



## Patents, Health Policy and Access to Medicines

Manthan D Janodia<sup>\*a</sup>, I Meenakumari<sup>a</sup>, MA Ganapathy<sup>b</sup>, VM Subrahmanyam<sup>c</sup>, N Udupa<sup>a</sup>, D Sreedhar<sup>a</sup>, Virendra S Ligade<sup>a</sup>

<sup>a</sup>Department of Pharmacy Management, Manipal College of Pharmaceutical Sciences, Manipal University, Manipal-576104, Karnataka, India

<sup>b</sup>IPR Patent Manager, Natco Pharma Limited, Hyderabad, India

<sup>c</sup>Department of Pharmaceutical Biotechnology, Manipal College of Pharmaceutical Sciences, Manipal University, Manipal-576104, Karnataka, India

Received: 10<sup>th</sup> Dec. 2010; Accepted: 09<sup>th</sup> Jan 2011

Address for Correspondance: [mdjanodia1978@yahoo.co.in](mailto:mdjanodia1978@yahoo.co.in)

**Abstract**— Intellectual property rights are the rights given to person over the creation of their inventions. They usually give the creator as exclusive right over the use of his/her invention for certain period of time, usually 20 years from the date of filing and in turn inventor has to disclose the invention. In a sense, it is a negative right as it excludes others from using the Intellectual Property without the permission of the right holder. © 2011 IGJPS. All rights reserved

---

**Keywords :** Patents, Health Policy, Medicines.

---

### ***INTELLECTUAL PROPERTY RIGHTS***

Intellectual property rights are the rights given to person over the creation of their inventions. They usually give the creator as exclusive right over the use of his/her invention for certain period of time, usually 20 years from the date of filing and in turn inventor has to disclose the invention. In a sense, it is a negative right as it excludes others from using the Intellectual Property without the permission of the right holder.

In law, intellectual Property is a form of legal entitlement, which allows its holders to control the use of certain intangible ideas and expertise. As we know traditionally each nation established and enforced its own intellectual property rights.

Until 1994, India was not a member country of GATT. But with the India becoming member of GATT in 1994, it has to comply with international norms of providing protection in all fields of technology, including pharmaceuticals, for both the processes and for the products itself. TRIPS agreement, entered into force on 1 January 1995. This agreement requires the member's nations of the World Trade Organization (WTO), which includes nearly all major trading nations to live up to, defines standards of intellectual property protection.

### ***IPR & ITS IMPLICATIONS***

- The owner of the property is free to use it as she/he wishes, provided the use is not against the law and to exclude others from using that owned item or property.
- The intellectual property rights apply a significant role in the economic prosperity and in the field of advancement and development of reliable, business, and technology of a country. The property and advancement in living standards of its citizen all around is an out come of their legacy in maintaining assets of intellectual property rights.
- The protection of IPR assets resource not only encourage its advancement and prosperity of economic interests but also encourages the activities if human creativity of manifold in inventing new and novel ideas to come in to life.
- In addition, registration under IPR Acts protects and gives an exclusive, monopolistic right of ownership of the intellectual property assets and it helps to identify and distinguish the source of goods or services.
- Intellectual property rights (IPR), apart from providing an incentive for innovative activity, also help create an atmosphere more conducive to progress.

It is common that any property, moveable or immovable is to be legally protected in order to prevent it from stealing, similarly the rights in the intellectual property created need also to be protected to prevent it from infringement. Intellectual property relates to information, which can be incorporated in tangible objects and reproduced in different locations.

### ***THE EMERGENCE OF TRIPS IN THE POLICY ON PATENTS***

Government protects intellectual property through patents. These grant exclusive manufacturing rights for a period of 20 years from the date of filing for the patent. In practice, because of the time taken to get a drug to market, the monopoly selling power is usually around 12 – 14 years. The industry argues that extensive protections of these rights are essential to generate to re-invest in research that is needed to ensure in continuing supply of new drugs. Only a small portion of the price of a drug is accounted for by managing property in large and controversial. India's patent policy, which emphasized public interest over monopoly rights, is in the process of shifting this balance towards greater protection if IPR.

Implications that emerge from this changing India's policy strategy are:

- The underlying social purpose of the patent systems is to provide an incentive to research and development, in the area of pharmaceuticals, for the development of new drugs.
- India, which has huge resource of talented scientific and technical man power and a sophisticated infrastructure on the pharmaceutical area, would appear to be well placed to take advantage of these opportunities.

The TRIPS sets out minimal standards for intellectual property generally modeled after those in developed nations with which all World Trade Organization members must comply.

### ***NURTURING ROLE OF PATENTS IN THE PHARMA INDUSTRY***

The pharma industry is one of the most intense "knowledge driven" sectors that are continually in a state of dynamic invasion. Diversities in life form and diseases pose stiff challenge to the design of specific and interested solutions. The process of "drug discoveries/inventions" is elaborate, requiring, on an average 8 to 10 years and costing 800 million to reach a new drug to the market. Thus, the intellectual property is the key imperatives in strategy formulation and implementation, preservation of exclusive market access and assuring the freedom to operate. The IPR portfolio in the process – knowledge-chain serves as an effective platform for the bench- marketing of intellectual assets and innovative capabilities of cooperation's, business entrepreneurs and researches, that has dominated 10 days world of mergers, acquisitions, strategic alliances, collaborations, licensing arrangements and venture capital funding in pharma and allied industries. Modern developments intervened with national approach, the gravity phase lay between the developments of classification large frame work in IPR are making the process in the "knowledge canopy" at multiple points in the "pharma knowledge – chain" a very complex process. Also at some time one has to address the theory socio-political issues involving bio-diversity, ethics and ownership of community knowledge, coupled with equitable sharing of benefits so or to arrive at an appropriate and workable IPR frame work.

TRIPS attempts to harmonize the IPR laws by bringing disparities into focus, since the formulation of the WTO on Jan 1<sup>st</sup> 1995, several nations have made significant changes in their national laws governing IPR. Thus, proper understanding and utilization of the laws in various countries would help in global positioning of pharmaceutical companies.

### ***IPR & ITS STATUS IN DEVELOPING COUNTRIES***

Before the Uruguay Round and TRIPs, Pharmaceutical patents and other intellectual property rights on drugs were widely recognized among major industrialized countries, but not many developing countries. As these 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 in these countries, which implied no one could claim an intellectual property right on such products. As a result, generic and economic medicines protected by a patent in other counters were widely available, usually at a lower price that the original patented drug. The generic medicines were either manufactured by local companies or improved, without having to ask the patent holder's permission. The practice has now come to an end. The inclusion of pharmaceutical patents in the new WTO/GATT rules has the exacerbated the problem of access to drugs in developing countries, by limiting or even disabling direct competition (generics) to new medicines until relevant patents expires (unless licenses are granted).

### ***DEVELOPING COUNTRIES' OBLIGATIONS UNDER TRIPS***

As all WTO members are bound by the TRIPs agreement its minimum standard for IP protection must be included and implemented in national laws within transitional periods allocated. The main TRIPS standards relating to pharmaceuticals, that countries must include in their patent law are: -

- 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.
- Protection of product directly obtained using a patented process.
- 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.

### ***CASE STUDY: NOVARTIS VS NATCO***

NATCO pharma opposed the application of Novartis India for grant of a patent for anti-cancer drug, Imatinib mesylate (Gleevec) useful in the treatment of certain forms of chronic Myeloid Leukemia. Natco filed a pre-grant application with the controller of patents, Government of India, challenging the validity of patent application (No 1602/MAS/1998) concerning crystalline modification of the drug. The ground of opposition is that the application for patent would fall within the concept of 'ever greening' as the polymorph claimed is the same as that of the 1993 molecule, thus resulting in no merit for the grant of a patent, a company release said.

NATCO also claims 'lack of novelty and inventive step' in the said application for grant of a patent. According to NATCO, the invention of the drug was made in 1993, and the Indian patent application merely claims a crystal form (beta) version of the same substance, hence, would not deserve consideration, the release added. Novartis had obtained exclusive marketing rights (EMRs) for the drug, in November, 2003.

To curb the widely prevailing practice called the 'ever greening' strategies which involves a manufacturer obtaining patent beyond the basic molecule, the Indian Patent Act was amended in April 2005, which excluded grant of patents to salts, esters, ethers, polymorphs and similar forms complexes, combination of known substance unless they differ significantly in properties with regards to efficacy.

### ***IMPACT OF PRODUCT PATENT REGIME ON PHARMA INDUSTRY***

#### Shifting from process to product patent regime

From 1947 to 1972, Indian Patent Act of 1911 accorded patent protection to products but high drug prices and insignificant domestic industry led to a reversal in policy. The provisions of the 1970 Act were amended to discontinue patent protection products while protection for processes continued. The changes also brought in licenses of right, liberal compulsory licensing provisions, reduction of patent protection from 14 years to 7 years (from date of application) and 5 years (from date of sealing) in the Patent Act, 1970. Process patents and accompanying changes laid down a strong foundation for Indian pharmaceutical industry. As multinationals watched in dismay, Indian companies went from strength to strength by producing cheaper versions of patented blockbuster drugs.

Now India has come a full circle and embracing product patents in line with WTO agreements. India as a signatory to World Trade Organization (WTO) implemented Trade Related Intellectual Property Rights (TRIPS) obligations.

Both sides of the coin

Introduction of product patents has far reaching implications for Indian pharmaceutical industry. For multinationals, product patents bring much needed relief. The country will see existing multinational strengthen their presence and new ones stepping in. On the flip side, product patents mean a paradigm shift for Indian companies requiring new strategies and skills. Though in near term the Indian players won't be affected of the new patent regime, in long run the monopoly could be a matter of concern on account of exclusivity through patent right of product. But in the long run the patent regime will bring in new hope in the industry through innovations.

| <b>Advantages</b>   | <b>Disadvantage</b>  |
|---|--|
| Technology up gradation through tie ups of Indian players with multinationals | No Reverse Engineering: a difficult time ahead   |
| Center for development: India could be a Research hub due to cost advantage   | Price Factor: mounting prices of drugs could be an issue                                 |
| Intellectual Property Rights (IPR) will Promote innovations.                  | Supply concerns: sourcing those drugs could bring a supply strain                        |
| All new drugs will come to India.   | Market Loss: Indian players will be asked to withdraw Rs. 3000 cr. Products from market. |

Options with Indian companies

There are few options available with Indian players. One option could be to get into supply of bulk drugs and active pharmaceutical ingredients (APIs) with the approval of the parent holder. The option of producing off-patent APIs will always exist. Another option would be to streamline the process of manufacture and to become the cheapest manufacturer of off-patent drugs. Given the distinction in reverse engineering that Indian companies have earned over the years, this prospect holds much promise. The third option lies in licensing globally successful drugs in India. Fourth option would be to position Indian companies as research and development centers for multinationals. The cost advantage and the availability of human capital at a low cost will prove irresistible to multinationals. Other opportune that exists for MNC companies in India is outsourcing. Cost will be the driving factor in this business, as most companies in regulated markets are facing severe price competition from low cost generics manufactured in India. These global corporations are likely to look at cutting costs by outsourcing their manufacturing to low-cost countries such as India.

In long run, only three kinds of businesses will remain, they are outsourcing, generic and research based. However, the risk and return embedded in these options vary.

***IMPACT OF NEW PATENT REGIME ON PUBLIC HEALTH***

The essential medicines need to be cheap and affordable for every one in order to achieve the right called right to access medicines. The patent legislation of the country was intelligently exploited by the Indian companies and were introducing new medicines developed elsewhere, but of course, manufactured by different methods (reverse engineering). The general public, the government and domestic pharma companies were beneficiaries of these provisions. The accessibility of modern medicines is always problem in India and other developing countries. Only one third of our population has access against the world average of two thirds. This is because of lack of money to buy medicines even if they are reported to be available at the minimum price. In developed countries, the costs of

medicines are born either by insurance companies or under a social security system. But, in India where most of the people pay for medicines from their own pockets, even slightest rise in price would affect the accessibility.

The industry and official source argued that 97 per cent of existing drugs are out of patent and hence there would be no significant price rise.

The medicines are an important component in public health system. They constitute around 35-40 per cent of health budget. The price rise would definitely affect the availability of medicines in health system and for patients too.

The non-availability of medicine destroys the credibility of the system. Global rights to health means right to access to essential medicines. The essential medicines need to be cheap and affordable for every one in order to achieve this right. The government needs to look into this problem and more emphasis needs to be given to the drug management process.

### ***REFERENCES***

1. <http://www.lexorbis.com/content.asp?catid=1&subid=8>
2. [http://www.wipo.int/academy/en/courses/distance\\_learning/catalog/pdf/dl\\_brochure\\_2006.pdf](http://www.wipo.int/academy/en/courses/distance_learning/catalog/pdf/dl_brochure_2006.pdf)
3. <http://www.lexorbis.com/content.asp?subid=2&catid=1>
4. <http://www.lexorbis.com/images/content/patent%20prosecution%20in%20india%20-%20flowchart.doc>
5. B. K. Keayla. (2004). Pre-grant opposition can be advantageous to India. Express Pharma Pulse pg 25
6. <http://www.lexorbis.com/content.asp?subid=1&catid=1>
7. <http://www.lexorbis.com/images/content/opposition%20flow%20chart.doc>
8. N.R.Subbaram (2005). Intellectual property – an introduction – what everyone should know about patents. Pharma book syndicate publishing Pg –1
9. Gopakumar Nair, “Truth lies some where in between” Express Pharma Pulse, pg 21-22.
10. Prabuddha Ganguly (2001). Intellectual Property Rights Unleashing the Indian Economy, Tata Mcgraw-Hill publishing limited
11. Dr.Parikshit Bansal (2005). IPR & its implications in small-scale industries, Express Pharma Pulse, April 14, pp-10.