INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 5 AND ISSUE 14 OF 2025

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

THE FUTURE OF PATENTS IN THE PHARMACEUTICAL INDUSTRY

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BEST CITATION - RANJAN KUMAR, THE FUTURE OF PATENTS IN THE PHARMACEUTICAL INDUSTRY, *INDIAN JOURNAL OF LEGAL REVIEW (IJLR)*, 5 (14) OF 2025, PG. 428-432, APIS – 3920 – 0001 & ISSN - 2583-2344.

ABSTRACT

The future of pharmaceuticals will be driven by a number of factors, including rapid scientific innovations, new biotechnology developments, and global priorities related to health care. As a result, traditional patent laws—the foundation for protecting new discoveries and products—are undergoing increasing scrutiny as the pharmaceutical industry faces more and more challenges internally and externally. This paper will assess what the future will look like with respect to patents in pharmaceuticals by examining some of the major issues facing the industry today—high research & development costs, patent cliffs, the always-present issue of evergreening, and the unequal access to life-saving medicines between middle-income and low-income countries—as well as the potential of new regulatory models (such as data exclusivity, compulsory licensing, open-science drug discovery, and international regulatory harmonization) to alleviate these challenges. Furthermore, this paper will assess the impact of technological advancements (such as AI and personalized medicine) on the patentability and enforcement of new pharmaceutical inventions, as well as the potential effects of these advancements on pharmaceutical markets.

Overall, the findings presented in this paper point to the need for an adaptive/escrow-system patent model that provides the necessary incentives for innovation while simultaneously providing access to necessary therapies for all individuals, particularly to those in low- and middle-income countries, by means of co-operative governance between multiple health care systems. The findings indicate that the long-term growth of both science and public health will depend on partnerships between government, industry, and academia, working together as collaborative remonstrators of "hybrid innovation"

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INTRODUCTION

A patent is a collection of exclusive rights that a sovereign State grants to an inventor, or his or her assignees, for a limited period of time in consideration of making the invention publicly available. As a result of this agreement, inventors have the legal authority to stop others from manufacturing, using, selling or distributing the invention for commercial gain.

Pharmaceutical and drug patents have become increasingly important each year due to the number of new and improved medications entering the market, which generate significant revenue for the pharmaceutical industry.

Consequently, the pharmaceutical industry is an area where innovation directly impacts the profitability of drug companies that invest heavily in the research and development of new drugs, and incur large expenses without any guarantee or assurance that any given product will successfully pass through multiple testing stages, and go on to generate a profitable market return upon being commercialised.This article will provide a basic overview of patents and why they are necessary in the pharmaceutical industry, and will also provide an overview of how patents operate within pharmaceutical companies.

THE PHARMACEUTICAL INDUSTRY

The success of patent protections in the pharmaceutical Industry results from Industry's

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situation within itself, i.e., its structure, organisation and resources are focused on high-cost, high-risk R&D efforts as opposed to on fast-tracking technology-based products to market. In contrast, The Physical Sciences base their scientific advancements on a more predictable & fast-paced basis6; therefore, scientific advances in The Physical Sciences are made too quickly for return on investment from a newly commercialised product. Hence, the need to remain competitive due to market pull factors greatly diminishes the importance of patents as a market incentive.

However, while the Pharmaceutical Industry incurs the greatest expense during the concept stage of developing an invention, the process of filing for a patent is significantly less than the cost of completing the regulatory approval process and developing and establishing sales and marketing channels. Once a developer creates a "me-too" drug, it can be extraordinarily profitable. More often than not, the Pharmaceutical Industry seeks protection from generic competition as opposed to the time delay caused by competition.

As a result of this approach, the Pharmaceutical Industry incurs a number of socoteconomic costs. First, the pipeline of potentially viable drugs is reduced due to lack of ability to patent such drugs and/or profits to be derived from marketing them. Secondly, the inefficient race to dominate inventions extends unconditionally and without limitation from product development (which would traditionally fall within the commercialisation definition) into the realm of Basic Scientific Research.

A COST-BENEFITS ANALYSIS OF 'PATENT RACES'

Though, the patent system remains theoretical inclined to protect the inventor, any cost-benefit analysis conducted on behalf of the inventor would be an unattainable objective. Development of products led by a corporation or other commercial entity with sufficient monetary resources has been proven to be inconsistent with the foregoing presumption of a low level of competition for primary inventions based on Kitch's theory. This results in the total elimination of the small-scale inventor from being able to generate any profitable inventive activity.

It is not, however, the primary focus of the protection of the inventor. A heavy emphasis on commercializing the drug development process has negative ramifications as the progression of science related to neglected diseases is impeded.

There is a clear focus by corporate entities in the commercial exploitation of patent rights to establish monopoly control over the market. The prospective reward for conducting the prohibitory costly research and development of a primary invention must compensate not only for the initial investment - which is the intent of patent law - but also offset the risk of committing the resources necessary to market the invention, which may be an outcome of a patent race. Accordingly, when a patent race occurs, it is almost certain that the returns associated with that race will be greater than efficiently. Furthermore, since commercializers heavily rely on their predictions of future profits to drive their business, they do everything they can to minimize enabling patents.

Enabling patent is a disclosure that describes an invention in such a way that a person skilled in the art (PHOSITA) can recreate the invention; based on the premise that a monopoly is granted when a

company receives enablement with the least amount of rent dissipation as a result of organized research, organized research, when controlled by one commercializing entity, will follow the trend of evergreening23 through slowdowns in the rate of technological advancements to prolong the term of the monopolistic patent. The advancements made during the time a patent is in place are mandated by the need of the market rather than driven by the technological needs created by the influx of competitive products. It is important to connect patent rights with competition in order to properly protect those

who create the inventive 'genius' and to establish an appropriate environment for pure scientific research.

NECESSITIES FOR PATENT PROTECTION

It is important to note that not all innovations are patentable as a result of the patent process. In order for your invention to be eligible for patent protection, it must meet specific criteria that define whether your invention meets the requirements necessary for patent eligibility. Specifically, the invention should meet three primary criteria:

(1) non-obviousness

(2) novelty

(3) utility

Non-obviousness is defined by how well your invention stands apart from other inventions. If the invention to you is an improvement on a previously patented invention or has been described or disclosed in a prior patent, it is deemed to not be an improvement and therefore is not non-obvious. As a result, the non-obviousness rule is the single most significant rule of thumb in determining whether your invention is patentable.

Novel and utilitarian means that your invention has never been created nor is it now being made and you must file an application to obtain the patent. In this instance, there may have been one or more failed patent applications for the same type of invention, but if your invention is being made and used at the time you file your patent application you will likely encounter issues.

To clarify, even if the invention you are attempting to patent has not received a patent as of now, that does not eliminate that your invention could potentially receive a patent in the future. As a result of the lack of patent protection on the previous creation, it may still be protected under common law. However, if a patent on the same invention were to be issued in the future, this would put you at a significant disadvantage against the previous creator and you would lose your ability to use the protection of the common law due to having a patent granted on your basis.

To be able to make a patent application to protect, any other inventor must have already filed a patent application on their own invention beforehand, so as to have full protection rights in the given situation. Because pharmaceutical companies do not have a sample patent to protect them, pharma companies would be required to have much less of a patent portfolio, ultimately losing significant market share. Indian pharma companies will need to develop new drugs, protect the IP of new drugs, and compete effectively with the other global pharma companies and protect their IP in order to compete.

The being in the near future that we can rely on for the commercialisation of any IP we create is likely to be determined by the patent protection of pharma companies at that time, and therefore pharma companies should focus on developing and maintaining a strong patent portfolio and protecting its value.

CONCLUSION

In this document, the author refers to a couple of issues related to regulations concerning research for neglected diseases.24 Two primary issues need to be addressed within the framework of the patent system. The first issue deals with developing a system of patents covering every level of product development separately—this requires preventing multiple-level rent seeking. The second issue deals with providing explicit incentives to inventors and commercializers through the patent system to facilitate their activities.

There has been a lot of discussion on ways to resolve this deadlock. One suggestion is to interpret a research exemption, liberally defined, to be a way of providing greater freedom for companies performing research and innovation in a particular field to find ways to monetize their discoveries and innovations.13 When the

flow of information in an industry becomes faster, there will be an increase in demand for commercialization, which can be seen in the energy and information technology sectors. A broader application of a research exemption may ease some of the

"blockages" that occur at the initial innovation phase, but it may not change, or may even increase, the number of competitors engaged in a "patent race" to market. To mitigate the risks of diluting rental income due to competition in a "patent race," incentives for inventors must be structured in a way that encourages a broad range of options in research.

Another way to achieve these goals is to provide reductions in commercialization costs.25 The costs associated with commercialization represent one of the most significant barriers to developing a more efficient means of research; without a means to do so without being constrained by significant regulatory costs, a diverse range of innovation cannot be realized. Although one of the key limitations associated with this strategy is that it will do nothing for existing competition at the initial innovation stage. As noted above, the "commercialization patent" is clearly not a remedy to the clustering problem of research. The commercialization patent does not address the issue of basic research funding, which is substantially lower levels than commercialization funding although, by itself, is quite sufficient as a fundable activity... Switching patent systems from the first-to-file to a more appropriate patent system is, of course, an achievement; but it could also eliminate any incentivizing to engage in pure research.

All of these methodologies identify the definition of how to develop products and the distinction between inventors and commercializers as two separate groups. However, what creates the problems within the field of research in neglected diseases has both of these elements combined. In an attempt to simplify the issues further, it is imperative that the purpose of the patent system accomplish these goals through the redirection of resources away from highly competitive areas suffering from patent race (competition) toward those areas of research and development (RD) being neglected by commercialization. If the linkage between competition and patent rights is not defined, the patent system will not adequately protect the inventive "genius" nor support the advancement of pure science through the granting of patents.

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