THE IP PRESS L. REV.
VOL. 1 ISSUE I1, JUNE 2023
ISSN: 2583-7702 (ONLINE)

# GENE PATENTING AND ACCESS TO HEALTHCARE IN INDIA: THE WAY FORWARD

*Raahat Tara* [*]

*ABSTRACT*

*Access to healthcare in these modern times is supremely reliant on the availability of continuously updated biotechnology and modes of treatment. Advocates of intellectual property protection call for extending the creation of such special interests to safeguard the rights of inventors and medical professionals by halting others from using or devising similar methods. Such personal economic rights of the creator need to be reasonably balanced with the damage it would cause to the health of the public if allowed to be exercised unfettered. The 1994 TRIPS amendment brought within the purview of patentability, microorganisms such as bacteria used in the production of vaccines. This amendment was further reflected in the 2002 amendment to India's domestic Patent law regime, but for how much longer can domestic legislations succumb to international obligations in the face of preserving public interest and sovereignty.*

*Keywords: Gene patenting, healthcare, TRIPS. Microorganism, biotechnology*

[*] *Raahat Tara, Student, Jindal Global Law School, 19jgls-raahat.t@jgu.edu.in*

## 1. INTRODUCTION

Advancement in the arena of biotechnological progress and development is seen to be a prominent promoter of domestic economies and has proved to be an increasingly central asset to the medical sector universally. Recent years have seen many such ground-breaking innovations in this area of research. Even more so with the onset of global medical emergencies such as the ongoing COVID-19 pandemic.

Medical research specifically focused on the human genome and its sequencing has grown rapidly and the vast domain of human genetics is no longer a complete mystery to the world of life sciences. The sequencing, identification of mutations and regulating or modifying these genetic components are all extremely important because of their implications for the improvement of human health[1]. Genetic tests also are being increasingly employed to flag those individuals who are more susceptible or at risk of certain life-threatening illnesses. The interaction of such technologies with the legal and ethical sphere is a contentious issue which is still being considered and understood by experts.

## 2. INNOVATION UNDER PATENT LAW

According to Bentley and Sherman, "a patent is a limited monopoly granted in return for disclosure of technical information"[2]. It is an exclusive right which is given for an inventive process or product. It can be a novel invention or could offer a novel way of achieving something already discovered or invented. Such protections are offered to protect the inventor's natural rights to the invention because of the mental labour exerted by them[3]. Others argue that their contributions must be compensated and rewarded by the granting of patent protection. The current international legislative framework consists of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)[4] and other Patent Law Treaties.

Article 27(1) of TRIPS[5] holds that "*patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*". Article 27(2)[6] on the other hand restricts the award of a patent if the jurisdiction recognises it to be necessary to preserve *ordre public* or if the award of

[1] Jorge L. Contreras, 'Narratives of Gene Patenting' (2016) 43 Fla St U L Rev 1133.
[2] Brad Sherman and Lionel Bentley, *Intellectual Property Law* (4th edn, OUP).
[3] Ibid.
[4] The Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1995) U.N.T.S. 299, 33 I.L.M. 1197 (TRIPS).
[5] The Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1995) U.N.T.S. 299, 33 I.L.M. 1197 (TRIPS) art 27(1).
[6] The Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1995) U.N.T.S. 299, 33 I.L.M. 1197 (TRIPS) art 27(2).

such a patent would go against morality in a bid to protect animal, human or plant life or health or if it endangers the environment.

In *Parke-Davis v Mulford*[7], it was held that merely claiming natural products does not guarantee patentability and "*if there is sufficient reason for granting a patent, then the subject-matter requirement will be satisfied even if the subject matter claims product of nature. It has been said that the difference between a discovery and invention is a difference in degree rather than its kind*".

## 3. GENE PATENTING

In the case of *Diamond v Chakraborty*[8], the court dealt with the issue of whether a live, human-made, genetically produced bacteria could be patented. The bacterium in question had been genetically engineered to break down petroleum, crude oil and its components. It was held that such living organisms could be considered patentable if "*a non-naturally occurring manufacture or composition of the matter-a product of human ingenuity*"[9]. It was noted that discoveries are non-patentable whereas inventions can be awarded protection under patent law. It was also reiterated that "*laws of nature, physical phenomena, and abstract ideas"* were ineligible for the granting of patent protection as such discoveries were natural and available for the usage of all[10].

In *Harvard College v Canada*[11], the Harvard mouse was a genetically engineered animal employed in research concerning the onset of breast cancer. These mice were engineered in a way which made them highly susceptible to breast cancer and were injected with carcinogens to ascertain their reactivity to the same. The courts ruled these mice to be non-patentable as under the statute in operation, manufacturing in a scientific process involved a non-living, mechanistic product[12]. It was held that the process of an organism developing post-fertilisation was a natural process which did not require any human intervention.

*Association for Molecular Pathology v Myriad Genetics*[13] is viewed as a landmark case in the area of gene patenting. The path-breaking judgement helped put a stopper to the contentious debates surrounding the legality of gene patenting in the jurisdiction of the United States. The Courts initially had decided to offer a blanket decision proscribing the granting of patents to all "naturally occurring human DNA sequences".

It has long been speculated and considered that certain forms of cancer are hereditary. In the case of Breast and Ovarian Cancer, significant research has proven that certain familial groups with women experience exponentially high susceptibility to the disease.[14] Numerous genetic mutations

*7 Parke-Davis v. Mulford* [1912] 196 F. 496.
[8] *Diamond v. Chakrabarty* [1980] 447 U.S. 303.
[9] Ibid.
[10] *Diamond v. Chakrabarty* [1980] 447 U.S. 303.
[11] *Harvard College v. Canada (Commissioner of Patents)* [2002] 4 S.C.R. 45.
[12] Ibid.
[13] *Association of Molecular Pathology v. Myriad Genetics, Inc.* [2013]133 S.Ct. 2107.
[14] Mark A. Chavez, 'Gene Patenting: Do the Ends Justify the Means' (2003) 7 Computer L Rev & Tech J 255.

in the BRCA1 and BRCA2 have been termed breast cancer susceptibility genes and are found in a large number of women of Ashkenazi, Dutch, Norwegian and Icelandic descent. In 1994, Myriad Genetics, a private company, was successful in sequencing and isolating the BRCA genes which enabled it to design tests which could identify the presence of such mutations in the DNA of women[15]. It then claimed autonomy and exclusive rights over such testing as it had been awarded nine patents concerning its research. Subsequently, they were sued by a variety of groups challenging Myriad's exclusivity rights as they impaired other diagnostic firms from engaging in similar genetic testing and were an impediment to easy and safe access to women's healthcare facilities for cancer prevention and treatment. The District Judge ruled for the plaintiffs and decided against Myriad. It was held that Myriad's claim of accessing patent protection was ineligible on the grounds of their apparent invention being "mental processes and abstract intellectual concepts"[16]. It was also held that their claim of having devised a method to identify potential cancer treatments was ineligible for patent protection as it was simply the application of the scientific method.

Myriad then appealed to the Federal Circuit Court, where its appeal was upheld and they were incorrectly granted patent protection on the reasoning that the isolated and extracted BRCA genes were distinct from DNA and were patentable[17]. On this account, the plaintiffs approached the Supreme Court of the United States and contested the lower court's decision by asking whether human genes could be patented. In a unanimous decision, the bench held that even though Myriad had invested significant amounts of effort, intellect and resources in identifying and segregating the BRCA genes, their claims to patentability could not be upheld because genes were a product of nature and this was not a scientific invention. To apply the product of nature doctrine to render a patent claim ineligible, it must be assessed whether there is a structural similarity between the claimed product or process and its naturally occurring counterpart[18]. In the case at hand, it was held that Myriad merely isolated naturally occurring genetic material and stamped its exclusivity on it. The company claimed large-scale innovation and dedication in its work to sequence the genes and laid stress on the narrative concerning how liberal patent policies result in economic progress for the entire economy. The Supreme Court underlined how the relation of hereditary genes with a predisposition to breast and ovarian cancer was common knowledge within the scientific community and that their research even though identified the exact location of the BRCA genes did not result in a novel creation[19].

In *Amgen v Chugai*[20], the US Federal Circuit Court was investigating patent rights over DNA sequences related to red blood cell production in the human body. The Court held that the "purified

[15] *Association of Molecular Pathology v. Myriad Genetics, Inc.* [2013]133 S.Ct. 2107.
[16] Ibid.
[17] Dipika Jain, 'Gene-Patenting and Access to Healthcare: Achieving Precision' (2014) 36 Hous J Int'l L 101.
[18] John M Conley, 'Gene Patents and the product of nature doctrine' (2008) Chicago Kent Law Review < https://scholarship.kentlaw.iit.edu/cklawreview/vol84/iss1/6/> accessed 31st September 2022.
[19] Jain (n 17).
[20] *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. and Genetics Institute Inc.* [1991] 927 F.2d 1200.

and isolated" version of the gene could be patented. In this context, purified and isolated means that researchers identifying and segregating the appropriate genetic coding region had successfully reproduced it outside the environment it naturally occurred in. It was also stressed by the Court that there was no invention of the gene and that in its naturally occurring context, the gene was a "non-patentable natural phenomenon" which was freely available and could not be exclusively reserved.

In *Myriad*[21], the court awarded patent protection to the cDNA which was generated. cDNA is clone of naturally occurring DNA which is engineered in laboratory conditions[22]. The process of its manufacture results in a lack of the non-coding regions of a gene. Hence, it is structurally distinct from natural genetic material.

## 4. GENE PATENTS IN INDIA

The Indian Patent Act, of 1970[23] is the governing legislation on patent developments and grants in India. Section 3(c)[24] of the Act lays down certain inventions or processes which cannot be patented. These include the mere discovery of any living thing or substances occurring in nature. According to Section 3(j)[25], plants and animals are also not patentable. The Indian patent office has granted patents in other cases in which the cDNA was not artificially synthesised but manifested from the existent natural genetic sequence. It can be inferred that naturally occurring genetic material cannot be patented in India but there is no definite legal provision to deal with such instances and legal questions. The India Patent Act had been amended in 2002 to include patenting of microorganisms to meet its TRIPS obligations. Critics of gene patenting contend that these chemically engineered genetic substances are discoveries and not inventions and under this differentiation do not fulfil the basic requirements for patentability.

## 5. ACCESS TO HEALTHCARE

Even though genetic patenting could usher in greater choice in treatments and an improvement in healthcare services and drugs to treat various debilitating diseases, it also brings with itself several ethical concerns[26]. Its proponents claim that gene therapy would result in a healthier tomorrow for developing countries but there is a disparity in the way different cultures interact with and accept such modification of life forms and how it interacts with their definitions of morality. Patenting genes can result in increased scientific research and reliance on devising treatment methods which employ this information and subsequently results in the reduction of access to treatments for those living in poorer areas of the world[27]. Research has proven that most laboratories are unable to

[21] *Association of Molecular Pathology v. Myriad Genetics, Inc.* [2013]133 S.Ct. 2107.
[22] Devina Rathod, 'Human Gene Patenting in India: An Analysis' (2022) 2 Jus Corpus LJ 851.
[23] The Patents Act 1970.
[24] The Patents Act 1970 s 3(c).
[25] The Patents Act 1970 s 3(j).
[26] Jain (n 17).
[27] Ibid.

provide these diagnostic tests due to the hefty fee that is required to gain access to these patented procedures and information.

In the case of *Myriad*[28], due to the initial patents which had been granted to the enterprise, smaller laboratories and testing labs were unauthorised to offer BRCA testing to the public and Myriad assumed a monopoly in this sector. The pricing set by Myriad was exorbitant and alienated a large section of the public from accessing healthcare facilities in relation to breast and ovarian cancer in the USA. Such gatekeeping of essential medical information and technology would have serious harmful repercussions in the developing and under-developing nations of the world.

## 6. SHOULD GENES BE PATENTED?

Since patenting genetic material has serious consequences by hindering access to life-saving healthcare facilities it makes a mockery of the principle of distributive justice which mandates that resources and knowledge be made freely and equitably available to all sections of the society[29]. Patent law even at the time of the raging COVID-19 pandemic was a severe obstruction to the easy availability of vaccines to all. A campaign spearheaded by the third world asked for the revocation of intellectual property formalities in providing the less-developed nations with knowledge on coronavirus vaccine production[30].

Pharmaceutical companies and the developed nations expressed large-scale anguish at this proposed relief and pledged to share more quantities of vaccines produced within their jurisdictions with the third world instead of offering patent relief[31]. Knowledge creation and research is concentrated in a small number of high-income nations and the third world is adversely affected by the gatekeeping of such important resources and intellect.

There are also arguments against gene patenting which hinge on environmental jurisprudence and the identity of natural elements as distinct from their economic value. Narratives of life forms and their genetic data being exploited and patented for economic benefit offer primacy to the property rights of humans[32]. This is an extremely anthropocentric approach to interacting with natural resources and results in reducing genetic material to a mere commodity.

## 7. WAY FORWARD FOR INDIA

Indian Patent law is officially silent on its treatment of patentability for genetic material and does not expressly exclude such patent rights. Article 8 of TRIPS[33] authorises domestic legislation to

[28] *Association of Molecular Pathology v. Myriad Genetics, Inc.* [2013]133 S.Ct. 2107.
[29] 'A patent waiver on COVID vaccines is right and fair' (*Nature*, 25 May 2021) < https://www.nature.com/articles/d41586-021-01242-1> accessed 31st September 2022.
[30] Ibid.
[31] Contreras (n 1).
[32] Ibid.
[33] The Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1995) U.N.T.S. 299, 33 I.L.M. 1197 (TRIPS) art 8.

account for public interest and develop or amend their laws in consonance with this. This read with article 27[34] which allows but does not mandate member states to patent diagnostic, surgical or treatments and plants, animals or biological processes, can be inferred to state that a member state may proscribe gene patents within its jurisdiction. Such a move if opted by the Indian legislature would not be violative of its obligations under TRIPS while also ensuring its citizens their protection of public health and access to healthcare facilities.

In the current scenario, India can also draw from China's policy of issuing licenses to various pharmaceutical companies allowing them to mass-produce generic versions of patented drugs and treatments[35]. Governments across the globe issue compulsory licenses which allow third parties to manufacture patented drugs at the time of an emergency. In *Bayer v Natco*[36], the Indian government authorised third parties to manufacture an anti-cancer drug called *sorafenib tosylate* which had been patented by Bayer. Section 92 of the Indian Patent Act[37] allows the government to award a compulsory license in the case of a national emergency, extreme urgency or for public non-commercial purposes.

Moreover, TRIPS also allows member states to refuse patents which go against *ordre public* or morality and is inclusive of instances in which "human, animal or plant life or health" need to be preserved[38]. Such policies would ensure just, balanced and equitable access to healthcare for the public.

## 8. CONCLUSION

Technology and scientific progress are enormously responsible for the progress that humanity has undergone and the niche area of genetic research offers multiple avenues for further development and alleviation of diseases. However, at the same time, there are also prominent cases of alienation from healthcare facilities for the poor as access to drugs and diagnostic treatments becomes more expensive with the award of a patent on such technology. Such patent policies have far-reaching impacts on public health and significantly disadvantage the third world. To ensure that the benefits accrued from scientific development and research are equitably made available to all stakeholders, the patenting system concerning biotechnology must be effectively regulated with a set of comprehensive and clear guidelines. Justice and fairness in the gene patent policy would aid people to benefit from their intellectual labour and also offer an incentive to engage in research to develop better facilities.

[34] The Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1995) U.N.T.S. 299, 33 I.L.M. 1197 (TRIPS) art 27.
[35] Jain (n 17).
[36] *Bayer v Union of India* [2013] Indlaw IPAB 20.
[37] The Patents Act 1970 s 92.
[38] The Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1995) U.N.T.S. 299, 33 I.L.M. 1197 (TRIPS).

The Indian legal landscape must efficiently incorporate compulsory licensing facilities within its jurisdiction and meet the demands of its own citizens' healthcare requirements while also calling for the relaxation of globally held patents. This would also ensure that researchers and private stakeholders are not disincentivised from coming up with better solutions and also accommodate the needs of the public by balancing public interest with scientific and economic progress.