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# Patenting of Life Forms: A Comparative Study of United States and Indian Laws

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PRASHANT SINGH<sup>1</sup> AND SWARAJ SINGH<sup>2</sup>

## ABSTRACT

*With the rise of Biotechnology the rise in attempts of owning Intellectual Property Rights over the invented method and products involving living forms has increased across the world. Despite having International Agreements like TRIPS and multilateral supervisory bodies like WIPO and WTO the approach towards the issue is not uniform across the world. Despite such difference in approach certain issues and concerns remain common to all legal systems such as the effect of exclusivity arising from granting of such rights more so in light of the fact that a welfare State has a duty to protect its citizens which involves ensuring right to health and that too at affordable rates which brings into question the unique issues faced by Developing States and third world states which are mostly under developed, in contrast to Developed States. Hence the present study becomes relevant.*

**Keywords:** Intellectual Property Rights; DNA, Genes, Life forms, Patent.

## I. INTRODUCTION

While the Intellectual Property Rights were recognised long time back in scattered agreements and conventions the TRIPS<sup>3</sup> agreement consolidated most of them and carried forward their legacy.<sup>4</sup> The said agreement has a kind of harmonised the Intellectual Property Rights (IPR) deliberations across nations with enough space for states to address their specific needs and reservations.<sup>5</sup> One such issue which is very basic and has far reaching consequence on human society is the issue of Patenting of life forms. As IPR are exclusive in nature granting of such right feels like sealing the fate of human evolution as while it limits the enjoyment of the right to the patent holder it further gives impetus to similar efforts by others. On the other hand if that invention is the only one of its kind then the price of using the same depends upon the owner of the rights and other factors of the market, in normal circumstances. Similarly, while the fact

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<sup>1</sup> Author is a PhD Candidate at Faculty of Law, University of Lucknow, India.

<sup>2</sup> Author is an Advocate at Allahabad High Court, India.

<sup>3</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994. Available at <[https://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](https://www.wto.org/english/docs_e/legal_e/27-trips.pdf)> accessed on 1 March 2023.

<sup>4</sup> See for eg TRIPS infra, Articles 1(3), 2-4, 9, 14-16, etc.

<sup>5</sup> See for eg TRIPS infra, Article 5 which considers agreements entered under auspices of WIPO, and Part VI which make special concessions for Least Developed Countries.

remains that ensuring IPR encourages in disclosure of useful knowledge another facet of the same is the fact that same could be used as a tool to hinder other research on similar product or method.

## II. PATENTING OF LIFE FORMS AND TRIPS

The patenting of life forms has gained much controversy and attention world wide since the very beginning of TRIPS IPR regime and is often considered a reason behind the booming biotechnology sector in contemporary world.<sup>6</sup> While the term 'life forms' may be used as a wide term which includes plants, animals and other life forms the exact meaning of the term appears to be problematic, at least from the patent law perspective.<sup>7</sup> One can start his or her investigation into the matter from the TRIPS Agreement. The main provision dealing with the patentable subject matter makes it abundantly clear that all inventions, provided that they are new, which involve an inventive step and are capable of industrial application are patentable and that includes life forms as well.<sup>8</sup> However the same has provided certain flexibility to the State parties to the agreement under which they can exclude certain subject matters from patentability which is necessary to protect *ordre public* or morality, including, to protect human, animal or plant life or health or to avoid serious prejudice to the environment. Also it has specifically given the right to the member states to exclude certain subject matters from patentability which includes plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.<sup>9</sup>

After reading the said provision one is of the view that patent on life forms are very much possible with limited discretion on the part of states to exclude certain kinds of life forms from patentability in normal conditions. However such discretion increases where such exclusion is necessary for the protection of public order and morality and the other mentioned grounds.

Now, since under the TRIPS patent on life form is possible the same has given rise to a number of problems since the state parties are required to make their domestic laws compatible with the TRIPS and since TRIPS just lays down minimum standards therefore the protection under the

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<sup>6</sup> Anna Kingsbury, 'Patenting Life: Human Genetics, Ethics and Patent Law' 3 YB NZ Juris 91(1999); Orijit Das, 'Patenting and Ownership of Genes and Life Forms: The Indian Perspective' 3 J World Intell Prop 577(2000); Chris R Byrnes, 'Patenting Life: TRIPS Article 27 & Bolivia's Proposal to Ban the Patenting of all Life Forms' 24 Geo Int'l Envtl L. Rev 245 (2012); Outros Artigos, 'The North American Decision in the Myriad Case: New Paradigms for the Patent Protection of the Human Genetic Code and Biotechnology' 13 Braz J Int'l L 514 (2016).

<sup>7</sup> David S Olson, 'Patent Protection for Genetic Innovation: Monsanto and Myriad' Cato Sup Ct Rev 283 (2012-2013).

<sup>8</sup> TRIPS supra, Article 27, see in particular clause 3(b).

<sup>9</sup> TRIPS supra, Articles 8, 27 clauses 2 &3, 30, 31.

domestic laws could only be expected to be more not less than that minimum standards (provided they are in compliance with TRIPS and which they have to be going by the language used in Article 1 especially the use of the word ‘shall’).<sup>10</sup>

This has raised much concern in the intellectual community as the matter is as much sensitive to morality as is for matters like food security and farmers right. Also the same has alarmed the scientific community as it can drastically affect the scientific research and researches in various fields of technology and its development. The same extends to medical usage as well as was the matter in the Myriad case<sup>11</sup>. The said effect may be positive as well as negative. While some are of the view that it will promote scientific temper and the material benefits involved it would lead greater efforts in research and development whereas the counter view is that such monopoly rights will inhibit growth in scientific research as the patent holder might exclude<sup>12</sup> others from using his patented subject matter or charge very high price for it which might kill the competition and affect the scientific growth.

Similar issue was in the aforementioned Myriad case in United States of America (US) where identification of specific human genes (BRCA1 and BRCA2), the presence of which helped in diagnosing cancer, was alleged to be a subject of patent right. The present case was not the first in its line as the US court had dealt with matters related to patenting of life forms before as well. But in present case the issue revolved around a part of human if at all genes can be said to be forming one. There were many cases dealing with other life forms such as microorganism. The most clear position is said to be after the decision given by US Supreme Court in *Diamond vs Chakrabarty*<sup>13</sup> where the patentability of a bacterium was at issue which was laboratory created and helped in oil spill removal as the bacteria was found to eat oil and thus very useful especially in preventing environment damage through oil spill at sea. The court in that case held that patent valid under the respective laws of the country. The main reason on which the court relied in that case was that the ‘Chakrabarty bacterium’ was new with markedly different characteristics from any found in nature and hence the product was non naturally occurring and thus does not fall into the exception to section 101 of the 35 US Code dealing with patent.

In the present case also the court applied similar reasoning however unlike the previous case here the outcome was partially different as the court found that the BRCA1 and BRCA2 genes

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<sup>10</sup> Ibid Article 1.

<sup>11</sup> Association for Molecular Pathology and others v. Myriad Genetics, and others No.12 of 2013 US SC. Available at <[https://www.supremecourt.gov/oral\\_arguments/argument\\_transcripts/2012/12-398\\_h3dj.pdf](https://www.supremecourt.gov/oral_arguments/argument_transcripts/2012/12-398_h3dj.pdf)> accessed on 1 March 2023.

<sup>12</sup> TRIPS supra, Article 28.

<sup>13</sup> 447 U. S. 303, 309 (1980)

were naturally occurring hence the patent was invalid however on the issue of cDNA the court held that since its not naturally occurring hence the patent was valid. Though actually cDNA do appear naturally but are comparatively rare. The said case however did not answer the question related to patenting of methods. However since Article 27(3)(a) gives the option to the state to exclude such diagnostic, therapeutic and surgical methods for the treatment of humans or animals the same might not be so alarming but in those subject matters where there is no such flexibility there is much reason to be alarmed. Given the importance of the case in recent scenario where we have seen the hesitant behaviour of relevant owner of patent rights in waiving their patent rights in the face of Covid 19 Pandemic<sup>14</sup> its better to do a brief study of the important arguments and findings of the Myriad case.

### III. MYRIAD CASE: IMPORTANT DETAILS

Each and every human being has genes which forms the basis for the hereditary traits in living organisms. Each human gene is encoded as deoxyribonucleic acid (DNA) which is shaped as a double helix with cross bars. Each cross bar contains two chemically joined nucleotides. Some of these nucleotides code for amino acid-which is used in the body to build proteins- and are called exons and those who don't are called introns. It is also possible to create synthetic DNA containing only exon sequences and is called complimentary DNA (cDNA).<sup>15</sup>

The Respondent, Myriads obtained several patents after discovering the precise location and sequence of the BRCA1 and BRCA2 genes, mutations of which can dramatically increase the risk of breast and ovarian cancer. Myriad's claimed exclusivity<sup>16</sup> was controversial and problematic for many reasons. If valid and comprehensive, the patents essentially would have meant that Myriad 'owned' the genes, for most practical purposes and applications. This ownership could have been used to thwart scientific progress and health care efforts that include, but were not limited to preventing academic researchers from pursuing studies in connection with the genes or Labs from offering tests related to the genes and Medical professionals from offering treatments related to the genes (as happened with Dr. Harry Ostrer).<sup>17</sup> Hence Petitioners, Association for Molecular Pathology and others, filed suit, seeking a declaration that Myriad's patents are invalid under Section 101<sup>18</sup> of Title 35 of United States Code. The

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<sup>14</sup> Manoj Kumar, 'India to push for patent waiver for COVID-19 vaccines at WTO' (Reuters 26 Novemebr 2021) available at <<https://www.reuters.com/world/india/india-push-patent-waiver-covid-19-vaccines-wto-2021-11-26/>> accessed on 1 March 2023.

<sup>15</sup> US Reports infra, p576

<sup>16</sup> See 35 United States Code, Section 154(a)1. '*right to exclude others from making' its patented composition of matter; also, S.271(a) '[W]hoever without authority makes. . .any patented invention. . .infringes the patent'.*

<sup>17</sup> US Reports infra, p585.

<sup>18</sup> 35 United States Code, Section 101 of the Patent Act provides: '*Whoever invents or discovers any new and*

District Court ruled Myriad's claim invalid as the subject matter of their claim was product of nature. On appeal the Federal Circuit initially reversed, but on remand, in light of *Mayo* case<sup>19</sup> the Circuit found both isolated DNA and cDNA patent eligible.<sup>20</sup> Finally the matter came to the Supreme Court.

The US Supreme Court started its inquiry from revisiting section 101 of the 35 U.S.C. and re-affirmed the implicit exception to it ie 'Laws of nature, natural phenomena, and abstract ideas are not patent-able'<sup>21</sup> as they were the basic tools of scientific and technological work...the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'<sup>22</sup> However, the rule against patents on naturally occurring things is not without limits and 'too broad an interpretation of this exclusionary principle could eviscerate patent law.'<sup>23</sup> Hence the Court found the following questions relevant in deciding the matter and the same is reproduced here-

1. Whether Myriads patents claim any new and useful composition of matter or instead claim naturally occurring phenomena?
2. Whether the fact that Myriads uncovered the precise location and genetic sequence of the BRCA1 and BRCA2 with chromosomes 17 and 13 renders the gene patentable?

The court held that Myriad neither created nor altered any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location as well as the order of the nucleotides existed in nature much before Myriad found them. Considering that neither Myriad created nor altered the DNA but found an important and useful gene the court held that discovery does not by itself satisfy the requirements of S.101 inquiry and thus discovery does not make them patent eligible. Citing Myriad's various patent descriptions the court understood that Myriad sought to import its extensive research efforts into the S.101 patent eligibility inquiry but extensive effort alone was insufficient to satisfy the demands of S.101 thereby the observation of the court seems to be stressing upon the concept of novelty and inventive step.

The court also ruled out the importance of the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2

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*useful . . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.'*

<sup>19</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U. S. \_\_\_\_ (2012).

<sup>20</sup> *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 566 U. S. \_\_\_\_ (2012).

<sup>21</sup> US Reports (October Term, 2012) p576. Available at<<https://tile.loc.gov/storage-services/service/ll/usrep/usrep569/usrep569576/usrep569576.pdf>> accessed on 1 March 2023.

<sup>22</sup> *Diamond v. Chakrabarty*, 447 U. S. 303, 309 (1980)

<sup>23</sup> US Reports supra.

genes. Hence, a naturally occurring DNA segment is a product of nature and not Patent eligible merely because it has been isolated.

However, while dealing with the issue of cDNA,<sup>24</sup> the court held that cDNA is non-naturally occurring as its creation results in an *exons* only molecule which is not naturally occurring and the lab technician unquestionably creates something new when *introns* are removed from a DNA sequence to make cDNA.

Moreover, the court clarified that it has not dealt with various issues such as methods related to the DNA sequencing and thus such issues were left open to further review. Which can be assumed to leave open space for a claim for patent based on unique inventive method to detect or find a typical gene more efficiently. Thus the Court unanimously affirmed in part and reversed in part the decision of the courts below it.

#### **(A) The effect on current discourse on the topic**

In conclusion one can say that the judgment though continued with its approach of keeping laws of nature, natural phenomenon, and abstract ideas out of the purview of patent as they are basic tools of scientific and technological work however the same already could be inferred from article 27(1) of TRIPS agreement which clearly says that the invention should be new and should involve inventive step and should be capable of industrial application. The same applies to life forms as well. Simply discovering something that was already there or something which is natural and obvious could not be said to be involving inventive step. However, if one has to answer about the method of discovery then the case would be different. There is much possibility that such new methods might be patentable as process are also eligible for patent. However the court kept itself away from answering that question.

Also, it sounds very ironic that if the court considered the patentability of the subject matter on the basis of its relevance as basic tools for scientific and technological work than on that ground even cDNA would not be patentable given the fact that most of the laboratories rely heavily on cDNA for their research.<sup>25</sup> Thus in US practice of the courts remains the same as far as laboratory created organisms living or non living are concerned. That is it does not matter the product invented is living or non living so far as its novel and is not naturally occurring. Thus it differs drastically from Indian practice in this regard.

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<sup>24</sup> Sarah Elizabeth Hagan, 'DNA Real Estate: The Myriad Genetics Case and the Implications of Granting Patent Eligibility to Complimentary DNA' 35 N III U L Rev 205 (2014).

<sup>25</sup> Lawrence O. Gostin, 'Who Owns Human Genes? Is DNA Patentable? Published in Viewpoint on 22 July 2013.<<http://jamanetwork.com/journals/jama/article-abstract/1717456>> accessed on 5 Dec 2016.

#### IV. INDIAN SCENARIO

In Indian case the said case would be of great academic significance as far as 'product of nature concept' is considered. Section 3 of the Patent Act, 1970, which is the relevant law on the topic (other could be the Protection of Plant Varieties and Farmers' Rights Act, 2001) expressly excludes plants and animal, in whole or part thereof, from patentability.<sup>26</sup> Moreover, the fact that the present case did not deal with the question as to the patentability of method does not affect in Indian scenario as the relevant Act excludes in clear terms the possibility of any such method related to treatment of human beings including diagnostics or to increase their economic value or that of their products.<sup>27</sup>

However, in case of microorganism as was the case in *Diamond vs Chakrabarty* the issue remains of much interest as microorganisms are patentable subject to the conditions of novelty which could be similar to that of the US case. Unfortunately there are no case laws available on these issues except one Calcutta High Court Judgment. In *Dimminaco A.G v. Controller of patent and design*<sup>28</sup> the Calcutta High Court held that a process for preparation of vaccine containing live virus is patentable since the term "manufacture" covers even living organism. So according to the Court even if the end product contains a live virus the process involved in bringing out the end product becomes an invention. Thus as regards microorganism the position of US and Indian Courts appear to be in tune.

In the light of the above discussion one feels that in the limited flexibility available in TRIPS, states have been of the view to exclude life forms like Human and animals from the purview of patentability but not so for other life forms such as microorganisms. Much deference has been given to the term natural or naturally occurring thereby suggesting that the question is open regarding the status of an invention creating a 'higher life form' in a laboratory.<sup>29</sup> However in case of India let alone human or animal life even the plant and seeds are excluded<sup>30</sup>. So India appears to be active in protecting natural species against laboratory created higher life form and its court or following the developing jurisprudence on the topic.

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<sup>26</sup> The Patent Act, 1970, Section 3(j).

<sup>27</sup> Section 3(i) of the Patent Act, 1970.

<sup>28</sup> 2002 cal HC IPLR 226.

<sup>29</sup> Shyamkrishna Balganesha, 'Patenting of Organisms: The Distinction between Lower and Higher Life Forms' (2000) 12 Student Advoc 144; Adrian Zahl, 'Patenting of "Higher Life Forms" in Canada' 23(5) Biotechnology L Rep 556 (2004).

<sup>30</sup> The Patent Act, 1970 Section 3(j).