

FREQUENTLY ASKED QUESTIONS ON PATENTS

Q. What is a Patent?

A. A patent is a limited monopoly given to an individual or corporations for a limited number of years for technological inventions in a particular territory, ordinarily a country. It is granted at the request of individuals/corporations by the Patent Office in the respective country. Hence, a patent is available within the territory of the granting countries. Nearly 97 percent of world's patents belong to developed countries.

Broadly, patents can be classified into process and product patents. A process patent grants a monopoly on the process of manufacturing of a product and not on the product itself. However, with a process patent it is always possible to make the product through another process. Therefore a process patent confers only a limited monopoly. On the other hand, a product patent gives a monopoly on the product itself and prevents others from manufacturing, selling, distributing and importing that patented product without the authorization of the patent holder. No other person can produce that product. Thus a complete monopoly results which leads to high prices and puts the patented drug out of reach of majority of people, especially in developing countries such as India.

Q. What is the impact of product patent on access to treatment?

A. It is important to remember that competition leads to lowering of prices and lack of it to high prices. When a product patent is granted by the patent controller to a single manufacturer, it creates a complete monopoly in that product or drug. As a result, there is no competition. This leads to high prices. This affects consumers and compromises accessibility and availability.

For example, in 2000, basic first-line antiretroviral drugs (ARVs) were only available from patent-holding Western pharmaceutical companies at the price of approximately US\$ 10,000 per person per year. In 2001, Cipla, an Indian generic company, announced that it would provide the same drugs at approximately US\$ 350 per person per year. Since then, with the entry of more generic competition in the ARV market, the prices have fallen even further, to approximately US\$ 120 per person per year. This dramatic decrease in prices would not have been possible if these drugs had been under patent protection in India.

Q. What is the justification for patent?

A. It is a supposed reward for disclosing the invention to the public. It is supposed to induce investment in research and development and advancement of science and technology.

However, in the pharmaceutical context, it is questionable whether patents protection provides the right type of incentives for innovation. For instance, of the 1,226 new drugs developed between 1976 and 1996, only one percent was for treatments of diseases primarily affecting the developing world. Because poor countries have less money to pay for drugs, the monetary incentives created by patent protection cause the pharmaceutical industry to ignore some of the most harmful diseases simply because those who are sick are too poor to pay. Moreover, many patents do not protect genuine "innovation," but are merely devices which allow pharmaceutical companies to extend their monopolies beyond the 20 years granted by the original patent.

Q. What are the main provisions of the Patents Act, 1970 vis-à-vis drugs?

A. The earlier Act did not protect product patents at all for drugs. It protected only the process of manufacture of the drugs, that is process patents. The period of patent protection was for a period of seven years. Through a process of reverse engineering, generic versions of new drugs could be legally produced. This allowed the Indian generic pharmaceutical industry to provide lifesaving medicines at a fraction of the cost of western multinational pharmaceutical companies, thus making drug costs in India

some of the lowest in the world. Due to the ability of the Indian generic industry to make safe, effective and affordable drugs, India now supplies about 50% of ARVs that are used in the developing world.

Q. What amendments were brought to the 1970 Patent Act in March 2005 and why?

A. The amendments were made because of the TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement. India signed TRIPS agreement which came into force on 1 January 2005. According to the TRIPS agreement, India was obligated to introduce product patent protection for pharmaceuticals, meaning that India's ability to continue to be the provider of affordable drugs to much of the developing world was threatened.

However, some key provisions were included in the Patents (Amendment) Act to ensure that frivolous patents on drugs were not granted at the cost of public health. One provision stated that changes or modifications to already existing drugs would not be granted a patent unless the change made the drug product more effective. This was designed to prevent a practice called "evergreening" whereby drug companies seek to artificially extend their 20-year patent term by subsequently patenting what are often trivial changes to the original drug product.

Q. Which drugs will be affected?

A. All drugs that were invented on or after 1 January 1995 (the date of India's entry into the World Trade Organization) are now eligible for patent protection in India. During the period from 1995 to 2005, the Indian government set up a "mailbox" for patent applications, so that the Patent Office could review these applications once India came into compliance with TRIPS. During that time, approximately 9000 patent applications for pharmaceuticals were filed with the Patent Office. However, during that same period, only about 300 new drugs were actually developed by the pharmaceutical industry. This suggests that the vast majority of patent applications in the "mailbox" concern modifications of already existing drugs. Already, some patents on key drugs have been granted. For example, Roche was granted the first product patent in India for a treatment for Hepatitis-C. Roche sells the drug at about Rs 250,000 (US\$ 5,800) for a 24-week treatment.

Q. What is Compulsory licensing and its implications?

A. To prevent the owners of medicines under patent from abusing their monopoly position, patent law all over the world allows for the government to issue "compulsory licenses" to allow other drug manufacturers to make the drug. The TRIPS agreement allows for the use of compulsory licensing mechanisms to ensure that patent protection does not prevent the public from having access to essential medicines. Thus, in cases of medical emergency, government use, or in some other circumstances, the government can issue a license for other companies to make a drug without the consent of the patent owner. However, in practice, it is often difficult to convince the government to issue a compulsory license. Both the United States government and the powerful pharmaceutical industry lobby have been known to apply intense pressure on governments not to issue compulsory licenses.

Q. What will be the impact of changes in India's patent Act on access to AIDS drugs in poor countries?

A. New patent monopolies in India will drive up the cost of medicines for treatment of AIDS as well as several other public health problems such as cancer, diabetes and heart disease to name a few in the medium and long term. This cost increases will burden poor people in India as well as in importing countries around the world. In the case of HIV treatment, people who develop resistance to the first line of treatment will find it difficult to go in for the second line which is 21 times more expensive.

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