BIOTECHNOLOGY PATENTING: COMPARISON BETWEEN USA AND INDIA

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Introduction

Biotechnology, at its most basic level, is a technology that revolves around biology: it uses cellular and biomolecular strategies and methods to produce various biological products, including food, medicine, recombinant proteins, medicinal drugs, agricultural and healthcare industries, etc. as an aid to better ourselves, our lifestyles and improve the health of our planet. As it can be seen, there has been a significant rise in the advancement in biotechnology due to major investment and development in scientific research.

It is known that for almost 6,000 years, we've relied on the biological processes by usage of microorganisms to create valuable inventions that are used everywhere in the world. [1] Biotechnology is split into multiple parts, each of which has attributes that are so unique from all the others that even a large set of simple principles cannot be applied to the entire field of biotechnology. Both genomics and tissue culture, for illustration, have distinct properties, functions, techniques, and byproducts. This field has been saving patients affected with HIV, Cancer, Hepatitis C. it has been significantly raising the life expectancy through its numerous breakthroughs throughout. [2]

Biotechnology is a hybrid domain involving chemical biology and fundamental biological sciences. The origin of early biotechnology can be traced back to the mid-twentieth century, i.e., the agricultural revolution in India. The father of the agricultural revolution in India is Rd. M.S Swaminathan; his research effort has introduced the concept of high-yield varieties of food grains and ever-since expanded into diverse food industries. The high-yield food grains helped India to overcome the disastrous fame during the chaotic world-war era.

[1] Biotechnology Innovation Organisation, *What is Biotechnology?*, 2020 https://www.bio.org/what-biotechnology

[2] Biotechnology Innovation Organisation , *Biotechnology Saving Lives & Transforming Healthcare in the 21st Century*, 2020, https://archive.bio.org/TransformingHealthcare

Biotech is not only limited to the engineering of cells for the welfare of humanity and the entire natural ecosystem. It also has catastrophic effects when engineered for the personal ill-benefits of an individual; ill-benefits include bioweapons used in bioterrorism, food adulteration, adulterated medical drugs.

Biotechnology is an intense intellectual domain involving significant financial investments and prolonged research. There is an increasing demand in biotechnology as it has the potential to be extended to various industries for commercial benefits. There is an absolute necessity to legally safeguard the intellectual properties and capital investments that are responsible for the process development and product.

Biotechnology and Patents

A patent is a proprietary right granted to an inventor by a legal institution. In lieu of a thorough declaration of the innovation, the creator receives exclusive rights to the patented process, concept, or innovation for a set duration of time. These are a type of intangible right. It plays a major role in prevention of the unique designs being plagiarized by others as it legally authorizes the inventor with the claim of their unique invention. These are of 3 kinds: Utility, Designs and Plant Patents.

Products developed by the usage of Biotechnology comes under the protection of utility patents section.[3] There is a sincere need to protect these products as there are numerous organizations which could develop the same product and ask for exclusive legal rights for the invention. A utility patent is for a discovery of a novel, significant and important machine, unique process of manufacturing goods, matter composition present in the products or even the creative process of designing or building or restructuring it.

Every country has its own set of process to deal with patents pertaining to invention. However, patenting inventions that revolves around biotech sector have various procedures that needs to be followed to be considered as exclusively patented or legally authorized in the market. It has been observed that, a lot of countries have significantly contributed and continue to do so to raise the value of this upcoming sector. India has 3% share with a value of $50 billion and it

[3] Smith, J., *The Complications Around Patenting Biotechnology*, Labiotech.Eu, 2020. https://www.labiotech.eu/startup-scout/amphista-therapeutics-protacs-cancer/

has been ranked 52nd as per the reports of Global Innovation Index in 2019. However, USA has the value of $112 billion and is the strongest globally present biotech player and investor.

Patent Rights and Biotechnological Inventions

"Patent is a monopoly right conferred by the Patent Office on an inventor to exploit his invention for a limited period of time. While an invention means a new product or process involving an inventive step and is capable of industrial application."[4]

It is not necessary for an innovator to seek for a patented product for his discovery; however, it is an optional component for a creator to take. Rather than just asking for a patent on his creation, the innovator can also choose to keep his innovation confidential. However, it is crucial to highlight that if a creator somehow doesn't apply for a patent for his invention, there is a serious chance of his innovations being publicly released to others, such as his competitors, through the transmission of information and someone who has such relevant data, and thus the competitors would be under no obligation to keep the invention secret. Several people may be able to manufacture the product using the same invention in this situation. The High Court of Allahabad held in Shining Industries v. Shri. Krishna Industries[5] that a creator cannot consider his innovation to be his intellectual right unless the discovery is secured by a title. As a result, it is regarded both beneficial and reasonable to file for a patent, thereby obtaining monopolistic power to use the innovation for a certain amount of time and preventing others from interfering with it.

This paper will now discuss the provisions given by the law and the case laws that are important in terms of product innovation or breakthrough in biotechnology.

Indian Patent Law

In India, the patent acts 1920 regulates and consolidates the laws and provisions that involves the function of patenting of these inventions in India. An invention can be solely patented under this act; however, section 3 of the act mentions what products cannot be termed as 'Inventions'.

[4] Mathur,I An Analytical Study on the patentable requirements" Fast Forward Justice, 2020 https://fastforwardjustice.com/an-analytical-study-on-the-patentable-requirements-of-biotechnology-inventions-india-usa-and-europe/

[5] Shining Industries V. Shri. Krishna Industries, Air 1975 All 231.

India lacks substantial information about what can be patented, furthering to create a lot of confusion and uncertainty, especially concerning the bio tech sector. [6]

Section 3b[7] of this act is used to regulate the prevention of any innovation which will cause harm to living beings. If the innovation causes harm to anyone or any living thing it will be disregarded and rejected. However, the patent is accepted for micro-organisms or microbiological processes involved. To add on, any modification to multicellular organism is also regarded as exclusions in this act. Moreover, Gene sequences and DNA which are disclosed are involved under this law, however, cells pertaining to human body and embryonic stem cells are included in the exceptions of this act.

Section 3c[8] prohibits the patenting of products which involves mere discovery of substances which are present in the ecosystem. This section can be corelated to section 3j which does not allow patenting on plants and animals. This section has prevented various organizations such as Monsanto from issuing patents on several types of cotton plants that are present in the country furthering to lose the opportunity of monopolistic control in the prevailing sector.[9] This event came up when Supreme Court of India had refused to overrule the decision of the high court to uphold the section 3(j) of Indian patent act to amend the implementation of trade related intellectual property rights agreement of the WTO.[10] This resulted in ban of patenting claims on such items as it can be a risk factor to research and innovation which will conclude in overall control and market monopoly by the private sector industries.

The patent system is mainly governed by the Patents Act, 1970, and Patents Rules, 2003. The former is as amended by the Patents Act, 2005. Under section 159 of the Patents Act, 1970, the Central Government is empowered to implement the Act and regulate patent administration. The latter is ever-changing in unison with society. An invention must possess four key elements

[6] P*roper Interpretation of Section 3(D) of the Indian Patent Act Could Save incremental innovations of existing pharmaceutical substances* , Patents and Patent law, 2020. https://www.ipwatchdog/2019/06/22/proper-interpretation-section-3d-indian-patent-act-save-incremental-innovations-existing-pharmaceutical-substances/id=110581/

[7] Section 3(b) in The Patents Act, 1970

[8] Section 3(c) in The Patents Act, 1970

[9] *Indian IP Jurisprudence is the real winner in the Monsanto cotton technology case*, Lexology.com, 2019. https://www.lexology.com/library/detail.aspx?g=c9efd6a6-fd91-4ae0-a414-0a2cc64e0b24

[10] Shiva,V., *Monsanto Fails To Block Hc Ruling on BT Cotton Seed Patent, Mathrubhumi*, 2020, https://english.mathrubhumi.com/features/specials/monsanto-fails-to-block-hc-rulingg-on-bt-cotton-seed-patent-1.2797955.

to be patentable; novelty, inventive/non-obvious, capable of industrial application, and it must not be a non-patentable invention as per sections 3 and 4 of the Act.

Sections 3 and 4 of the Act render derivatives of a substance that do not increase the efficacy of a known substance. As a result, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other known substance derivatives shall be considered be the same substance. [11]

The concept of patents has emerged to safeguard the products from competitors. The Patent Act was initially introduced in 1856 and has undergone several amendments. Notable amendments were in 1872; it was renamed as "The Patterns and Designs Protection Act" under Act XII of 1872; this amendment protected the designs of the invention. In 1883, it protected the novelty of the invention and introduced a grace period of six months to file an application after the date of release of said invention. In 1911, it was renamed to "The Indian Patents and Designs Act". This amendment was monumental as it was the first time the Controller of patents was in charge of patent administration.

Further, in 1957, the Government of India appointed Justice N. Rajagopala Ayyangar to examine the revision of patent law, and the bipartite Report was submitted in 1959. The Report pointed out India as a "country whose interests demand urgently the working of patented inventions within as short a time as possible and to the fullest extent reasonably practicable.[12] As a result of the Report, another bill was introduced known as Patents Act, 1970. This new act would replace the existing Act, but the 1911 Act would still apply to the design of an invention.[13]

The first part of the Report emphasized retaining the current patent system irrespective of its shortcomings. It also suggested giving allowance to only process patents involving drugs, medicines, food, and chemicals. The current patent system (1970 Act) only granted patents towards the manufacturing process of the invention and not the invention itself. As a result, individuals could attempt to engineer the same product through a similar process. Thus, the

[11] Government of India, *History of Indian Patent System*, 2020 https://ipindia.gov.in/history-of-indian-patent-system.htm

[12] Delhi High Court, *Rajagopala Ayyangar Report*, 2020 http://www.delhihighcourt.nic.in/library/reports/Rajagopala_Ayyangar_Report_Report_on_patent_law.pdf

[13] Government of India, *History of Indian Patent System*, 2020 https://ipindia.gov.in/history-of-indian-patent-system.htm

patent holder would not obtain any advantage for possessing a patent. Not only is a product patent more secure than a process-only patent, it also does not promote the invention of original products that can be patented; instead, it promotes inventing inexpensive processes to produce generic drugs.

On January 1st, 1995, India signed the Trade-Related Intellectual Property Rights Agreement (herein referred to as TRIPS). As mentioned earlier, some products cannot be patented if they are derivatives of already known substances. The pharmaceutical industry benefitted substantially before the signing of TRIPS as it was able to produce generic drugs, which were inexpensive versions of expensive patented drugs engineered by industry-leading innovative biotech organizations. Since India could no longer sidestep the process of innovating and invention products, India's number of patents filed has not been impressive. The silver lining is that India has proved to be an attractive investment destination due to its ability in manufacturing infrastructure, development of intellectual manual labour etc. The country had experienced a short successful stint before crashing down.

Foreign patents mostly from the US, Japan, and Germany accounted for more than 45% of the patents in the year 2016. Statistically also, the total number of patents filed between 2015 to 2018 were 5,11,947, out of which 3,90,878 constituted foreign patent registrations. The Indian innovators post the launch of the Government's 'Make in India' programme have not gone anything beyond the maximum of 30% share in patent registrations in the country. [14]

The Indian legal system is complicated, but that cannot be used as an excuse in the case of failure. Although it was a valiant effort by late Justice Ayyangar, the country has not been able to progress ahead. The TRIPS agreements have not helped India's case either; it did not leave any wiggle-room with respect to national laws in developing nations as the laws enforced were exactly the same as the laws in developed nations.

Novartis International AG is a Swiss multinational pharmaceutical company based in Basel, Switzerland. It is one of the largest pharmaceutical companies in the world. Novartis was refused a patent in India for its anti-cancer drug Gilvec under section 3(d) of the Patent Act, 1970; mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy is not patentable. The multinational company failed to get

[14] Suman,A. , *Ayyangar Committee Report Vis A Vis Trips Agreement*, The IP Press, 2021 https://www.theippress.com/2021/03/30/ayyangar-committee-report-vis-a-vis-trips-agreement/

a patent in India as it was discovered. India is also known as generic medicine capital of the world. Thus, many Indian companies began to sell generic Gilvec. Patented drugs are much more expensive than generic drugs because research and development require a substantial amount of investment. India's generic drug market is estimated to be around $ 13 billion-a-year and increasing. The advantage of producing generic drugs of the highest quality is that the drug becomes much more affordable than a patented drug. The average Indian cannot be able to afford a patented drug. Shares in Novartis' Indian unit ended 1.8 percent lower after falling as much as 6.8 percent after the verdict. Natco Pharma stock ended 5.4 percent higher after earlier gaining nearly 11 percent and Cipla gained 1.3 percent, beating the benchmark index which ticked up 0.15 percent. Indian law bans firms from extending patents on their products by making slight changes to a compound, a practice known as "evergreening". The Supreme Court said Glivec does not satisfy a patent's "novelty" requirement, Pravin Anand, lawyer for Novartis, told reporters.[15]

American Patent Law

35 U.S.C. 103 of United States Patents Act, states the prerequisites for patenting an invention and these should be fulfilled to avoid any foreseeable consequences. An invention can be termed as 'obvious' when other people in the same specialization can easily resonate and figure out a production technique for the product with existing inputs.

The significance of this law is relevant as a biotechnology is known for combining multiple factors of production. For an individual or an organization seeking for a patent, the innovation must not be gained by utilizing and merging common inputs with basic techniques resulting in production of predictable results. [16]

India lacks the source of pre-existing case laws unlike USA. India has rarely experienced a breakthrough to have substantial information to deal with these novel products. USA has case laws that can aid in the process of defining what can be granted a patent in biotechnological breakthroughs. As seen in Association for Molecular Pathology v. Myriad Genetics Inc, a product can be patentable as per its allowance of alteration in its formula of production and to what extent the product can be modified or changed. The change in chemical formula used is

[15] Kulkarni, K., Mohanty. S., *Novartis Loses Landmark India Cancer Drug Patent Case*, Reuters, 2013 https://www.reuters.com/article/us-india-novartis-patent-idUSBRE93002I20130401

[16] Quinn, G., "When is An Invention Obvious?" – Ipwatchdog.com / Patents and Patent Law". https://www.ipwatchdog.com/2014/02/01/when-is-an-invention-obvious/id=47709/

acceptable as it's a fact as per Judge Lourie of US Supreme court because isolation of a DNA causes a non- natural occurrence of molecule but not resulting in change in quality of the DNA.[17]

Funk Bros. Seed Co. v. Kalo Inoculant Co. was the case which raised the question of patenting of micro-organisms before the Supreme Court of USA. The case mentions a discovery that relates to Rhizobium bacteria which is capable of inoculating seeds of plants to various cross inoculation groups of the same group. The court held in this case that a little elevation of species due to lack of invention within the limits of the patenting statutes because the species which was produced as a result had no novel bacteria and no change in the six other species of bacteria formed. [18]

In the landmark case of Diamond v. Chakraborty, the courts held that everything made by human effort has the right to be patented. The court declared in the judgement that 'product of nature' test is really essential to decide if the said invention is formed due to human effort or was a natural product. The product claiming patent rights will be denied the rights if its observed that it lacks human effort and was a product of nature. [19] This further resulted in allowance of patenting rights to unique natural living organisms such as bacterium as mentioned in this case in the USA.

In regards to patenting of genes, Congress has been debating over the matter currently. In a recent landmark judgement, Supreme Court of USA banned human genes patenting due to risk of reduction in the topic of medical research and development as private organisation will have the exclusivity to prohibit any research if the gene is owned by them. Patents have however been granted to many multi-cellular organisms, rabbits, modifications of genetics in rats and so on. In USA, gene sequences and genetic therapies are also permitted patent rights.

Pharmaceutical Patenting in India and the US

In the field of pharmaceuticals in India, Section 3(I) of the Patent Act acts like a method of 'medicinal treatment' which involves a process of governing medicines through injections,

[17] The US Supreme Court, Association for Molecular Pathology et Al. v. Myriad Genetics, 2013, https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf
[18] US Supreme Court, Funk Bros. Seed co. v. Kalo Inoculant Co, US reports, vol. 333, 1948, https://www.lawcornell.edu/supremecourt/text/333/127
[19] US Supreme Court, Diamond v. Chakrabarty, Justice US Supreme Court, Vol. 447, 1980, https://supreme.justia.com/cases/federal/us/447/303/

orally, dermal patch. However, method of treatment is done by surgery for cosmetic or therapeutic purpose is not subject to patent rights.

For patenting, usage of phrases like 'diagnose an individual' 'receiving test sample from an individual' and 'indication that the individual is suspectable to a disease' should be refrained.

The specification of the method to be 'in-vintro' (the working necessary to be done outside of a living organism) while claiming the discovery is required. Governing the invention and method for cosmetic purpose. Blast (basic local alignment search tool) result for the claimed product can be submitted to showcase that the product is a distinct form of the already existing natural sequences having novel substitutions. [20]

The act governing patenting which had been introduced in 1970 was initially kept on the side-lines by this sector. The reason behind patenting this sector is the amendment in 1999 wherein the nation was mandated to provide the patent rights to products relating to pharma and agrochemical sectors. As the nation was obligated under TRIPS, the act was amended again in 2002. [21]

Unlike India, in the United States of America, there is no complex process to patent medical components other than the known medical devices used to check all the components required to be eligible to claim patent rights. For instance, in Intellectual property update recently it was noted that patent infringement against Medtronic included procedures used to de-rotate various vertebrae of an injured spinal portion. [22]

The patent law in the US along with FDA legislates the products which are generated in the pharma sector. The patent holder has the exclusive rights for 20 years during which the holder has the rights to sell, use, develop and so on with the discovery. Patents in pharmaceutical industry involves procedures of creation and chemical portions involved.

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[20] Tyagi, P., *Finding Escape Routes: Can Your Invention Avoid or Overcome Section 3 (I) of Indian Patents Act* Lex Orbis, 2017, https://www.mondaq.com/india/patent/586550/finding-escape-routes-can-your-invention-avoid-or-overcome-section-3-i-of-indian-patents-act-method-of-treatment

[21] Mazzola, P., *WTO-TRIPS obligations and Patent Amendments in India: A critical Stocktaking*. , Healio, 2020 https://www.healio.com/news/orthopedics/20170804/primer-on-patenting-methods-of-medical-treatment-in-the-united-states-and-abroad

[22] Mazzola, P., *Primer on Patenting Methods of Medical Treatment in the United States and Abroad*, https://www.healio.com/news/orthopedics/20170804/primer-on-patenting-methods-of-medical-treatment-in-the-united-states-and-abroad

However, the period of term held by the patent holder changes in the Food and Drug Administration as it gives only 5 years of exclusive rights when a new chemical portion is involved in the product creation. This is helpful as it restricts other companies for 5 years to seek exclusive rights for an Abbreviated New Drug Application comprising of the same new chemical portion.

Conclusion

The USA have been aided by numerous case laws to create a framework for its guidelines and principles relating to the patenting of several discoveries involved in the biotechnological sector in the industry. This was a necessity as the complex nature of products arose from this sector. In India, things are different. The essential point to comprehend in India is that any medical treatment required for any living being (animals and human beings) to heal them from an affected disease or rise in the monetary value, is not included for claiming patent rights in the Indian Patents Act 1970. This can be correlated with the complex 'method treatment' test used in India in comparison to USA, which only necessitates the need to be a new and non-obvious discovery. To get over this limitation in India, the guidelines should be followed as India prohibits the patent of living beings in its entirety along with any processes followed in the production of plants and animals. This can be observed in Monsanto case wherein the Supreme Court held that the High Court's judgement on the prohibition of patenting of plants and animals as a whole or partially.

Looking at USA, the scene is very different. As seen in the Diamond v. Chakroborty case, USA does not restrict the patent rights of created or invented living beings that are entirely distinct in its being. The patent law followed permits patent rights to DNA sequences as the law takes into account the alignment of the subject matter involved. This law is the reason the USA consents to grant patents for living organisms with a peculiar gene sequence used to add through the biotech sector using its unique procedures.