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Complications in Patenting Biotechnology

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ABSTRACT

Biotechnology is a unique science which deals with the modification of natural processes and living organisms. The intellectual property rights regime, around the world has transformed through the growth of research and development undertaken in the field of biotechnology. Ever since the US Supreme Court granted patent rights to a genetically engineered micro-organism, the field of biotechnology has gained mammoth significance. Further, patents have been granted to genetically engineered plants and human genetic material. With such enormous growth of research in this field, several revolutionary and innovative trends have been adopted in the recent times, which has resulted in new found challenges for authorities granting patents. The nature of the field prevents the application of an individual generic patent model for the varied classes of biotechnology. This paper will examine and analyse the effectiveness and complexities of patenting biotechnology inventions and existing lacunae in the law.

Keywords: *Biotechnology, patent, complexities, lacunae.*

I. INTRODUCTION

Article 2 of The Convention on Biological Diversity[2] defines Biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." In the 21st century the field of biotechnology has emerged as a whole new industry in itself and patent protection for biotechnological inventions has gained enormous commercial importance. Since, the parties involved in the research and development of biotechnological inventions make large investments in the terms of capital and other resources, it is understood that they would want to protect their research and enjoy the benefits arising out of the same.

A patent guarantees a 'right to exploit' to the holder of such patent; if the patent holder is able to prove that the invention up for patent apart from being new is also not obvious and has industrial application., the holder has an exclusive right to manufacture the product which is patented. [3] The patented invention then can become part of public domain only if the duration of the patent has expired. The term 'biotechnology' includes any technology that uses living

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[2] The Convention on Biological Diversity, Article 2, 1992
[3] P. NARAYANAN, PATENT LAW 1 (4th ed. 2006)

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entities, such as microorganisms, animals and plants.

The nature and scope of patent law and practice is such that it is currently facing some serious difficulties in keeping up with the immense development of the scientific progress in biotechnology. Thus, colossal complications emerge in the form of issues relating to inventive step, sufficiency of disclosure and questions relating to the permissible breath of claims. There has been a significant amount of litigation which proves that courts have found it extremely difficult to come to a conclusion on what actually is the general knowledge of a skilled person at the time of the making of the biotechnology invention.[4] The motive underlying patent law is to inspire scientific research, new technology and industrial development. The advent of new inventions of commercial utility can be encouraged through the grant of an exclusive privilege to own, use or sell the product or a method patented for a limited time.[5]

Also the problem of opposition of special interest groups cannot be ignored because these interest groups oppose the idea of genetic engineering and are especially against the existence of patents in this field.[6] In the world today, biotechnology carries with itself an inherent need for the modification of patent laws to an extent that these laws are able to meet the requirements of the prevalent developments in the field of science and technology. These interest groups often argue on the basis of the nature of the products of biotechnology as the products which are consequent are natural products; which does not seem like a valid entitlement because a claim for patent in regards to a natural product may even be valid if it is structured in such a way that a line of difference can be drawn between the product which is found in nature and the product which has claimed for a patent, which can be also proved by portraying certain physical characteristics which in a sense imply novelty.[7]

II. THE INDIAN PERSPECTIVE

India in its patent policy ensured that more significance was given to interests of the public rather than monopoly rights. This is currently evolving into a policy of laying down a balanced protection of intellectual property rights.[8] The changes in India's policy is understood to be the result of the emergence of TRIPs in the World Trade Organization.[9] Indian patent practice and jurisprudence with respect to the patenting of biological materials are relatively new and thus

[4] PHILIP W. GRUBB & PETER R. THOMSEN, PATENTS FOR CHEMICALS, PHARMACEUTICALS, AND BIOTECHNOLOGY, 275-276 (5th ed. 2010)
[5] Bajaj Auto Ltd. v. TVS Motor CO., 2008 ILLJ 726 Mad
[6] Grubb & Thomsen, *supra*. at 276.
[7] Parke-Davis vs. H.K. Mulford 189 F 95 (SDNY 1911)
[8] TIFAC, Intellectual Property Rights, Vol.5 No. 8, p6, (1999). (Available at http://www.pfc.org.in/fac/augbul.pdf)
[9] Agreement On Trade-Related Aspects of Intellectual Property Rights, Jan 1st 1995, 1869 UNTS 299; 33 ILM 1197 (1994)

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not quite standard or constant. Developing countries have a different set of interests and priorities to focus on as compared to their developed counterparts, this has led to problems in harmonizing International and domestic patent laws. Developed countries have consistently pushed for such harmonization for several decades, in other words, a one fit for all international patent system.[10]

An invention relating to a product or a process that is new, involving inventive step and capable of industrial application can be patented in India. However, it must not fall into the category of inventions that are non-patentable as provided under Section 3 and 4 of the (Indian) Patents Act, 1970. The 2005 amendment of the Patents Act 1970 provided for the grant of product patents in any field of technology. This would include the field of biotechnology, subject to certain restrictions such as the obligation to protect public interest. This amendment acknowledges International Depository Authorities as provided for by the Budapest Treaty.[11] Biotechnology inventions are looked at, similar to other inventions. The Patents Act attempts to reconcile the issues of applicants and examiners of patents by dealing with how to protect, subject to the advice of Courts and the Intellectual Property Appellate Board, biotechnological inventions.

The criterion required to be fulfilled for the grant of a Patent and the disqualifications for the same can be found under Sections 2, 3 and 10 of the Act. Section 2(1)(j) deals with the novelty, inventive step & industrial applicability of products or processes.

Novelty: It is the duty of the applicant seeking protection of the intellectual property right to satisfy the criteria of 'novelty, distinctiveness, uniformity and stability".[12] For the grant of a patent, it is necessary to not only fulfil the test of novelty but the requirements of the inventive step and industrial applicability.[13] In order for a patent to be valid, it must not be something that is already available in the public domain, but the inventor's own discovery. A patent is granted to an invention which is new and useful that is, it must satisfy the requirements of novelty and utility.[14]

In Europe, as laid down by Article 54 of the European Patent Convention, an invention can be considered new if it does not form part of the state of the art.[15] A substance is new if it is observed that there is no recognized existence of such substance previously. This essentially

[10] David V. Radack, *GATT Brings Major Changes in U.S. Patent Law*, JOM, p. 79, (1995).
[11] Office of the Controller General of Patents, Designs and Trade Marks; Guidelines for examination of Biotechnology applications for patent, March 2013. (Available at: http://www.ipindia.nic.in/whats_new/biotech_Guidelines_25March2013.pdf)
[12] Emergent Genetics India Pvt. Ltd v. Shailendra Shivam and Ors, 2011 (125) DRJ 173
[13] Merck Sharp and Dohme Corporation v. Glenmark Pharmaceuticals, 223(2015) DLT454
[14] Biswanth Prasad Radhe Shyam v. Hindustan Metal Industries, 1979 2 SCC 511
[15] European Patent Convention, art 54, Oct 15th 1973.

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means that it is necessary for a substance occurring in nature to be isolated from its surroundings.[16] On the other hand, in the United States of America, the requirement of novelty is satisfied if it is shown that the product or process has not been known or used by any person in the Country.[17]

It is important to differentiate between patentability and patent eligibility, looking into the Indian patent act for the differentiation is not fruitful. Section 3 which provides for exclusions ad exceptions can be sourced partly from common law and '*de novo'* policy.[18] It has been laid down in *Novartis v. Union of India* that the addition made to Section 3(d) by way of an amendment was intended to set up a secondary tier of requirements for chemical substances and pharmaceutical products. This was not only meant to pave the way for genuine inventions, but also to provide checks on attempts of repetitive patenting and using false grounds to extend the term of the patent.

Inventive Step: Section 2(ja) of the Patents Act 1970, defines inventive step as, a feature of an invention that involves technical advancement and that which makes the invention not obvious to a person skilled in the art. It is further expressly provided that the lack of an inventive step is a ground for revocation of the Patent. [19] It is therefore pertinent to state that the definition of inventive step under the Patents act does not accord for differential treatment of any type of invention, specifically, medicinal, chemical, industrial, etc. It is rather a general test to specify any advancements made in technology and the criteria of non-obviousness of an invention.[20] The objective of the requirement of the inventive step is to complement the requirement of novelty and increase the scope of relevant prior art beyond anticipatory prior art.[21]

The requirement of Non-obviousness is identified in Europe under Article 56 of the European Patent Convention which states: "An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art." In the United States of America, the same concept is laid down by Section 103 of the Patent Act of 1952, which states that: "A patent may not be obtained, though the invention is not identically

[16] The European Parliament and of the Council on the Legal Protection of Biotechnological Inventions, Directive 98/44/EC; Article 3(2): "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature"

[17] Conditions for patentability; novelty, 35 U.S. Code § 102

[18] Sivaramjani Thambisetty, *Novartis v Union of India and the Person Skilled in the Art: A Missed Opportunity*, LSE Law, Society and Economy Working Papers, 2/2014.

[19] Patents Act, 1970, 64(1)(f)

[20] F. Hoffmann-La Roche Ltd vs Cipla Ltd, Mumbai Central, 2009 (40) PTC 125 (Del)

[21] A. Nelson, *Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective*, North Carolina Journal of Law and Technology, p.1, 2004.

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disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which such subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

In the United States of America, a person with 'ordinary skill in the art' is always one with a single field of expertise in their country. In the European Union on the other hand, it can be a person with ordinary skill in another field, if such person were prompted to seek resolution in such other field. This shows that the requirement of the inventive step or non-obviousness is lower in the United States than in the European Union.[22]

Industrial Applicability: Section 2(ac) of the Patents act states that "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry. In *Osi Pharmaceuticals vs Intas Biopharmaceuticals*[23], the Madras High Court stated that a patented product was incapable of industrial application. The Patent in the suit was in relation to a compound called `erlotinib hydrochloride' and the said product was unstable in nature. The Court therefore laid down that it could not be used commercially.

III. SUBSTANTIVE MEASURES FOR PATENTABILITY AND MODERN BIOTECHNOLOGY

One of the most basic requirements for an invention to fall within the scope of patentability is that the aforesaid invention should fall within the scope of patentable subject matter. The decision by the Supreme Court of United States[24] in the case of *Diamond vs. Chakrabarty*[25] has allowed the advent of patentability to take place in public domain with the various other scientific and industrial achievements. It is through these efforts that the United States of America in today's world has emerged a very dominant player in the field, and none other than the Supreme Court the sole reason for success behind it because of its expansive interpretation of patentable subject matter.

Though it is this approach which promotes the progress of biotechnology, it does also have for certain shortcomings, because of the antithetical relationship shared by the size of public domain and the scope of patentable subject matter. With an increase in the scope of patentable

[22] K. Saito & R. Sweeney, Assessment of Inventive Step or Obviousness in the United States, Europe, and Japan, (available at http://www.law.washington.edu/casrip/harmonization/PDF/obviousness.pdf).

[23] Osi Pharmaceuticals vs Intas Biopharmaceuticals, MIPR2012(1)223

[24] The United States Supreme Court in the following case held that the invention put forward by Chakrabarty portrays the production of a new bacterium with several different characteristics apart from the ones which are already found in nature thus having a potential for relevant patentable utility.

[25] Diamond vs. Chakrabarty, 447 US 303 (1980).

subject matter an inherent decrease can be observed in the size of public domain which in a way can be considered to be a sort of '*tragedy of anti-commons,* [26]this to a large extent can also be considered as a barrier between information and its availability to the public.

Therefore, the main object of the policy makers then would be to create a balance between the size of public domain and the scope of patentable subject matter. Only laws of nature, physical phenomenon, and abstract ideas fall outside the scope of patentable subject matter.[27]

Utility can also be considered as a measure which is of prime importance because it provides a guarantee per se on the usefulness of a particular invention which is eligible for a patent grant. The Chakarabarty[28] decision has encouraged the granting of a large number of patents to bio-tech inventions and other living organisms. The Supreme Court of United States while invalidating patent for the process for making a novel steroid compound for lack of any demonstrable utility, held that utility could not be established until there exists a specific benefit in available form. It further stated that a patent is not a hunting license; it is not a reward for the search, but compensation for its successful conclusion. [29] But with regards to the concept of utility the sheer requirement for the maintenance of high standards which will then be strictly implemented will cause a blockade and avoid a lot of patents, thus blocking research and development.

IV. CONCLUSION

In conclusion one can presume that a balanced framework can be achieved through broad and expandable subject matter with certain exceptions for research, novelty, non-obviousness and higher standards of utility.[30] The application and adoption of patent law to the ever expanding field of biotechnology is still considered to be a source of many problems which adversely affect the patent system throughout the world, thus causing an obstruction in the progress of the field of biotechnology. These problems which remain coherent in the field of patenting can only be solved through a change in the law regarding the patentability of biotech inventions.

This change in law can be achieved by policy makers through the implementation of a balanced approach which will consider a proportional arrangement between subject matter with certain exemptions from research and a proper system of checks and balances on the standards to pass through the requirements of utility, non-obviousness and novelty. It is also essential to maintain

[26] '*The tragedy of anti-commons'* relates to an event when many individuals enjoy certain rights of exclusion in a scare resource. Heller, M.A. "*The tragedy of Anti-Commons*." Harvard Law Review, January 1, 1998.
[27] Parker vs. Hook, 437 US 584 (1978).
[28] Diamond vs. Chakrabarty, 447 US 303 (1980).
[29] Brenner vs. Manson, 383 US 519 (1996)
[30] Dr. Kalyan C Kankanala, *Complications in Patenting Biotech Inventions., Biotech Patent law*, 36. (1st ed. 2007).

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the independence of the Judiciary in deciding cases according to specific situations. A consensus must be achieved on how to optimize the patentability requirement for the field of biotechnology and whether such requirements should be similar to other technical fields. This should then balance incentives between basic researchers and applied technicians to aid in the development of research and bring advancements to the field.

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V. REFERENCES

Cases:

- Bajaj Auto Ltd. v. TVS Motor CO., 2008 ILLJ 726 Mad
- Parke-Davis vs. H.K. Mulford 189 F 95 (SDNY 1911)
- Emergent Genetics India Pvt. Ltd v. Shailendra Shivam and Ors, 2011 (125) DRJ 173
- Merck Sharp and Dohme Corporation v. Glenmark Pharmaceuticals, 223(2015) DLT454
- Biswanth Prasad Radhe Shyam v. Hindustan Metal Industries, 1979 2 SCC 511
- F. Hoffmann-La Roche Ltd vs Cipla Ltd, Mumbai Central, 2009 (40) PTC 125 (Del)
- Osi Pharmaceuticals vs Intas Biopharmaceuticals, MIPR2012(1)223
- Diamond vs. Chakrabarty, 447 US 303 (1980).
- Parker vs. Hook, 437 US 584 (1978).
- Brenner vs. Manson, 383 US 519 (1996)

Books:

- PHILIP W. GRUBB & PETER R. THOMSEN, PATENTS FOR CHEMICALS, PHARMACEUTICALS, AND BIOTECHNOLOGY, 275-276 (5th ed. 2010)
- P. NARAYANAN, PATENT LAW 1 (4th ed. 2006)

International Conventions:

- The Convention on Biological Diversity, Article 2, 1992
- Agreement On Trade-Related Aspects of Intellectual Property Rights, Jan 1st 1995, 1869 UNTS 299; 33 ILM 1197 (1994)
- European Patent Convention, art 54, Oct 15th 1973.
- The European Parliament and of the Council on the Legal Protection of Biotechnological Inventions, Directive 98/44/EC; Article 3(2): "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature"

Internet Sources:

- TIFAC, Intellectual Property Rights, Vol.5 No. 8, p6, (1999). (Available at

http://www.pfc.org.in/fac/augbul.pdf)

- Office of the Controller General of Patents, Designs and Trade Marks; Guidelines for examination of Biotechnology applications for patent, March 2013. (Available at: http://www.ipindia.nic.in/whats_new/biotech_Guidelines_25March2013.pdf)
- K. Saito & R. Sweeney, Assessment of Inventive Step or Obviousness in the United States, Europe, and Japan, (available at http://www.law.washington.edu/casrip/harmonization/PDF/obviousness.pdf).

Articles:

- David V. Radack, *GATT Brings Major Changes in U.S. Patent Law*, JOM, p. 79, (1995).
- Sivaramjani Thambisetty, *Novartis v Union of India and the Person Skilled in the Art: A Missed Opportunity*, LSE Law, Society and Economy Working Papers, 2/2014.
- A. Nelson, *Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: A Global Perspective*, North Carolina Journal of Law and Technology, p.1, 2004.
- Heller, M.A. "*The tragedy of Anti-Commons*." Harvard Law Review, January 1, 1998.
- Dr. Kalyan C Kankanala, *Complications in Patenting Biotech Inventions*., Biotech Patent law, 36. (1st ed. 2007).

Statutes:

- Patents Act, 1970
- Conditions for patentability; novelty, 35 U.S. Code § 102

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