

A Study of Patenting of Micro-Organism: With Special Reference to India

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Abstract: This research paper deals with biotechnology patenting in India and the factors primarily responsible for the same. Furthermore, it deals with patenting conditions both in India, Europe and the USA. It deals with stages of patenting as well as the procedure involved, concluding with the comparative analysis of these different patenting mechanisms.

Keywords: *Patents, Biotechnology, Micro-Organisms, factors, positions, etc.*

Biotechnology patenting in India is still in its infancy even in 2019. Three factors are primarily responsible. First, product patents on substances capable of use as medicine, drug, or food could not be obtained from the Indian Patent Office prior to January 1, 2005, when India completed implementation of TRIPS required amendments to its Patents Act. Second, even though process patents had always been available (albeit with short terms) despite the pre-2005 ban on chemical product patents, it was not until 2002 that a court overturned the Indian Patent Office's policy of rejecting claims to processes that produced a live product. Third, India's patent laws were amended in 2002 to explicitly include "biochemical, biotechnological, and microbiological processes" within the definition of potentially patentable "chemical processes."

These paradigm shifts away from India's earlier anti-patent product regime, coupled with a rapidly expanding biotechnology industry fueled by investments from both the private and public sectors, portend a surge in biotechnology patenting activity in India. Moreover, the Indian government symbolically emphasized the importance of biotechnological innovation by granting the first chemical product patent under India's post-TRIPS patent regime to a biologic: Hoffman LaRoche's Hepatitis C therapy, a branched pegylated interferon sold under the brand name Pegasys¹ A number of Indian firms that make "bio-generics"¹⁰ or

¹On March 2, 2006, the Indian Patent Office granted Patent No. 198,952, entitled "A Physiologically Active Branched PEG-IFN α Conjugate," to the Swiss pharmaceutical giant Hoffman-La Roche AG. This biologic, sold under the brand name Pegasys, is a new-generation therapy for Hepatitis C. See OFFICIAL J. PAT. OFF., May 19, 2006, at 10,000 (publishing notice of grant of Indian Pat. No. 198,952, on Application No. 1032/MAS/1997, assigned to Hoffman-La Roche AG), available

“bio-similars” have developed proprietary processes to manufacture first-generation biologics no longer under global patent protection, such as recombinant human insulin, erythropoietin, interferon, and granulocyte colony-stimulating factor.²

Subject Matters of Patentability

Any patent application must go through two stages before actual patent rights are awarded by the Patent Office. The first of these inquiries deals with eligibility of invention to be invention without restriction, that determines what types of inventions can be considered for patent protection. Patent eligibility thus performs a gatekeeper function. If an invention is not patent eligible, no other provision of the patent law can secure patent rights for that invention. Patent eligible inventions are not, however, automatically entitled to protection. Each such invention must thereafter be examined under a second, well-known set of requirements: novelty, non-obviousness, and disclosure. These are more specific inquiries that ask whether or not the claimed invention merits the protection of the state by being a sufficient advance over the existing body of patented materials and by being supported by a sufficient disclosure to provide the public with notice and scientific teaching.

Invention v. Discovery

The question as to whether certain substances isolated or derived from naturally occurring living organisms are "inventions" or "discoveries" has triggered widespread discussion. Its operating principle, which is traceable back to the nineteenth century, is entirely straightforward: one cannot patent a product that occurs in nature in essentially the same form. For more than a hundred years, the Patent Office and the courts have denied

at http://ipindia.nic.in/ipr/patent/journal_archieve/journal_2006/pat_arch_052006/official_journal_19052006.pdf ; OFFICIAL J. PAT. OFF., Oct. 28, 2005, at 24,056 (summarizing patent application data), available at http://ipindia.nic.in/ipr/patent/journal_archieve/pat_arch_102005/official_journal_28102005.pdf; P.T. JyothiDatta, Roche Gets Product Patent on Hepatitis C, Hindu Bus. Line, Mar. 2, 2006 (reporting grant of first pharmaceutical product patent to issue under India's new patents regime to Roche for Pegasys product), available at <http://www.thehindubusinessline.com/2006/03/03/stories/2006030302040200.htm>. Last accessed on 02/09/2019.

² Kowalski et al., “The Quest for Generic Biotechnology Pharmaceuticals in the USA”, 11 J. COM. BIOTECHNOLOGY 271, 272 (2005).

patentability to claims on what have been regarded as true products of nature. The phrase has actually been used in two different but related ways. In the first sense, product of nature refers to a composition of matter that does not comprise patentable subject matter because it is indistinguishable from something that occurs in nature. To illustrate this meaning, the USPTO Manual of Patent Examining Procedures gives the example of a shrimp with the head and digestive tract removed.³ In its other sense, the phrase refers to claims that failing the novelty and/or non-obviousness tests because they are drawn to known natural products that have been derived from a new source or process,⁴ or are in only a marginally purer form than is found in nature.⁵ We shall focus primarily on the first sense subject matter but, as we shall see, the two meanings have sometimes become intertwined.

The product of nature doctrine appears as early as 1889, when, in *Ex Parte Latimer*,⁶ the Commissioner of Patents rejected a claim on a new article of manufacture . . . consisting of the cellular tissues of the *Pinus australis*[southern pine] eliminated in full lengths from the siliceous, resinous, and pulpy parts of the pine needles and subdivided into long, pliant filaments adapted to be spun and woven. In the initial rejection of the claim, the examiner emphasized the identity of the claimed substance and its natural counterpart: The claim and description do not set forth any physical characteristics by which the fiber can be distinguished from other vegetable fibers. Hence, since the fiber claimed is not, and cannot be, distinguished from other fibers by any physical characteristic, the claim therefore must be refused.”⁷ This case has laid down following elements for product of nature:

- A product whose physical characteristics are indistinguishable from those of its naturally occurring counterpart does not constitute patentable subject matter.
- Alternatively, it may be said that such a product is non patentable because it lacks novelty.
- Neither the novelty of a process used to produce a product of nature, nor the unprecedented status of its discovery, can cure the inherent non patentability of the product.

³ U.S. Patent & Trademark Office, Manual of Patent Examining Procedures ' ss. 706.03(a) (8th ed. Aug. 2001).

⁴ Donald, S. Chisum, Chisum On Patent ,2001, p. 39—40.

⁵ Ibid.

⁶ 1889 Comm'r, Dec. 123 (1889).

⁷ Id. at 124.

- The utility and consequent value of the product is irrelevant to its status as patentable subject matter.

However, Section 3(c) of the Indian Patent Act provides that, “The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature”

It is quite clear that it does not prohibit any invention which is result of human intervention, where living beings has been used initially for conducting experimentation.

Moreover, Draft Patent Manual of India reads that there is a difference between discovery and invention. A discovery adds to the amount of human knowledge by disclosing something already existent, which has not been seen before, whereas an invention adds to the human knowledge by creating a new product or processes involving a technical advance as compared to the existing knowledge.⁸

A scientific theory is a statement about the natural world. These theories themselves are not considered patentable, no matter how radical or revolutionary an insight they may provide, since they do not result in a product or process. However, if the theories lead to practical application in the process of manufacture of article or substance, they may well be patentable. A claim for formulation of abstract theory is not patentable. For example, the fact that a known material or article is found to have a hitherto unknown property is a discovery and not an invention. But if the discovery leads to the conclusion that the material can be used for making a particular article or in a particular process, then the article or process could be patentable.⁹

Patenting of Micro- organisms

Indian Position

Article 27(3)(b) of TRIPS Agreement allows member states to deny patents for “plants and animals, other than microorganisms, and essentially biological processes for the production

⁸ Draft Patent Manual, 2008, para 4.4.1., p. 56.

⁹ Id.at 56, 57.

of plants or animals other than non-biological and microbiological processes.” As a result, TRIPS makes it obligatory for all its signatories to extend patents for microorganisms, non-biological, and microbiological processes. Further, animal and plant parts, and altered plants and animals are not explicitly included in the exemption, which means TRIPS may also require patenting of biological organisms. In compliance with TRIPs, the Patents Act 1970, as amended in June 2002, gives patent rights for new microorganisms. Section 3(j) of the Act excludes from patentability “plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.” 2002 Amendment of Indian Patent Act added explanation to chemical process, which states; chemical processes include biochemical, biotechnological and microbiological process.¹⁰ Other areas involving microorganisms are also patentable in India. For example, a synergistic composition containing the microorganism, which is either new or known, and a process using microorganisms to produce a substance can both be patented. Also, the process of biosynthesis of a new microorganism is patentable. Microorganisms that are lyophilized as an end product are patentable.

The Act does not specify the patentable invention ambit, but it does in specificity limits the non- patentable subject matters.¹¹ But even before the amendment Calcutta High has addressed the issue of whether a process involving microorganisms that are living as an end product can be patented.¹² It should be noted here that the definition of invention, which was litigated in the case, has been amended since this case was decided.¹³ Prior to the case, the applicant had requested a patent for the process of creating a vaccine to protect poultry from infectious bursitis. The Controller of Patents determined the process was not an invention because the end product produced by the process contained a living organism, and thus was not patentable. The applicant appealed the Controller’s decision to the Calcutta High Court. The Controller claimed a patent is given only for a process that results either in an article,

¹⁰ Explanation to section 5 of the Act as amended in 2002.

¹¹ Ibid. Section 3.

¹² *Dimminaco AG v. Controller of Patents and Designs and others*,

¹³ Under the old definition, an invention was “any new and useful (i) art, process, method or manner of manufacture; (ii) machine, apparatus or other article; [or] (iii) substance produce by manufacture, and includes any new and useful improvement of any of them, and an alleged invention.”

substance, or manufacture and a vaccine with a living organism is not an article,¹⁴ substance,¹⁵ or manufacture. The court used the normal dictionary meaning of manufacture, because it was not defined in the Patents Act, and determined manufacture is where “the material in question after going through the process of manufacture has under-gone any change by the inventive process and it becomes a material which is different from the starting material.” The court determined this meaning does not exclude the process of preparing a product that contains a living substance from patentability.

The court found that no statute precluded a living end product from the definition of manufacture. Also, the court decided that “since the claim process for patent leads to a vendible product, it is certainly a substance after going through the process of manufacture.” The court ultimately concluded that “a new and useful art or process is an invention,” and because the process is new and useful, it “is apparently patentable under section 5 read with section 2(j)(i)” of the Patents Act. The court determined that “where the end product is a new article, the process leading to its manufacture is an invention.” Although the definition of invention has been amended, this change may actually enhance the court’s invention argument, because now the elements of manufacture, article, or substance are no longer required. Rather, the new definition merely calls for a new, non-obvious and useful product or process. As noted above, the court determined the vaccine was new and useful and made no discussion about the end product containing living material in reaching this conclusion. However, other changes to the act may change the case’s outcome. For example, section 3(j) was added to the Patents Act after this case and now excludes essentially biological processes for production or propagation of plants and animals from the definition of invention. In that case, the court cautioned that claims for patentability should “be considered by the controller on the principle of section 3” of the Patents Act.¹⁶

¹⁴ The Controller claimed the dictionary meaning of article is a “material thing, item, a thing of a particular class or kind as distinguished from a thing of any class of kind.” The Controller said the definition does not cover living things.

¹⁵ The Controller showed “substance” is not defined in the Patents Act, and thus the dictionary meaning of “species of matter of a definite chemical composition or a solid or real thing as opposed to appearance or shadow” or “the muscular tissue or fleshy part of any animal body” also did not describe a living thing.

¹⁶ Ott, Robyn, “Applying The Patents Act To Living Materials In India”, 2 OKLA. J. L. & TECH. 17 (2004), p. 5. Available at <http://www.okjolt.org/images/pdf/2004okjoltrev17.pdf>, last visited on 15.09.2019.

Position in United States of America

The US Supreme court in *Diamond v. AnandChakrabarty*,¹⁷ started a new jurisprudence with respect to biotech patentability. In This case Respondent filed a patent application relating to his invention of a human-made, genetically engineered bacterium capable of breaking down crude oil, a property which is possessed by no naturally occurring bacteria. A patent examiner's rejection of the patent application's claims for the new bacteria was affirmed by the Patent Office Board of Appeals on the ground that living things are not patentable subject matter under 101. The Court of Customs and Patent Appeals reversed, concluding that the fact that micro-organisms are alive is without legal significance for purposes of the patent. In this case patent claims were of three types: first, process claims for the method of producing bacteria; second, claims for an inoculums comprising a carrier material floating on water, such as straw and the new bacteria; and the third, claims to the bacteria themselves. The patent examiner accepted the first two claims but rejected third claim on the basis of product of nature and living things are non patentable under US laws.¹⁸

US Supreme Court held that a live, human-made micro-organism is patentable subject matter under 101. Respondent's micro-organism constitutes a "manufacture" or "composition of matter" within that statute. In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress contemplated that the patent laws should be given wide scope, and the relevant legislative history also supports a broad construction. While laws of nature, physical phenomena, and abstract ideas are not patentable, respondent's claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter - a product of human ingenuity "having a distinctive name, character [and] use."¹⁹

Supreme Court added that genetic technology was not unforeseen when Congress enacted 101 require the conclusion that micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. The unambiguous language of 101 fairly embraces respondent's invention. Arguments against patentability under 101, based on

¹⁷ 447 US 303, 309 (1980).

¹⁸ Id at 306.

¹⁹ Id at 308-310

potential hazards that may be generated by genetic research, should be addressed to the Congress and the Executive, not to the Judiciary.²⁰

Further said that Chakrabarty had produced a new bacterium with markedly different characteristics from any found in the nature. The Court went on to say that the test for determining whether an invention falls within the scope of product of nature is whether the invention in question involves a hand of man. The Court further said that micro-organism were patentable as manufactures or compositions of matter and that congress did not intend to keep them out of the scope of patentable subject matter.²¹

Position in Europe

Europe was ahead of the United States regarding issue relating to patenting of living beings. In 1969 in Germany, a patent was claimed on a method for breeding doves with red plumage, German patent office rejected the patent on the ground that the method was not repeatable and the Supreme Court confirmed the same. It was the first case, which opened the door for patenting biotechnology inventions. Further, in the early 1970s, five years before the United States the German Federal Supreme Court upheld patent protection for new micro-organisms if the inventor were to demonstrate a reproducible way for its generation.²² In the meantime the European Union adopted the European Patent Convention laying down a comprehensive framework on the law relating to patents. The convention excludes patents for essentially biological processes but it does not exclude patenting of products of non- essentially biological processes.

It was held in T356/93 that micro-organisms are patentable as products of microbiological processes²³ and micro-organisms were defined as generally unicellular organisms with

²⁰ Id. at 314-318.

²¹ Id. at 311.

²² Wagner (1976), p. 335

²³ Rule 23b (6)Of the Implementing Regulations of EPC provides that a microbiological process means any process involving or performed upon or resulting in microbiological material and rule 23c © provides that a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety as patentable subject matter.

dimensions beneath the limits of vision, which can be propagated and manipulated in laboratory.²⁴

Conclusion

The fact that the subject matter of many products of biotechnology is incredibly complex, particularly where the subject-matter is a living organism. Indeed, they have not been constructed by man, such subject matter truly is a "black box" and therefore virtually impossible to describe. Complete disclosure of an invention is a fundamental requirement in order to obtain patent protection. In all other technologies, every aspect of the elements of inventions are known²⁵. In jurisdictions which allow for the patenting of biotechnology a concession to this fundamental requirement is made, namely, allowing for the deposit of samples of the patented subject matter. Such deposits are part of the "complete description" of the invention and the deposit is said to "supplement" the complete description.

A further feature of invention in biotechnology which distinguishes it from other fields of technology, and which flows from the fact that the subject matter is so complex, relates to the fundamental requirement that all patentable invention must be non-obvious. This assessment is made by a mythical "technician skilled in the art." Invention in biotechnology typically draws on a number of discrete fields of technology. This makes identification of the "skilled technician" challenging and leads to the concern that the "technician" may not be properly identified.

A further complicating factor peculiar to biotechnology, arises in respect of the fundamental requirement that all patentable invention must be new. This is a problem in biotechnology because the object of much effort in biotechnology industries is to produce synthetic versions of substances which exist in nature. If the substance exists in nature, arguably a synthetic version is not "new." Such fundamental issues raise the following question:

²⁴Schertenleib, Denis, "The patentability and Protection of Living Organisms in The European Union", EIPR, 26(5), 2004, p. 203.

²⁵ Id., at 37.

If biotechnology industries are to continue to grow, do the means for acquisition, and the very nature of a bundle of patent rights for advances in the biotechnology field need to be redefined?
