the Manual of Patent Practice and Procedures, obtaining a patent grant has become tougher in India. The percentage of applications being abandoned during prosecution and the percentage of applications which are not being requested for examination (which are high) are indications to this perception.

Compared to enforcement of other forms of intellectual property rights, patent enforcement is expected to be different in India. Many corporates in India, opt for "defensive patents". With the new amendment of "Reversal of Burden of Proof" on process patents, it is considered prudent to possess a process patent (if the process meets patentability criteria) to ward off potential process infringement suits. Such corporates would prefer not to push on infringement related enforcement actions. In light of the higher public debate "decibels", it appears prudent to be a "Patent Dolphin" than a "Patent Shark" in enforcement strategy in India especially in the pharma field and for at least next five years.

The "research exemption" equivalent to "Bolar Provision" in 35 USC of USPTO is available in Section 107 A(a). Research on molecules, which remains protected under the product patent is permissible, under the Act, without fear of infringement. The language of this section "patented invention solely for uses reasonably related to the development and submission", now interestingly interpreted in the US Supreme Court in Certiorary Judgement in Merck vs. Integra, has made it open for research without attracting litigation. The additional provision section 47(3) which exempts patented articles or processes for purpose merely of experiment or research including the imparting of instructions to pupils is excellent and seems to have been incorporated anticipating potential infringement action against education institutions (as in Madey vs. Duke in USA).

Over and above the Compulsory Licensing provisions under sections 83 to 91, the government has also empowered itself to intervene for use of patented inventions, in national interest by involving Sections 92, 99 and 100 to 102. The provisions for export of patented pharmaceuticals to overseas countries in need of patented inventions against their compulsory licences are also available in section 92A. "Working of patented inventions" as detailed in Sec. 83, Sec.146(2) and Rule 131(1) and the need for filing Form 27 to the Patent Controller regarding "working of the patented invention" on commercial scale in India, within 3 calendar months of the end of each year, opens up a

Pandora's Box for patent revocations (in addition to other provisions for revocation) and related and resultant litigations. Patent Controllers are sure to be kept busy, not only with increased patent prosecutions, compulsory licence and royalty decisions, pre and post-grant oppositions and patent revocations.

Enforcement of patent rights in India is also likely to be impacted unpredictably by the acute lack of awareness of patent basics in the judiciary and even the legal fraternity, atleast as of now. A patent infringement is first to be filed in a District Court. With a counter-claim of invalidation, the suite moves to the High Court. Unlike in advanced patent litigating countries like USA, Europe or Japan, the awareness and understanding of grounds of infringement, exceptions to infringements etc are also poor and vague in India. Another important aspect in India (unlike in US & EU) is that no time frame is prescribed for legal recourse in India. The pendency of patent cases, especially of the main suit, is likely to remain a deterrent for enforcement for few more years.

In the light of above described enforcement climate, India might see increasing practice of voluntary licensing, IP/Patent related alliances and co-working relationships. Carried forward provisions in the Indian Patent Act, for working of a patent in India, Compulsory Licence provisions, government use provisions, provisions for both pre-grant and post-grant oppositions (unique to India) and multiple grounds open for revocation of a patent in India are likely to create an atmosphere of conciliation, compromise and co-working rather than confrontation, which is probably good for community, though not so delightful to the legal fraternity.

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