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IPR AND PHARMACEUTICAL INNOVATION: LAW, MEDICINE AND MARKET

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The topic of intellectual property rights (IPR) is very important when it comes to the innovation process within the pharmaceutical industry. It determines the way the discovery and development of innovative products are conducted, pricing strategies adopted, and even distribution practices. The link between law, science, and market is extremely strong within the pharmaceutical industry, as the outcome of innovations here may lead either to life-saving products that would benefit thousands of people or loss-making drugs after several years of research.

This is where the importance of the right becomes obvious: intellectual property law ensures the creators of the products have a certain legal term of protection during which they will be able to recover investments and earn profits. In the case of the pharmaceutical industry, these terms are granted through obtaining patent rights, regulatory exclusivities, trademarks, and trade secrets. Otherwise, other companies might simply copy the invention after its approval and make it unprofitable for the innovator to invest more money into scientific research.

Patents are the most prominent type of pharmaceutical IPRs. Definition of the purpose of a patent – granting exclusive rights to exclude any other person from making, using, offering for sale, selling and/or importing into the territory the patented product. When it comes to pharmaceutical patents, there is also the option of having the scope of protection include not only the molecule but also its manufacture, formula, delivery method, administration method, or specific application.

The problem with pharmaceutical patents, on the other hand, is that it is not perfect. Indeed, one of the biggest criticisms is access. With patent protection, high prices become unavoidable; hence, such medications can remain out of reach for many who need them, particularly in

LMICs. Therefore, the dilemma is: how to achieve equilibrium between innovations and health?

The solution, however, is not always straightforward. Various methods can be employed within a legal system to temper the exclusiveness that arises through IPRs. One such measure is compulsory licensing, whereby in specified cases the government may compel the use of a patented innovation even without the patent holder's consent. Patents opposition systems, price control measures, competition laws, and rigorous patentability requirements serve to guard against any possible abuse of this process and ensure that public interests are safeguarded. Such an effort at striking a balance was notable in the case of India. This country's patent regime, especially post-introduction of product patents for pharmaceuticals in 2005, sought to promote innovations without allowing evergreening practices.

At this juncture, it would be apt to highlight the fact that Section 3(d) of the Indian Patents Act of 1970 does not permit the grant of a patent in respect of an invention which consists of the creation of a new form of a known substance unless the newly invented form involves any improvement in the efficiency of the substance over its existing known form. One of the pertinent cases in this context is that of Novartis AG v. Union of India (2013) 6 SCC 1.It became a landmark decision in world's pharmaceutical patent laws as it established that Indian patent law does not provide protection to trivial inventions that do not bring benefits.

Moreover, the Indian authorities awarded India's first compulsory license to Natco for Bayer's cancer drug, named sorafenib tosilate/Nexavar.

The ruling was based on statutory issues as per the Patents Act, where, among other things, the reasonable requirements of the public were not satisfied, and the drug was not available at a reasonably affordable price. The example shows that even though pharmaceutical patents offer exclusive protection to the inventors of medicine formulas, they may be limited depending on certain factors.

In another case, the Indian judiciary also dealt with the issue of patent protection in infringement matters relating to pharmaceutical products. F. Hoffmann-La Roche Ltd. v. Cipla Ltd. concerned a dispute about an anti-cancer drug – erlotinib – with the court considering issues of patent validity, infringement, and public interest. This case exemplified the real problem of the conflict between patented products and low-price generics. Despite the aggressive stance taken by patentees with regard to protecting their patents, courts still had to balance their interests against those of other parties.

It should be noted that in India, there are no anti-patent sentiments. On the contrary, the national patent law is intended to promote innovation while providing enough room for competing products.

Law does not exist in isolation. Innovation in drugs is affected both by market structure and by laws on intellectual property rights. Drug discovery and development is a multi-stakeholder process involving various groups, including academic institutions involved in research and development of innovations, biotech companies, large multinationals, generics manufacturers, government institutions, hospitals, doctors, public health institutions, etc. Concerns relating to venture capital investment, licensing agreements, mergers and acquisitions, public-private partnership, logistics, etc., affect the success of innovation in developing an effective drug. In most cases, intellectual property rights act as the law underpinning commercial activities in technology transfer and development.

There are social aspects that make the pharmaceutical industry different from other industries. This aspect stems from the fact that drugs affect people's health and, therefore, human welfare. The reason for this is because the medicines will influence the well-being of humans, hence the welfare of people. It implies that all the pharmaceutical intellectual property rights should pass the ethical standards test concerning the cost, accessibility, equality, and right to health. Issues like those experienced in AIDS and coronavirus infections have shown how the pharmaceutical intellectual property rights may conflict with human health during emergencies. On an international basis, there are policies such as Doha Declaration Regarding the TRIPS Agreement and Public Health (2001) stating that the intellectual property laws have to support the well-being of people.

Intellectual property rights do not have to be bad. They can be useful. The laws about intellectual property for the pharmaceutical industry need to be fair. If the companies that make drugs do not get reward for making new medicines, then they will not make as many new medicines. On the one hand, if they get too much reward, then it will take a long time for cheaper versions of the medicines to be available, and the medicines will be too expensive for many people.

So the best thing to do is to find a ground. This means making a system of laws that will give rewards to the companies that make new medicines, but also make sure that people can get these medicines.

In other words, when referring to the pharmaceutical sector, innovation does not involve just medication but also the law. Property protection will motivate individuals to discover and will entice investors, which will help to develop new drugs for those in need. But, such an approach must be for the benefit of all parties involved. It should take into account both sides of the matter equally.

CITATIONS

1. *Novartis AG v. Union of India*, (2013) 6 S.C.C. 1 (India).
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3. *Bayer Corp. v. Natco Pharma Ltd.*, Compulsory Licence Application No. 1 of 2011, Controller of Patents (Mar. 9, 2012) (India).
4. The Patents Act, No. 39 of 1970, § 3(d), Acts of Parliament, 1970 (India).
5. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001).