International Journal For Advanced Research In Science & Technology
A peer reviewed international journal www.ijarst.in
IJARST
ISSN: 2457-0362

ROLE PLAYED BY PATENT LAW IN PHARMACEUTICAL INDUSTRY

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ABSTRACT
Over thousands of years, Homo sapiens have developed sophisticated political and legal structures, cultural practices, and technological advancements. There's no denying that they are a powerful demonstration of the creative potential of the human mind. In addition, innovations and creativity are fundamental to human life; nonetheless, they often present perplexing and obfuscating legal or social quandaries, such as to what extent it is acceptable to modify or alter the natural or physical environment. Or, what are the ethical and societal consequences of technological advancements? In this paper, we investigate the relationship between patent law (a component of the complex legal system) and one such problematic technology, biotechnology in the pharmaceutical industry. Intellectual Property Rights (henceforth IPRs) and patents need to be briefly described for context before we can go on to delineating or defining the many difficulties or quandaries involved therein and before we can determine the boundaries of the current study.

KEYWORDS: Patent Law, Pharmaceutical Industry, human mind, human life, physical environment, Intellectual Property Rights.

INTRODUCTION

Intellectual property rights include the distinct category of property1 known as "Intellectual Property" (henceforth IP). The term "creations of the human mind" perfectly describes what intellectual property is Inventions, books, logos, sculptures, etc., fall under category 2. The term "legal rights governing the use of such creations" is often used to define intellectual property rights. Third, the items that this IP covers or refers to are not those that can be touched, but rather they are abstract or intangible. These have no bodily existence at all. So, intellectual property rights are literally "rights to a concept “Fourth, IPRs are everywhere and incredibly important since innovation and creativity are so basic to human existence. These fuel the "knowledge economies"5 that drive the contemporary world. Unsurprisingly, they are foundational to a wide variety of policy discourses; they form an increasingly vital part of the law; they play a significant role in international commerce; and they are at the center of a wide range of issues and controversies, some of which fall within the purview of this article.

The phrase "intellectual property" is interesting since it is believed to be a "generic term used to refer to a group of legal regimes" that emerged in the 20th century. Separation between "industrial property" and "copyright" existed in the past, presumably as a result of the different legal foundations laid down in the Conventions of Paris7, Berne8, and Rome9. Patents, utility models, industrial

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designs, trademarks, service marks, trade names, indicators of source or appellations of origin, and the suppression of unfair competition are all included in the latter, referred to here as "industrial property."10. We cannot limit ourselves to a definition of "industrial property" that applies "only to industry and commerce proper" here. When referring to the latter, "copyright" refers to both "literary and artistic works"12 and "neighboring rights." This kind of separation is archaic today.

The current WIPO Convention states that,

For the purposes of this definition, "Intellectual Property" refers to "rights relating to literary, artistic, and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and all other rights resulting from intellectual activity in the industrial, scientific, literary, or artistic fields."

It may seem out of place to include "scientific discoveries" here. Notably, WIPO does manage "a system for the international recording of scientific discoveries" in accordance with Geneva Treaty. This is done "to promote information on new scientific discoveries, for the benefit of the scientific community and the world at large".

PATENTS: THE RIGHTS & EXCEPTIONS

The exclusive rights granted by a patent include the ability to stop anyone from producing, using, and offering for sale, selling, or importing a product that is the subject of the invention without the permission of the owner.

This limitation applies even if the "making" is done differently from the patentee's claimed method. The person who "independently reached the same invention"40 is disadvantaged by a patent since, as has been noted, "unlike trade secrets, a patent" functions against them. Additionally, TRIPS states that An exclusive right to: "(b) where the subject matter of a patent is a process, to prohibit third parties without the owner's consent from using the process and from using, offering for sale, selling, or importing for those purposes at least the product obtained directly by that process."

If a different method is used, the aforementioned restrictions on the "product obtained directly by that process" are nullified. However, the scope and depth of protections are impossible to ignore. All members of the WTO system must provide the aforementioned wide rights to one another. It should come as no surprise that the language of section 4842 of the Patents Act in India is almost similar to that in the United States. The owner of a patent has the "right to assign, or transfer by succession, the patent," as well as the ability to license the invention to others. In addition, TRIPS specifies within the realm of patent rights, it is permissible for members to establish certain exemptions, albeit with limitations. These exemptions must not unduly impede the customary utilization of the patent, nor unjustly undermine the lawful interests of the patent holder. In making such determinations, due consideration

must be given to the legitimate interests of third parties.

PHARMA-BIOTECHNOLOGY PATENTING: A MILLION RAGING CONUNDRUMS

Hereinafter referred to as "pharma-biotech," "pharma-bio," or "bio-pharma," our field encompasses a wide range of disciplines and technologies, including but not limited to: stem cells; vaccines; xenotransplants; cloning; so-called "nature derived drugs"; biopharmaceuticals; genetic researches; genomics; "isolated and purified genes"; genetic testing; and so on. Researchers are not concerned with the safety or regulation of agri-biotech products like terminator-seeds or genetically modified foods. Now, as will be briefly discussed below, pharma-bio monopolies are sadly exceedingly divisive or dilemmatic and full of many burning conundrums. The points of view or concerns listed below are by no means complete. Indeed, their presence, together with the existence of competing philosophical perspectives and concepts, which we fully debate or negotiate with in subsequent chapters, inevitably makes pharma-bio-patenting a highly productive study topic.

It is noteworthy that patents often elicit polarized opinions. There exists a historical debate over the provision of monopolies for scientific innovations and technology. Numerous individuals have expressed concerns over the adverse effects of patents on the prevailing principle of open science and the process of commercializing fundamental research. The user's text does not provide any information or context. Moreover, patents might be seen as impeding "the accessibility of knowledge and essential medications." The United States court, indeed, acknowledged that, Patent protection, in essence, has both positive and negative implications. On one side of the argument, the provision of exclusive rights offers financial motivations that stimulate the process of creativity, innovation, and discovery. However, the aforementioned exclusivity can hinder the dissemination of information that could potentially facilitate and stimulate innovation. This hindrance may occur through various means, such as an increase in the cost associated with utilizing patented ideas, necessitating expensive and time-consuming searches of existing patents and pending patent applications, as well as necessitating the negotiation of intricate licensing agreements.

PATENT COOPERATION TREATY

Patents have geographical limitations. Thus, "individual patent applications for each country where protection is sought" are required. It requires "expenses for translation, patent attorneys in the various countries, and payment of fees to the Patent Offices," all while the applicant "often does not know whether he is likely to obtain a patent." The "every single patent office with which an application is filed has to carry out a formal examination of every application" requirement is another important aspect to consider. Thus, a solution was required "to lessen the doubling up on work that must be done by applicants and national Patent offices." In this case, the "Patent Cooperation Treaty" (abbreviated as "PCT") is the correct answer. This "agreement for international cooperation in the field of patents" is monumental. However, it "does not provide for the

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grant of international patents," which is an interesting omission. Just "rationalization and cooperation with regard to the filing, searching, and examination of patent applications and the dissemination of the technical information contained therein" is all it does. Therefore, grants continue to be a function of national governments. Since "the PCT does not compete with but, in fact, complements the Paris Convention" and "is a special agreement under the Paris Convention open only to States which are already party to that Convention," it is clear that the PCT is not a direct competitor of the Paris Convention.

TRIPS & INDIA

Several of the TRIPS provisions were addressed in our first chapter and in the preceding section. We also highlight a few more that are essential to remember. After that, we briefly discuss some of the complaints that have been raised throughout the years about TRIPS.

Paris becomes Mandatory:

It included the requirement that "members shall comply with" applicable provisions "of the Paris Convention" in respect to patents. "nothing" in TRIPS "shall derogate from existing obligations that Members may have to each other under the Paris Convention". Therefore, it made that convention obligatory in effect.

The "National Treatment" and MFN clauses:

It restates the principle of "National Treatment" and establishes the groundwork for "Most-Favored-Nation Treatment" (or MFN), as already indicated. Since the former is true, Subject to the exclusions previously given in, respectively, the Paris Convention, "each member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection of intellectual property." Similarly, the term "most favored nation" (MFN) implies that, with some exceptions, every benefit, preference, privilege, or exemption provided by a member country to the citizens of another country must be promptly and unconditionally extended to the citizens of all other member countries.

The Exhaustion Rule:

In addition, the document states that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights" (with the exception of Articles 3 and 4). The "freedom to incorporate the principle of exhaustion of rights into their domestic law with national, regional, or international reach" is therefore a point of discussion among commentators. The notion of "First Sale" exhaustion states that "once a patented product has been sold anywhere under the authority of the patent holder, the patent holder has no right to prevent further sale or importation anywhere in the world." As a general rule, the holder's IPRs are depleted after the first sale.

Patent Provisions, Controversies & Indian Amendments:

The patent system bears some responsibility for the negative publicity surrounding TRIPS. That "the issue of patentability and the exclusion thereto was one of the main areas of controversy in the TRIPS negotiations" is a common claim. The "uniform" and "minimum"

epoch-spanning rule that "patents shall be available for any inventions, whether products or processes, in all fields of technology" is the source of this phenomenon. This had profound effects since "at the time," as the story goes, "fifty countries did not confer patent protection on medicines, and in some cases, on other products such as food and beverages." No pharmaceutical monopolies were granted in India, either. Negative consequences, such as the collapse of local generic businesses and a decrease in so-called "access to medicines" as a result of price increases, resulted from reversing these policies. Some have stated that

"It was quite evident from the outset"... "Extension of patentability, particularly to pharmaceuticals, in those countries that did not recognize it was a major objective of the proponents of GATT disciplines on intellectual property." The pharmaceutical sector likely lobbied heavily for the TRIPS Agreement and succeeded in convincing the U.S. government to establish a connection between intellectual property and trade issues".

CONCLUSION

The pharmaceutical industry is the primary focus of research among them. This is why we focus on pharma-biotech. Regulatory processes and pricing control are only two examples of the many angles from which pharma-bio may be studied. However, in this case, we can only talk about monopolizing it or patenting it. Since this is the case, we focus on pharma-bio patents. We limit our attention to problems that arise before a patent is granted, such as whether or not the invention meets the necessary criteria for protection (what constitutes a "invention," or "subject matter") and what those criteria are. We include the so-called "disclosure requirements" or written specification requirement under the latter criteria and "failure to satisfy even a single requirement renders the invention patent ineligible." The previously described "anticommons problem" is investigated as well. Biopiracy and so-called "Access and Benefit Sharing" (or "ABS") modalities are also investigated, but only to the extent that they interact with or are connected to patenting.

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