

GETTING IN TUNE

The Patents (Amendment) Act 2005 brought some relief from the earlier amendments that tried to be more loyal than the king to the WTO, but India still faces the challenges of harmonising IPR with other relevant laws without compromising public interest, such as the controversial New Seeds Bill. To that extent, WTO is not just about IPR, but also about distorting our domestic policies in accordance with the American vision of world trade, argue

Vivek Sharma, Hardeep Singh Oberoi and N. Raghuram

The introduction of agriculture and Trade Related Intellectual Property Rights (TRIPs) for the first time into the multilateral General Agreement on Tariffs and Trade (GATT) during the Uruguay Round of negotiations in the 1980s and their culmination in the agreement signed at Marakkesh, led to the formation of World Trade Organisation in 1995. Having completed the 10-year grace period offered to developing countries to comply with the provisions of WTO, India today faces the challenge of harmonizing its IPR laws to comply with TRIPs, and at the same time protect its national interests with reference to its economic and development needs, indigenous knowledge, agriculture and biodiversity. It has also become imperative that all the related national laws such as the patents act, the Protection of Plant Variety and Farmers Rights Act (PPVFR), the Biological Diversity Act, The Plants, Fruits and Seeds Order, The New Seeds Bill and the Environment Protection Act are all complementary and compatible with one another.

The Indian Patents Act (1970), which allowed only process patents and not product patents, provided shorter protection periods and excluded agriculture and other areas from the scope of patentability was seen by many as a model for other developing countries. However, in order to comply with the TRIPs Agreement, the Indian Patent Act (1970) has been amended twice in 1999 and 2002. A third Amendment was introduced by means of an ordinance on 26 Dec 2004, before it was further modified and passed by the Parliament in March 2005. Through these amendments, product patents as well as process patents are now permitted with a uniform protection period of 20 years, and are now extended to agro-chemicals, food and biotechnology products including genetically modified organisms, apart from drugs and pharmaceuticals. IPR protection to Plants will be covered by the Protection of Plant Variety and Farmers Rights Act (PPVFR).

The criteria clarified

Fortunately, some of the controversial clauses that were introduced in the previous amendments and the

Third Amendment ordinance were reversed when the draft patents bill was discussed in the parliament. These include some of the contentious issues such as the criteria for patentability, compulsory licensing and pre-grant opposition. The Patents (Amendment) Act, 2005, that has been passed by the parliament now clarified that an "inventive step" means a feature of an invention that "involves technical advances as compared to the existing knowledge or having economic significance or both..". The amendments also incorporate a new definition for "new invention" which is "any invention or technology 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 patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of art." The amendments also give a definition for "pharmaceutical substance" as being "a new entity involving one or more inventive steps". The new amendments have now also Restored Pre-grant Opposition to Patents. These modifications were critical to minimize the damage to Indian interests.

Mailbox items

During the grace period (1995-2005) for the implementation of WTO obligations, the Indian government had to provide for a 'mailbox' to receive applications for product patents as an interim measure, so that the applicants can enjoy the priority date when the product patent regime eventually comes into force. However, some Indian companies are producing these drugs based on the disclosures from the patents granted to those applicants in other countries, without inviting infringement. The fate of these Indian companies after the product patents come into force in India was not clear. The latest amendments have now clarified that Indian companies that are already producing drugs for which applications for product patents are pending in the 'mailbox' can continue to produce them after payment of a royalty even if the drug is placed under a patent. Specifically, it states: "...the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises." This came as a big relief not only to those companies producing these drugs at affordable prices, but also to patients who need them. However, whether the drugs will continue to be affordable after product patent comes into force will depend upon how the term "reasonable royalty" is defined.

Compulsory Licensing

Compulsory licensing has been one of the most contentious issues in the WTO agreement. This refers to the right of the government of a country, say India, to allow the production of a patented drug by another company, by forcing the patent holder to license it to that company for a royalty fixed by the government. This may become essential to

meet epidemics or other national contingencies at affordable costs. However, this provision was allowed by WTO only under exceptional situations, national calamities and emergencies, and the earlier amendments to the Indian act did not clarify whether the licensees could export them. The latest amendments have now provided that when patented drugs are produced under compulsory license in India by Indian companies: "the license is granted with a predominant purpose of supply in the domestic market and that the licensee may also export the patented product, if need be in accordance with Section 84(7) (a) (iii)". The act has allowed the exports of patented drugs produced through compulsory license in the country, to developing countries with no manufacturing capacity. This comes as a big relief to Indian companies such as those supplying patented AIDS drugs under compulsory license to South Africa.

Further improvements

It is possible to make further improvements to take advantage of the flexibilities available under TRIPS. For example, in case of mailbox applications, the patent regime should be applicable from the prospective date of filing to minimize the impact of payment of royalties. Similarly, rather than using the vague term 'reasonable royalty' to the Patent holders in cases of compulsory licensing, which can lead to steep hikes in the prices of medicines, royalty percentage should have been fixed. For instance, Canada has fixed royalty at 2 per cent, leaving no scope for any ambiguity or wishful interpretations. The Indian Patents (Amendment) Act 2005 doesn't allow Indian residents to file patents overseas without the approval of the Indian Controller of Patents, which is a major setback to Indian researchers. The amendments also lack a clear definition of new entities, and defining it can solve the problem of evergreening of patents by companies. The reversal of burden of proof has also not been adequately addressed. As

opposed to the normal principles of justice where an accused is deemed innocent unless proven guilty and the burden of proof is on the accuser (plaintiff), the current provisions of WTO have shifted the burden of proof to the accused. This could mean that large companies with huge patent portfolios can intimidate smaller competitors with accusations of infringement, and the accused have to prove their innocence. Interestingly, in all the other areas of dispute settlement in WTO, all available jurisprudence clearly shows that the burden of proof is on the plaintiff and not the accused. Therefore, there is no objective reason for India to accept this reversal of burden of proof in the case of patents, however subtle it may be.

TK and Biodiversity

Human communities have acquired traditional knowledge over millennia through their interaction with their surrounding environments, including the use of available biological resources for various benefits. The indigenous knowledge relating to categories such as agricultural knowledge, medicinal knowledge and biodiversity-related knowledge forms a monumental resource of a country. Any commercial appropriation of this traditional knowledge (TK) is largely attributable to the knowledge, innovations and practices of local communities and hence, a share of benefits must accrue to the creators and holders of TK. Similarly, ever since the international Convention of Biological Diversity (CBD) was signed on 29 December 1993 at Rio de Janeiro, biodiversity is also a national resource of a country just like other resources and hence a commercial value arising it must benefit the country or locality. CBD has three major objectives: the conservation of biological diversity, the sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources. Article 8(j) of the CBD also provides for respecting, protecting and rewarding the Knowledge, Innovations and Practices (KIP) of local communities.

Biodiversity and TK have a special relevance for India. India is one of the major centers for world biodiversity and has been recognized as one of the twelve megadiversity countries of the world with 47,000 known species of plants, 500 varieties of mammals, 2000 species of birds, 30,000 types of insects and a wide variety of fish, amphibians & reptiles, innumerable microbial species (tens of thousands). Some of the areas like the Himalayan region; A & N Islands may be far richer in diversity with hitherto unknown biological diversity. Many of the cultivated plants have also originated from India. India also has an affluent traditional and indigenous knowledge coded as well as uncoded and being sustained by informal means. Considering the declining rate at which patentable new drugs are discovered and the huge time lags and financial uncertainties in the modern drug discovery process, traditional medicinal systems and other forms of TK have suddenly acquired immense prominence among MNCs as a goldmine for discovering new drugs. Similarly, prior to CBD, foreign companies or researchers could freely use the native Indian biological diversity for various patentable inventions and commercial exploitation. Improper or inadequate documentation of TK in India has also made it difficult to check patents based on traditional knowledge in public domain, due to lack of availability of information with patent examiners. Even when there has been available documentation, the time, effort and money involved in getting individual patents examined and revoked in foreign patent offices is prohibitive.

These issues were addressed through the Biodiversity Bill, 2000, followed by the Indian Biodiversity Act, 2002. Section 36(iv) of this act provides for protection of knowledge of local people relating to biodiversity through measures such as registration of such knowledge, and development of a sui generis system. In order to ensure equitable sharing of benefits arising from the use of biological resources and associated knowledge, Sections 19 and 21 stipulate prior approval of the

Biopiracy?

Some examples of patents based on Indian Traditional Knowledge and Genetic resources

Basmati Rice	RiceTec
Turmeric	University of Missisipi medical center
Neem	W.R. Grace & Co., UK and USDA
Karela, Jamun and Brinjal	Cromak Research, US
Aswagandha	Reliv International Inc
Amla, Vasabr,	Natreon Inc.
Saptarangi and Bel	
Hessian (Jute cloth)	UK firm by EPO
Ginger	Granted for eight ginger formulations by USPO
Tea	Patent applied for manufacturing and packaging
Arogyapacha (Trichopus zeylanicus)	US patent
Atta Chakki	Con Agra Foods
Vegetable Pulao	Nestle

Information compiled from various sources

National Biodiversity Authority (NBA) before their access. While granting approval, NBA will impose terms and conditions, which secure equitable sharing of benefits. Section 6 provides that anybody seeking any kind of intellectual property rights on a research based upon biological resource or knowledge obtained from India, need to obtain prior approval of the NBA. Section 18(iv) stipulates that one of the functions of NBA is to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource. The grounds for rejection as well as revocation of a patent application were extended to non disclosure or wrongful disclosure of the source of origin of biological resource or knowledge in the patent application as well as incorporating provisions to include anticipation of invention by available local knowledge, including oral knowledge, as one of the grounds for opposition as also for revocation of patents, if granted. Indian efforts have also been concerted to biodiversity identification and documentation, establishment

of gene banks, biodiversity conservation with 13 bio-reserves already in place and 13 more proposed, and the documentation of traditional knowledge and prior art.

THE PVPFR AND THE SEED BILL

India used the WTO provision of sui generis system of IPR protection in the case of plants and adopted the Plant Variety Protection and Farmers Rights Act (PVPFR). This provides for registration of new plant varieties instead of allowing plant patents, and also secures the farmers' rights to save and reuse or exchange the seeds of the protected varieties, as well as the breeders' rights to use them for the development of new varieties. This was extremely critical to save the Indian agriculture from the vagaries of patenting. However, the controversial Seed Bill pending before the parliament is likely to undo some of the farmer-friendly provisions of PVPFR. Without adequate provisions for enforcement, this act introduces compulsory registration of seed producers, processors and traders with state authorities and has a provision for self certification

of seed varieties. It does not comply with farmers' rights and plant breeders' rights on traditional varieties provided under the PPVFR and also deviates from it on other key issues like disclosure of the origin of the variety. For example, The PPVFR allows Plant Breeders Right (PBR) for a variety on voluntary registration, but the compulsory registration requirement of the seed bill can lead to a situation where one can procure PBR's i.e. exclusive commercialization right for a variety unregistered under PPVFR by registering it under the seed bill. Moreover, the Seed Bill allows registration for multiple parties, allowing free for all seed trade for any variety, including those that enjoy exclusive commercialization rights under PPVFR. In case of hybrid seeds whose parentage is not disclosed, registration under the Seed Bill can result in monopoly commercial rights. Moreover, the bill does not contain any mechanism to ensure seed supply and price control, like the compulsory licensing provision under PPVFR. The seed bill allows patent-like monopoly for hybrid and transgenic seeds and therefore can be used to deny the right of free access to all plant varieties for breeding new varieties provided under PPVFR.

The Seed Bill also creates loopholes in some of the provisions of the Biodiversity Act and the Environment Protection Act to benefit the seed industry. For example, since the seed bill does not seek clarification on the origin of variety, it can be used as a platform by seed companies to bypass the disclosure provisions made in the Indian Biodiversity act meant to prevent biopiracy. This provision in the Seed bill can be used to export seeds without enforcing plant breeder rights, thus legitimizing piracy. The disclosure of origin is also critical to ensure the benefit sharing arising from seed sale of traditional varieties of tribals and farmers. The seed bill also allows the provisional registration of transgenic plant varieties for two years even before official approval under the Environment Protection Act. This will result in compromise in environment and human safety if the

seed is subsequently found to be unsafe, as the new varieties released into the environment on the basis of provisional registration can never be fully retracted.

The self-certification provision under the seed bill requires multi-location test data, for which no competent institutional framework has been established. This places the financial burden of these tests on the seed variety developer. Moreover, this provision can be used by private companies for exaggerated performance claims. Though the seed bill allows compensation to the farmer if agronomic performance claimed by the seed provider is not met, but this can be done only through District Consumer Courts. This is very difficult for small illiterate farmers residing in remote villages. Therefore, adequate mechanism to easily claim compensation should be incorporated in the Seed Bill. The PPVFR has provisions for pre-grant opposition and therefore Seed Bill should also incorporate such provisions.

Other concerns

Since the laws that govern IPR are essentially national laws, inventors are required to obtain patents separately in every country. In order to facilitate the process of obtaining patents in multiple countries without losing the priority date, several countries including India signed the Patent Co-operation Treaty (PCT) that allows member nations to assign priority date based on initial examination conducted by the patent office in any one of the member countries. However, the right to grant or reject the patent still rests with the patent offices of individual countries. This is true even after WTO came into being, as WTO only harmonises the national IPR laws among the member countries, but cannot do away with them. In principle, this means that despite the uniform WTO framework, the patent examiners in different countries can come to different conclusions regarding granting or rejecting a patent application.

After undermining the role of United Nations, WIPO and PCT by

bringing IPR, environment and labour issues under the purview of WTO for uniform enforcement throughout the world, the developed countries are again reviving and reforming the PCT to limit the flexibilities available to the local patent offices in the PCT member countries. According to a recent proposal pending approval, among the several dozens of PCT member countries, a smaller core group of about a dozen countries will be chosen to conduct preliminary examination of the patent applications on behalf of all the others. Once a patent application is declared valid by any one of these countries, other PCT member countries will not be allowed to reject that application on local grounds, and will also be duty bound to assign the priority date accordingly. India is being offered the carrot of membership of this PCT core group, in order to agree for this proposal. While the lure of preventing rejection of Indian patents in other PCT countries may tempt India to agree to this arrangement, India will also have to lose its right to reject patents acceptable to other PCT core countries.

In summary, WTO is not only about IPR, but also about bringing in international uniformity in the domestic policies of business and trade in accordance with the wishes of the developed nations, especially USA. It is one of the most powerful instruments of globalisation, liberalization and privatization (GLP). A whole range of national laws and policies will have to be modified to make India fully WTO-compliant, and the biggest challenge faced by India and indeed many developing nations is to ensure that national interests are adequately protected while falling in line with multilateralism.

Vivek Sharma, Hardeep Singh Oberoi and Dr N Raghuram are research scholars with the School of Biotechnology, Guru Gobind Singh Indraprastha University, Delhi

