
Intellectual Property Rights

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Cyber-based American-Indian Pharmaceutical Education And Research Group is offering a common platform for expressing ideas on any aspect of pharmaceutical sciences and its allied subjects. Drug development needs a close interaction of several allied scientific areas and the American-Indian Pharmaceutical Education And Research Group is open to members of the Bioinformatics, Biotechnology, Clinical Research, Immunology, Life Sciences, Pharmacology, SAS-Programming and Pharmaceutical industry or Academia. One of the unique features of the American-Indian Pharmaceutical Education And Research Group is the monthly discussion and during October 2002, these group members have exchanged views on Intellectual Property Rights. A concise report on this topic is presented here. In future, the American-Indian Pharmaceutical Education And Research Group has plans to conduct online symposia and conferences.

India provides patents in the pharmaceutical sector. Section 5 of the Patents Act presently restricted to the 'methods' or 'process of manufacture' and not extended to the 'substances/products' themselves. However, as per Trade-Related Aspects of Intellectual Property Rights (TRIPS), India still has time until January 1, 2005 to extend patent protection to this area. Further, in World Trade Organization (WTO) rules the ten-year transition period also available for providing product patents to pharmaceutical products.

However, the scenario post 1995, which is the beginning of post GATT (General Agreement on Tariffs and Trade) period, is slowly changing. Indian Pharmaceutical Industry has started to generate their own IPR and many companies now have filed and been granted product patents. Dr. Reddy's, Ranbaxy, Wockhardt, Torrent, Zydus Cadila, Sun, NPIL and Glenmark are among the leaders in this direction. (This list is only an approximate one and may not be very accurate. Interested readers may please check an article published in BusinessWorld last year titled Molecule Millionaires). More companies are falling in line and investing in drug discovery research to generate IPR. CSIR institutes and CDRI have a number of patents to their credit. How-

ever, the pharmaceutical research institutes such as the pharmacy colleges in India barring a few, are not fully aware of the implications of protecting their research by patents and are also not aware of how to go about filing patents. The patent offices in India need to be upgraded. There is also a dearth of good patent lawyers in India. A few organizations are offering courses on IPR round the year that industry and academic personnel get more knowledgeable about IPR issues.

The scenario in Japan:

In November 1996, Gimp's Intellectual Property Rights Committee, R and D Committee, and Drug Evaluation Committee jointly formed a working group, which formulated a petition, which was submitted to the MHW. The contents of a petition called for the following:

1. Data in drug approval applications should be published only at the sole discretion of the originator of the data in terms of drug safety assurance, appropriate use, and scientific assessment.
2. Data in new drug approval applications should only be used for the benefit of the originator for a reasonable period of time. Third parties, including government authorities, should not be able to use or quote these data in other applications or examinations.

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3. Taking into account the financial value of the application data and the protection systems in place in the EU, the "reasonable" period of protection should be 10 years from the day when approval of the drug is granted or from the date of notification of the results of reexamination or reevaluation.
4. Even during the period of protection, a third party may use the application data for profit only with the approval of the originator of the data (including agreements involving reasonable compensation for the use of data as intellectual property). Similarly, during the period of protection government authorities may quote application data for original drugs in examination of drug approval applications by third parties, or omit the same data from drug approval applications by third parties, only with the approval of the originator of the data.

The scenario in European Union:

In major European countries, there are clear rules on the period that application data of original drugs must be protected. In the EU, the application data of original drugs that are approved by the EMEA and the data applied in other EU member countries following the approval in one member country must also be uniformly protected for 10 years. Even original drugs approved by only one EU member country are afforded protection for the same 10-year period in the UK, Germany, France, and other major EU countries.

The scenario in USA:

In the USA, drugs containing new active ingredients have market exclusivity for 5 years; other original drugs have market exclusivity for 3 years, independently from the protection of their patent rights.

Article 39(3) of TRIPS relates to "data exclusivity", while India has amended the patent law to meet the TRIPS compliance through PATENT (AMENDMENT) ACT 2002 a third amendment is due before 2005 to provide product patent provisions. The most critical issue will, however, be the issue of "data exclusivity" which will hit the Indian generic industry hard if implemented as per Japanese and U.S standards. It is too good to be true, compared to a few years before, when no one was even remotely interested in patents, except by research students while doing library search for processes development.

IPR like trademarks, copyrights, designs are in effective use in India and reasonably well enforced. Patents, geographical indications, biodiversity, plant varieties are in

policy-finalization/enactment. Minimum standards are prescribed by TRIPS, enforced by WTO (World Trade Organization) and managed by WIPO (World Intellectual Property Organization), which is a UN organization.

What is TRIPS?

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was negotiated with other international trade agreements during the Uruguay Round trade negotiations of the GATT from 1986 to 1994. As one of the World Trade Organization (WTO) agreements, it is totally binding for all WTO Member States (whether a previous GATT Member or a new WTO one).

The TRIPS Agreement sets minimum standards in the field of intellectual property (IP) protection (such as copyrights, patents, and trademarks) that all WTO Member countries have to respect. To achieve this goal, WTO Members have to modify their intellectual property laws to make them consistent with the new WTO standards. For instance, the TRIPS Agreement states that all patents shall be available for at least 20 years from the filing date, whereas before TRIPS the patent term varied greatly among countries (7, 10, 17 or 20 years). All WTO Members have to incorporate this 20-year patent term in their own patent law.

What will change with TRIPS?

Before the Uruguay Round and TRIPS, pharmaceutical patents and other intellectual property rights on drugs were widely recognized among major industrialized countries, but not in many developing countries. As there were no international standards on the scope of patent protection, countries had very different regulations on IP protection according to their own needs. In the pharmaceutical sector, some 40 countries did not provide patent protection for pharmaceutical products. Patents were simply not available for pharmaceutical inventions in these countries, which implied that no one could claim an intellectual property right on such products. As a result, copies of medicines protected by a patent in other countries were widely available, usually at a lower price than the original patented drug. The copies were either manufactured by local companies or imported, without having to ask the patent holders' permission. This practice is now coming to an end. Copies of patented drugs will remain on the market but it will no longer be possible to manufacture and market copies of new patented medicines in those 40 countries, unless the original manufacturer has chosen not to seek any patent protection there.

Under the TRIPS Agreement, all WTO Members have

to make patent protection available for pharmaceutical inventions in their countries. A company that has invented a new pharmaceutical product or process has, since 1 January 1995, been able to apply for at least a 20-year patent protection in any WTO Member country. The inclusion of pharmaceutical patents in the new WTO/GATT rules has the potential to exacerbate the problem of access to drugs in developing countries, by limiting or even disabling direct competition (generics) to new medicines until the relevant patents expire (unless licenses are granted).

When does TRIPS apply?

It is only in regard to transitional periods that the TRIPS Agreement takes into consideration Member States' different levels of economic development. Developed countries were given until 1996 to comply with TRIPS standards by modifying their patent law if necessary, developing countries had until 2000, and least-developed countries have until 2006 (with possible renewal). The transition periods were provided to developing and least-developed countries to give them enough time to implement the various TRIPS standards on intellectual property rights (copyrights, trademarks and patents) at national level.

However, as patents were not available for any pharmaceutical products in some developing countries in the pre-TRIPS era, a supplementary transitional period is allowed for countries still not granting patents for pharmaceutical products when the WTO came into force in 1995. This 5-year supplementary period means that the developing countries affected do not have to grant pharmaceutical products patents before 2005, unless they decide to revise their patent law before then.

Which drugs will be affected by the new patent rules?

The TRIPS Agreement requires WTO Member States to introduce patent protection only to products "invented" after 1 January 1995, i.e. products for which a patent application has been filed in a WTO Member State after 1995. This means that, in accordance with TRIPS, products already on the market cannot be given patent protection, because if they are already marketed, they are not new, and so do not meet the TRIPS conditions necessary to grant a patent. Therefore, only new drugs or new indications, formulations or processes invented after 1995 should be patentable in all WTO Member countries.

However, because developing and least-developed countries are entitled to transitional periods, and some will not grant drug patents before 2000, 2005 or 2006, a special

provision in the TRIPS Agreement preserves the novelty of drugs that may be invented between 1995 and the end of the transitional periods. Developing and least-developed countries not granting drug patents must have a system, often referred to as a "mail-box" system, to store patent applications as from 1995 until the transitional period expires. At this time, the various patent applications waiting in the "mail-box" will be examined according to the TRIPS standards and, if granted, the patent term, which starts from the filing date, will last for what remains of the 20 years.

What are developing countries' obligations under TRIPS?

Since all WTO Members are bound by the TRIPS Agreement, its minimum standards for IP protection must be included and implemented in national laws within the transitional periods allocated. These are only minimum standards however, and WTO Member countries may provide for greater IP protection than required in the Agreement. For instance, in Europe and the United States, pharmaceutical patents may be extended (beyond 20 years) for up to 5 years, to compensate for the long delays in obtaining marketing approval for a drug. The patent extension will vary from country to country (since there is no international standard) depending on the date of marketing approval. However, the pharmaceutical patent cannot be extended for more than 15 years from the date of marketing approval in European countries, and 14 years in the United States.

The main TRIPS standards, relating to pharmaceuticals, that countries must include in their patent law are:

1. Availability of patents for both pharmaceutical products and processes inventions that are new, involve an inventive step (i.e. non-obvious) and are capable of industrial application (or useful);
2. Protection of the product directly obtained using a patented process;
3. Availability of procedures at national level to enable patent owners to protect their rights against infringement.

In addition, if exceptions to patent rights and compulsory licenses are incorporated in patent legislation, they should be, respectively, limited and conditional to conform to the TRIPS Agreement.

Relevant web sites:

<http://www.col.ops-oms.org/medicamentos/politicas/PharmaWTOAgreement.doc>

[http://www.genderandtrade.net/WTO/TRIPS.](http://www.genderandtrade.net/WTO/TRIPS)
<http://www.wto.org>
<http://www.wipo.org>
<http://academy.wipo.int>
<http://www.uspto.gov>
<http://ep.espacenet.com>

<http://pk2id.delhi.nic.in>

For more information on this group discussion please check AI-PEAR-GP web site at http://groups.yahoo.com/group/ai_pear_gp/ and for membership please write to sbagga_pear@yahoo.com.
