

# **ECONOMIC ANALYSIS OF MYRIAD GENETICS CASE: LAW AND ECONOMICS APPROACH**

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## *ABSTRACT*

In this article, an attempt has been to make science and economics come together, by looking the law on patenting of genes from a law and economics perspective. Law and economics being an interdisciplinary field, it has been used in various fields of studies, and in this paper, the primary inter-relation is to view a recent judgment of US Supreme Court, Myriad genetics case from the law and economics perspective. Author firstly deals with the nuances of the judgment, its implications, its benefits and the economic analysis of the same. The question that is posed in the paper is, is the rationale of the judgment, i.e. the ratio decidendi an economically efficient outcome. Economic efficiency is discussed in plethora of literature, however this paper focuses on economic efficiency of not only the case, but also the various doctrines used by courts to see patentability of the object in question. An underlying theme that pervades the topic is, can something found in nature be patented? Isn't nature a free and universal resource, not subject to notions of IP law. Patenting of genes is a controversial topic, which has many sides to it. However, the author has completely focused on the objective analysis from economic perspective, excluding all moral and ethical issues that are generally available in literature on this topic.

## INTRODUCTION

Genetic patents have been in the eye of the storm with rise in biotechnology endeavors of humans to unfold the mysteries these genes of our hold. There are pro-patent activists and there are people who criticize the patent regime on genes, however without taking a moral stand, in this paper we analyze the much talked about 2013 judgment of US Supreme Court which is Association of Molecular Pathology v. Myriad Genetics Inc<sup>1</sup>. However, this analysis would look into a much broader scope also which is looking into the economic feasibility of genetic patents and various doctrines that have been created by US Courts, and focus on the inter-disciplinary branch of law and economics. Law and economics is offered as a different subject in many foreign countries however in India, it is comparatively new, and literature on economic theories of patents is still evolving.

The main focus is to link the Myriad judgment and show the economic aspect of the doctrines that are used in study of granting patentability to genes. There are various implications of the judgment worldwide which will also be discussed. Intergenerational justice which was created out of this judgment will also be analyzed in detail. The paper starts with a discussion on the 2013 judgment, and its implications and is taken forward to drawing a nexus between economic theories of patents and coming to a conclusion that the judgment is based on economically sound rationale. However, with the author's limited scope of study, there is also contrary literature which is available. This is essentially a normative paper, and thus will build upon existing literature available in this field. However, the scope is narrowed and specialized to tailor it to the judgment being analyzed.

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<sup>1</sup> No. 12-398 (569 U.S. June 13, 2013)

### **Case Facts and Issue**

Myriad Genetics is a company formed by scientists at University of Utah, and their major breakthrough discovery was finding the exact location of genes BRCA1 and BRCA2 which were basically isolated from a human genome sequence and by using those tests scientists could test women for increased probability of breast and ovarian cancer. In 1990s there was immense data that many women were falling prey to breast and ovarian cancer, and therefore the scientists felt the location of these genes could be used to find out mutations in the patient to see if they had an increased risk of these types of cancers. They were granted a patent for this invention, however there was some unrest on patenting of human genes. There were other institutes and doctors in the field that conducted BRCA1 and BRCA2 tests, and they were sent notices to stop there testing by Myriad by virtue of their patents. Therefore, the situation which existed was that Myriad had virtually captured the health market in this sector. This led to filing of the suit by Association of Molecular Pathology. In the federal court there was disagreement among the bench whether the isolated DNA created synthetically in lab called complementary DNA (cDNA) was patentable or not.

**Issue:** The primary issue which was before the court was the status of patentability of the BRCA1 and BRCA2 gene and the isolated synthetic chemically generated isolated cDNA.

### **Judgment**

Essentially the argument of petitioners was that the isolated of specific genes from human genome responsible for cancer generating properties was product of nature and not eligible to patent under 35 USC § 101 and is covered by *Diamond v. Chakraborty*<sup>2</sup>. *Diamond* judgment clearly held down that laws of nature, products found in nature, abstract ideas cannot be subject to exclusivity and therefore patent cannot be granted. 35 USC §101 reads as follows, “*Whoever invents or discovers any new and useful. . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.*” *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>3</sup> also dealt with the balance of giving patent on inventions using laws of nature and not broadening the scope of

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<sup>2</sup>447 U. S. 303,

<sup>3</sup> 566 U.S. \_\_\_\_ (2012)

patents to cover all things found in nature. Relying on this the majority decision held that Myriad had not invented anything new by finding the location of BRCA1 and BRCA2 gene, which already existed prior in nature. It is well established rule of patent law that patents can be granted on inventions and not on discoveries. Myriad merely discovered something which nature had hidden from us, and did not alter, modify or in any manner change the structure of the gene found in nature. Court definitely agreed with Myriad that they had a major research achievement in their field however the fact that the research and the result was groundbreaking does not in any manner make it eligible under §101 especially when the matter is not novel. Myriad in their claim highlight their efforts to discover these genes from millions of nucleotide contained in chromosome, but mere research efforts and hardwork will not entitle any invention patent protection especially when it is unfolding of nature's handiwork and not one of the researcher. Court also made an analogy with the *Funk Brothers Seed Co. v. Kalo Inoculant Co*<sup>4</sup> where the patent was sought to be taken on the naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil. The court here precisely laid down the proposition that something which is naturally occurring and merely found or discovered by the person is not subject matter of patent. It was also pointed out the flaws in the patent application, since Myriad did not ask for a method patent but essentially a patent on the gene itself or the information that was encoded in it. The method used by Myriad was also one used by lab technicians who were in the field of genetics. Had they actually used a method of isolating which was novel, they could be eligible for method patent.

Therefore, as a conclusion BRCA1 and BRCA2 genes which were isolated were not patentable.

However, the opinion differed when it comes to cDNA which was laboratory created. Naturally occurring DNA has exons and introns, however the one created synthetically is only-exon molecule not found in nature. It is a derivative of DNA, but something new, not found in nature as naturally occurring. Here the opinion of the court as to limits of product of nature doctrine come into picture, as all inventions will draw upon some well-established scientific principles and therefore construing the doctrine too strictly will inhibit the growth of patent law, as almost everything will be unpatentable due to this doctrine and allowing everything found in nature to

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<sup>4</sup>333 U. S. 127 (1948)

be patented will be creating monopoly over natural resources. So something which is primarily based on naturally occurring DNA segment will be patentable if it is derived as something new.

### **Implications**

With the coming of the judgment, scientific community divided as to its effects.<sup>5</sup> Some said it was a victory for scientists who need not now bother about being sued by patent holders, which will result in free flow of research and access to research will result into better medicine and medical treatments for patients. Patients, have a reason to rejoice since it is well known that granting a patent would make the patent holder increase cost of the drug to recoup his own costs of research which would mean higher prices for treatment<sup>6</sup>(dealt further in detail later). Therefore, social benefit has definitely increased, however the core idea behind patent law i.e. incentive to create might be taken away in this since biotechnology firms, researchers, geneticists might be left in lurch whether they will be able to recover their costs in future or not. The fact some however were pessimistic about the judgment, and were vocal about their apprehensions, as to the effect it will have on biotechnology industries since there are some areas which cannot strictly be categorized as DNA and cDNA etc. and so firms will now have to work in an area of uncertainty about their research coming within the ambit of patent protection or not. There is also a growing literature that this judgment has created a resurgence of trade secret protection for biotechnology companies<sup>7</sup>, which was earlier over-shadowed by the patent protection granted. This judgment also recognized that earlier practice of US Patent Office was to grant patent on genes, however that is being diverted from through this ruling. Therefore, more biotech companies would want that any invention in the form of isolating any gene from a DNA segment which has a potential therapeutic use is kept as a trade secret and then directly marketed in some form, so that invention is commercialized. Trade secret has an advantage in this aspect over

<sup>5</sup>Emma Barraclough, *What Myriad means for biotech*, Available at [http://www.wipo.int/wipo\\_magazine/en/2013/04/article\\_0007.html](http://www.wipo.int/wipo_magazine/en/2013/04/article_0007.html) (accessed on 11 January 2016)

<sup>6</sup>Mildred Cho, *Patently unpatentable: implications of myriiad court decision on genetic diagnostic*, Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2955823/> (accessed on 11 January 2016)

<sup>7</sup>Michael Baniak, *In setting genes free Supreme Court decision will put greater emphasis on trade secret protection in biotech*, Available at <http://www.tradesecretslaw.com/2013/06/articles/trade-secrets/in-setting-genes-free-supreme-court-decision-will-put-greater-emphasis-on-trade-secret-protection-in-biotech/> (accessed on 11 January 2016) ; A.M Bakshi, *Gene Patents at Supreme Court: Association of Molecular Pathology v. Myriad Genetics* Journal of law and Biosci (2014) 1 (2) 183-189; Robert Cook-Deegan, John M. Conley, James P. Evans & Daniel Vorhaus, *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?* 21 Eur. J. Hum. Genet. 585 (2013).

patent, since patent is granted for limited number of years but trade secret has unlimited duration, and as long as the owner of the trade secret is able to keep his information confidential away from public eye, he is entitled to trade secret protection. But unlike patent, trade secret is not protected from reverse engineering. Therefore, biotech firms investing enormous sums of money in research might be over-taken by rival firms by simply reverse engineering the end product. Now turning into law and economics approach, trade secret has higher individual value in two cases where the invention is known by the inventor to be unpatentable or where the procedure for obtaining patent is costly and tedious. In this scenario, trade secret are an cost efficient alternate to patents, however trade secret is encouraging duplication of resources, which is the antithesis of what patent seeks to do.<sup>8</sup> The wastefulness of resources due to lack of information among biotechnology firms whether a particular area of genetics has already been discovered or not will result in erosion of useful resources which could have been put to better use.

This judgment has left in air the position of the patents granted to isolated gene earlier. Though during the continuing term of protection, there protection will remain intact, but it will definitely put questions to their further research on similar lines.

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<sup>8</sup>David Friedman, William Landes and Richard Posner *Some Economics of Trade Secret Laws* Journal of Economic Perspectives Vol.5 No.1,61-72, p. 64,65



## **ECONOMIC INTRODUCTION**

Legal aspect of patent, has been sufficiently dealt with in the prior sections. However, the economic analysis of the genetic patents, has been so far an uncharted territory. This paper focuses on how genetic patents, which is in itself a controversial subject of law and ethics, should be seen from an economic viewpoint. By use of both these branches, an interdisciplinary approach is sought.

## **GENETIC PATENTS: ECONOMICS OF PRODUCT OF NATURE DOCTRINE AND PUBLIC TRUST**

To begin with, we start by defining the two concepts, “products of nature doctrine” which is creation of courts, and “public trust doctrine” which has legal and economic contours to it. Product of Nature concept basically begins with the idea that ‘nature has no ownership.’ It proposes an exception to certain kinds of patents, by stating that things or products which are naturally occurring are not subject to patent. “Fundamental point is that the mere discovery of a naturally occurring phenomenon is not patentable because it is not an invention.”<sup>9</sup> The same requirement has been laid down in multiple case laws, and by reading 35 U.S.C. 101, which is the basis for granting of patents to any innovation under the US law, it has been an established position that physical phenomenon of nature is not patentable.<sup>10</sup> Secondly we move on to define what is meant by public trust doctrine. In simple words it states that natural resources, are available for the public in general, and they shouldn’t belong to any person exclusive for use, and the state should take steps to preserve the resources from monopolizing in favor of any individual.<sup>11</sup> The doctrine enunciates that “certain interests are so intrinsically important to every citizen that their free availability tends to mark the society as one of citizens rather than serfs; that certain benefits derive so directly or particularly from nature that they should be available to

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<sup>9</sup> John Conley, *Gene Patents and Product of Nature Doctrine*, Chicago-Kent Law Review Vol.84 Issue 1, 2009, p. 113

<sup>10</sup> *Diamond v. Chakraborty* 447 U.S 303 (1980) Available <http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=us&vol=447&invol=303> (accessed on 30<sup>th</sup> March 2015)

<sup>11</sup> Detailed Analysis at, Joseph L/ Sax, *The Public Trust Doctrine in Natural Resource Law: Effective Judicial Intervention*, Michigan Law Review, p.471-566, 1970

the entirety of a populace; and that certain uses of property have value only to the extent that they are public.”<sup>12</sup>

However, generally the public trust doctrine has been applied to immoveable tangible property, and available literature also points out towards the same direction. Therefore, notions of classical concept of public trust are not applicable to IPR, however, when we focus our attention of products of nature theory, it becomes more pronounced than ever before that something which is God made and available to all in abundance cannot be subjected to monopoly. *Diamond v. Chakraborty*<sup>13</sup> is of relevance at this juncture since it shows how natural resources should not be made subject to exclusivity. However, this case saw a departure from the continuous practice of not giving patents on living organism, by allowing patent on genetically modified bacteria which could break crude oil.

Arguing on its application or non-application to IPR, especially genetic patent, author will give an appropriate approach in understanding the economic analysis of products of nature doctrine and genetic patents. However, it is worth noting that public trust doctrine has more affinity to the Jeffersonian view of property rights, wherein it is perceived that individuals hold property personally as a trustee for the common benefit of the society.<sup>14</sup>

Now we further draw a link between these three concepts, genetic patents, public trust and products of nature doctrine. Intellectual Property is drastically different from real Property. Any kind of exclusion or exclusivity of thought or innovation is going to be an absurd idea. It is indeed a well settled position that knowledge and innovation are public goods.<sup>15</sup> We see a developed country like Britain, in their House of Commons Select Committee Report on Science and Technology, favoring genetic research and geo-engineering to be a public good and there are

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<sup>12</sup> Association for Molecular Pathology v. Myriad Genetics Inc. No. 12–398, decided on June 13, 2013, Text of Attorney of Amicus Curiae, p.16 Available at <http://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/7616/ICTA%20Amicus%20Brief.CAFC.12.6.10.pdf?sequence=1> (Accessed on 30<sup>th</sup> March, 2015)

<sup>13</sup> *Supra* fn.2

<sup>14</sup> R. Prescott Jaunich, *The Environment, the free market and property rights: Post Lucas Privatization of the Public Trust* Public Land Resource Law Review, Vol.15 p.172, 1994

<sup>15</sup> Richard Posner, '*Intellectual Property: The Law and Economics Approach*' Journal of Economic Perspectives Vol.19 No.2 2005, p.64; Peter S. Menell, '*Intellectual Property: General Theories*' p.133,137 Available at <http://levine.sscnet.ucla.edu/archive/ittheory.pdf> (accessed on 31 March 2015)



disadvantages of giving patents on it to private individual.<sup>16</sup> Patent is a way in which you control the attributes of public good, which means that you giving an exclusive right to an individual, which would otherwise be a public good, and could be used by everyone freely. Specifically, by endowing innovators with property rights on their discoveries, patents are a legal means of affecting the excludability attributes of an otherwise pure public good.<sup>17</sup> Now, the problem of giving private ownership in the form of patent on genetic research will lead to the debate of products of nature being given to private individuals, which is against the very nature of physical phenomenon.

Debate of intergenerational justice is also worth noticing here. A quick reading over data on this subject will show us a brief idea on the term “intergenerational justice”. It simply means we own a responsibility towards people of future generations, and our action should not put them to disadvantageous position. It is in essence similar to sustainable development, however a more philosophical concept, touched upon by stalwarts like John Rawls, Derek Parfit etc. Not embarking upon the moral aspect of patenting genes, will it be economically efficient for our generation to grant patent on genetic material, if we relate it to position of future generations. UN General Assembly ventured in this territory by drafting Universal Declaration of Human Genome and Human rights and gave a guiding proposition not to give patent on genes since they are part of common heritage. The common heritage idea is similar to public trust doctrine. However this is an ancillary line of thought, which will depend upon the result of economic efficiency of product of nature doctrine itself.

We now try and find the economic efficiency of product of nature doctrine. Author Jonah Jackson<sup>18</sup> provides the advantages of this doctrine, and says it is based on sound economic rationale. He points out towards three criteria, which are hindrance, necessity and democratic principles, for the reason of exclusion of natural phenomenon out of patentability. Describing each of them he says that giving a patent on natural phenomenon like laws of gravity etc. is

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<sup>16</sup> Memorandum submitted by Tim Kruger, Available at <http://www.publications.parliament.uk/pa/cm200910/cmsselect/cmsstech/221/10011316.htm> (accessed on 31 March 2015)

<sup>17</sup> Corinne Langinier&GianCarloMoschini, ‘*The Economics of Patent: An Overview*’ Working Paper 02/WP/293, p.2,3 Available at [http://www2.econ.iastate.edu/research/webpapers/paper\\_2061.pdf](http://www2.econ.iastate.edu/research/webpapers/paper_2061.pdf) (accessed on 31 March 2015)

<sup>18</sup> Jonah Jackson, ‘*Something Like the Sun: Why even isolated and purified genes are still products of nature*’ Texas Law Review, Vol. 83, p. 1466, 14677

going to hinder progress, and states as follows, “Were a monopoly to be granted, funneling all future research across such a broad range of subjects through a single monopolist risks significant transaction costs and outright deterrence.”<sup>19</sup> Necessity signifies that incentive needs to be given in the right places for the progress of science, and it is necessary only when there is something ‘new’ that is created, and not merely application of fact which is a scientific truth. Lastly elaborating on democratic ideals, he points out towards a famous case of *Funk Bro Seeds*<sup>20</sup> where court used the words “storehouse of knowledge of all human being” implicating an idea that some things are for entire population, and needs to be free from reserved rights over it, because of their very nature it needs to be for everyone. This is more on the lines of the public trust concept discussed above. This approach is primarily focused on the logical reasoning of why product of nature doctrine was evolved in the first place. Author also proposes an alternate view of seeing the doctrine as efficient. Before a matter comes up for litigation, it goes through the national patent office, which sees the claims of the party as to any new invention, and decided whether the invention is a merely a discovery, which means whether is it something that already existed or is it more than that, and is a result of human mind. The difference between discovery and invention has been given in *Reynolds v. Herbert Smith & Co., Ltd*<sup>21</sup> and it held as follows, “Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result”.<sup>22</sup> Therefore, a patent can only be given by the authority if it is an invention and not merely a discovery of previously unknown fact which always existed in nature but was not known, and was merely found out during a process. Now if product of nature doctrine is seen through this prism, merely discovering a gene will not make it eligible for patent and this has its roots in the cost and benefit analysis.

The marginal cost (social cost of his research plus the private cost) which a patentee incurs before he goes to patent any genetic sequence will generally include the R&D costs, the other

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<sup>19</sup>*Id.* p.1466

<sup>20</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)

<sup>21</sup>(1902), 20 *R.P.C.* 123 (Ch. D.)

<sup>22</sup>*Id* p.126

miscellaneous costs of laboratory, material required, tools and the investment of time and energy behind a particular area of research. But at the same time if the end result is merely a genetic sequence previously unknown but discovered, without any modification done by the researcher, without any addition, just as it was in nature, and then if patent is granted, it will be huge detriment for further research using that product. So if patent is granted on laws of earth's rotation, or magnetic field laws, it will require all subsequent users to get a license from the patentee to use these basic science rules and to make something innovative. The entire science community will then be paying royalty for information which should be available to all. This is the exact reason why in Myriad Genetics case judges were reluctant to grant a patent on something which was merely a discovery, had chances to be worked upon in future and thereby instead of holding those resources in the hands of few, the reason that it was inter-related to human health, it should be allowed to be used freely. If royalty is to be paid for something found in nature, all of us need to pay royalty to the government for the smallest of resources that we use. So Myriad Genetics is similarly based on sound economic reasoning. Therefore, by way of product of nature doctrine, the loss of benefit to the society is controlled, and the marginal cost will then look really insignificant in its comparison. Quoting Funk Bros. Case, it can be said that mathematical formulas to compute the circle's circumference or multiplication tables are not subject to any kind of patent, because they are for everyone to exploit and make something out of it. Therefore, the social cost to the society by not availing the benefit of a patent are lower than the benefits derived from not granting a patent, which can be looked into from public trust, which showed us how society as whole need some resources collectively. We can find that more a product is closer to a law of nature of natural phenomenon, the more chances are that patent will be rejected. Law of nature is a decreasing function of grant of patent. However, ideas of "isolated and purified genes" need to come in, which will be dealt in the further sections.

**Law of Nature  $\infty$  The inverse of grant of patent**

## **SHIFT AWAY FROM PRODUCTS OF NATURE: ISOLATED AND PURIFIED GENE DOCTRINE**

The author base their further discussion on how product of nature became redundant and then the scientific community saw the birth of new doctrine, “isolated and purified” gene doctrine. In the previous section, we gave out how this doctrine was economically efficient, and cogent reasons were provided, however there happened to be certain practical difficulties while dealing with the same in real world, especially one of them being that it gave rise to “subjective understanding” to what law of nature is by the patent examiner. This doctrine has its own flaws, which became a barrier for scientists and researchers some of which have been given in an article named *The Natural Complexity of Patent Eligibility*<sup>23</sup>, where out of the many reasons cited one of the reason was that this doctrine is not defined by any court, and the definition of “laws of nature” or “product of nature” are different in scientific community and legal community, which makes it lacking clarity. Also we find a very logical reasoning against such a doctrine, given in *Merck & Co. Olin Mathieson Chemical Corp*<sup>24</sup> which rejected this doctrine as a barrier for a patent and it was held that ‘all tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials’<sup>25</sup> Therefore, due to all these deficiencies, isolated and purified gene test came into picture. Before understanding the economics behind it, and its efficiency, we define the concept.

We start by defining “modified isolated human gene” which is defined comprehensively, and which will be accepted for the purpose of this paper also as “A sequence that has been altered in some way from its naturally occurring counterpart, for example, the isolated gene sequence is

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<sup>23</sup> Jacob S. Sherkow, “*The Natural Complexity of Patent Eligibility*” Iowa Law Review, Vol.99 p. 1140

<sup>24</sup> 253 F.2d 156 (4<sup>th</sup> Cir. 1958)

<sup>25</sup> *Id.* 161-162

altered to code for an altered protein with improved properties from the wildtype. These isolated gene sequences do not have a counterpart in nature.”<sup>26</sup> Isolated and purified doctrine is a permitted exception to products of nature doctrine, which have helped researchers obtain patent, which is based on the concept that when an inventor makes a product which is genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”<sup>27</sup> This fine distinction has been understood by court in *Myriad Genetics* which has allowed patent on cDNA, and categorically laid down the law that the lab-technician discovers something new not previously found in nature. Simple put it means that if, by way of isolation or any other process which brings the gene out of its natural state, since it is done by human ingenuity, and requires intervention by man. However, some researchers also feel cDNA patent also has been erroneously granted since cDNA if used by other health care providers will infringe *Myriad’s* patent and cDNA is an important research tool. This is going to virtually end competition and costs of licensing and the ultimate patient paying for his any genetic testing will shoot up.<sup>28</sup> (Merck case)<sup>29</sup> European System is more developed in this aspect and there is a specific law in EU, under Article 3.2 of Biological Directive of EU, which states that even if a product occurred in nature, but if that biological material is isolated from its natural state or is made through a technical process it can be said to be an invention.<sup>30</sup> Similarly, Article 5 specifically states that isolated gene sequences are patentable.<sup>31</sup> In multiple case laws like *Amgen Incv. Chugai Pharmaceuticals*<sup>32</sup>, *In re Bergstrom*<sup>33</sup> which held two hormones which did not occur in nature in purified form, and were made by the scientist were patentable, *Diamond v. Chakraborty etc.* have supported this proposition. *Parke-Davis & Co. v. H.K. Mulford & Co*<sup>34</sup> an oft quoted case, which happens to be

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<sup>26</sup> *supra*fn.5

<sup>27</sup> Matthew M. Karlan, “Patent Policy, Natural products, and the gene patent debate: Seeking the proper judicial mode of Analysis” NYU Annual Survey of American School Vol.67 Issue 95 p. 98

<sup>28</sup> Lara Cartwright Smith, *Patenting genes: What does Association of Molecular Pathology v. Myriad Genetics mean for genetic testing and research?* Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3982540/> (Accessed on 12<sup>th</sup> January 12, 2016)

<sup>29</sup> *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir. 1958).

<sup>30</sup> EU Directive on Biotechnological Patent 98/44, Available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044> (accessed by 3 April, 2015)

<sup>31</sup> *Id*

<sup>32</sup> 502 US 856

<sup>33</sup> 878 F.2d 1446

<sup>34</sup> 1911 U.S. App. LEXIS 5245



the foundation of this doctrine, dealt with artificially produced and isolated adrenaline, which was granted patent protection.

Now we move to its economic understanding. We start with the Rent dissipation theory. In their paper, *Patent Law and Rent Dissipation*,<sup>35</sup> author Mark Grady and Jay Alexander have explained this concept and they have said, “Rent Dissipation theory posits that profits from Innovation often realizing benefits far greater than the innovator’s development cost. Difference between the price society pays and its actual cost of development is Rent, which is given to the innovator in the form of monopoly right, otherwise competition by imitators would discourage innovation by making it unprofitable.”<sup>36</sup> They further say that those patents are prone to get patent protection where it is signaled that in future there is large potential for improvement, the reason being blocked improvements would have less social value, since there would be expenditure of resources behind that innovation and there will be a race to improve it first and get a patent on it, which will dissipate the rents.<sup>37</sup> Further one can explain this concept in the following manner, “some patents will confer rewards that exceed the inventor's development costs. Where these excessive rewards are expected, inventors will often compete with each other to be the first and only inventor to win the patent. These competitions can be socially unproductive because they often duplicate inventive activity and divert resources into the inventive sphere even though society would be better served were these resources used elsewhere. At a limit, the total net social benefit derived from an invention can be depleted entirely in a race to develop the invention quickly, perhaps too quickly.”<sup>38</sup> The more the scope of improvement, the more research will be carried, which results in “gold-rush” situation, since everyone would want to make a some improvement, in the product, e.g. a gene, with every improvement of gene, if patent protection is given, it is going to result into net loss, because not all researches are successful, and not patent application result into patent, which makes a deadweight loss of the sources already invested in that research of improvement which could have, and had the potential of being utilized into something else. *Morton v. New York Eye Infirmary*<sup>39</sup>, which is quoted by

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<sup>35</sup> Mark F. Grady & Jay I. Alexander, “*Patent Law and Rent Dissipation*” Virginia Law Review, Vol. 78 Issue 1, Symposium of Law and Economics of Intellectual Property Law, 1992, p.305-350

<sup>36</sup> *Id* p.308

<sup>37</sup> *Id* p.321

<sup>38</sup> Mathew Erramouse, “*Staking Patent claims on Human blueprint: Rewards and Rent dissipating Races*” 43 UCLA Law Review, (1996), p.973

<sup>39</sup> 17 F.Cas 879, Available at [http://www.patents4life.com/wp-content/uploads/2011/11/Westlaw\\_Document\\_10\\_44\\_191.pdf](http://www.patents4life.com/wp-content/uploads/2011/11/Westlaw_Document_10_44_191.pdf) (accessed on 5<sup>th</sup> April, 2015)

Grady and Alexander, and they further their theory, by saying that Dr. Morton's use of ether as anaesthetic wasn't an invention where further improvement was possible, and in the court, patent was in fact not given, but the economic rationale was that in the language of the author an "elegant" invention with no further improvement scope requiring no patent protection. However in that case, patent was not granted on the terms that it was a different application of ether in surgeries, by increasing the volume of vapor, done by well established techniques and "It is nothing more, in the eye of the law, than the application of a well-known agent, by well-known means, to a new or more perfect use, which is nor sufficient to support a patent."<sup>40</sup> Applying it to genetic patents in specific, isolated and purified genes doctrine essentially focuses on purity of a gene, or DNA molecule, which would mean that an innovator needs to have isolation of gene, but merely purification of the gene while retaining its natural functions isn't enough for patentability. We also see that the other standard which needs to be fulfilled which is the "markedly different characteristics" test, which is an indication that the gene which is isolated is something novel, fulfilling §101 requirement of novelty and has different properties attributable to it. Quoting from the judgment, we find that Court has correctly appreciated these factors and the exact passage has been reproduced for convenience "Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule. "Author proposes to show that the US Supreme Court has been able to take into account the economic understanding, though not mentioned in the judgment but has definitely based its reasoning on well-recognized differences in genetics. We also see that a lot of subjectivity comes into play when we talk about how a product is pure, and to what level of degree. The issue arises when purity is interpreted broadly, since any mind of purity, without a utility attached to it. In

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<sup>40</sup>*Id.* p.5-6

economic terms, “If the courts uphold patents for improvements in purity too loosely, without requiring a considerable advancement in utility, then society will suffer a monstrous deadweight loss. Not only would society lose when inventors compete over the rights to the original invention, but it would further lose when the prospective inventors expend large quantities of capital in search of relatively worthless purification. This suggests that the primary consideration in determining whether an enhancement in purity amounts to novelty should be the economic utility of the advancement. In other words, the level of purity that should be required to surpass the scope of the original patent should be sufficiently high to avoid giving prospective inventors an incentive to dissipate society’s profit, while at the same time low enough to encourage improvements which will increase the overall benefit to society.”<sup>41</sup>Therefore, a doctrine of isolation which ensures that the invention has some utility, can be more economically efficient, since it will give a return in terms of “information” or in terms of economic benefits, or health benefit etc. to the society. In this respect, the law clearly functions as a reflection of economic rationale, whereby, § 101 of USC, focuses on utility as criteria for a patent. It requires the patent to have “specific and substantial use” as per the 2001 Utility Guidelines of the USPTO<sup>42</sup>, which ensures that a utility driven isolation is given patent protection, requiring that the invention to be patented has a particular benefit which is clear and has present benefit available to the public. This utility driven approach in the genetic patent world, will lead to higher efficiency, in terms of reducing social cost. A patent can be granted on your isolated gene, only for the purpose envisaged, and not by tying up with you for all purposes, whereby for the period of patent, due to high royalty (which any innovator would want to recoup costs) or due to lack of information on the side of potential researchers and the innovator, the patent gene will fail to be of use to society at a broader level.<sup>43</sup>Taking this argument forward, Myriad could only use the patented cDNA genes for cancer research only, and it was free to be used for other medical or scientific research. The fact that their patent claim did not include method claims, anyone if able to reproduce cDNA by any other method, is definitely entitled to use it for research on any other diagnostic area.

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<sup>41</sup> Richard Seth Gipstein, “*Isolation and Purification Exception to general Unpatentability of product of nature*” Columbia Science and Technology Law Review, p.37 Available at

<http://www.stlr.org/download/volumes/volume4/gipstein.pdf> (accessed on 4<sup>th</sup> April 2015)

<sup>42</sup> USPTO, Final Guidelines for Determining Utility of Gene-Related Inventions (2001)

<sup>43</sup>HarleenKhanijoun, “*Gene Patents and Access to genetic Diagnostics tests*” p.19, 20 Available at

[https://tspace.library.utoronto.ca/bitstream/1807/33266/1/Khanijoun\\_Harleen\\_K\\_201211\\_LLM\\_thesis.pdf](https://tspace.library.utoronto.ca/bitstream/1807/33266/1/Khanijoun_Harleen_K_201211_LLM_thesis.pdf) (accessed on 5<sup>th</sup> April, 2015)

Therefore, when we talk about isolated and purified doctrine, economic rationale of granting patent protection to them can be when, we have high utility standard, because a low utility standard, would essentially allow patent over an entire gene sequence without understanding the future uses of it, and giving an exclusive right to research on its potential uses. But a high standard of utility will ensure that not only does the research have some benefit to the society, the researcher will be doubly sure of the benefits, and only then patent will be granted. Plus, by granting patent on a specific use envisaged, without being greedy to have control over all the uses the genetic material might have will be further helpful for society, and is also answering the criticism that genetic patents will lead to dominance over someone's genes in totality, which will not be the case. Further, a purified gene sequence will solve the problem of further race to modify the gene, and it controls the "inventing around the patent" (which occurs when getting a patent is easier) and it helps the researcher to not have a mindless exploitation of resources, without considering any utility the research might give to the society.<sup>44</sup>

Pre-Patent situation: The marginal cost to society will increase, because there can be government funded researches also in genetic area, and the use of resources in isolating and purifying a gene, with specific utility is going to be borne, in the form of diversion of resources, that too for a long period of time, since genetic discoveries do not happen over-night. On X axis we have taken, time for research and Y axis we have taken costs to the society, but we must observe that during this period where innovation is in research stage, the isolation and purification will be done only from the aspect of providing a higher utility to the society, and having well defined use to the gene, and not a competition who will be the "first innovator" who can take patent on all potential use without knowing fully the utility his/her purification of the gene has to offer. This will result in a competition for more utility approach which is a kind of compensation by the competing innovators to the society, by giving them a purified or isolated gene, which exists outside nature, has properties which can be helpful in field of medicine, diagnostics, genetic disorders etc.

This upward curve shows with every increase in time invested for research, cost to society increases. Therefore, when a utility based research in the area of genetics is done, and the compensation is given in the form of isolated and purified gene which has utility.

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<sup>44</sup> Sean C. Pippen, "Dollars and Lives: Finding Balance in the Patent 'Gene Utility' Doctrine" B.U.J Science and Technology Law Review, Vol.12 Issue 2, p. 19-20, 2006 Available on [http://www.bu.edu/law/central/jd/organizations/journals/scitech/volume122/documents/Pippen\\_WEB.pdf](http://www.bu.edu/law/central/jd/organizations/journals/scitech/volume122/documents/Pippen_WEB.pdf) (accessed on 5<sup>th</sup> April, 2015)

However, one must be cautious, because rent dissipation cannot in all circumstances be bad. Rent dissipation cannot be analyzed in a vacuum and should be considered in view of whether the rent dissipation is created by healthy competition.<sup>45</sup> For e.g. if there are ten firms researching on HIV/AIDS and they have knowledge that by isolating a gene, assuming it to be a gene X, and they purifying, having other processes of mutation etc. it can be a potential cure for this deadly disease, and the market has no cure or no medicine for it, then duplicative research by all of them, will not be rent dissipation. Assuming research cost for all the researches is constant at a price Y (includes all the cost the ten firms will undertake). The total cost to the society is: 10Y on a gene X. Now, if even two firms succeed, and they make different medicines, or therapeutic drugs out of it, which are different from each other, using different processes etc. both of them can get patents, and the benefit to the world will be much higher, which can be called as Z here. Therefore, this research was not rent dissipation, it was in a situation of competition for a product. Here  $Z > 10Y$ , because in a utility based approach which we have proposed, patent will be granted on the particular medicine or therapy and not on the isolated DNA/gene structure which is still available for the other 8 firms to carry their research on.

Therefore, in conclusion, isolated and purified genes doctrine coupled with utility based approach and try to minimize rent dissipation, should be the aim of law, and it should help maximize the benefits of the patent to the society.

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<sup>45</sup>PhaneshKoneru, "To promote the progress of useful articles? An analysis of current utility standards of Pharmaceutical products and Biotechnological Research Tools" IDEA The Journal of Law and Technology, 38 IDEA 625, p.637, 1998. Available at [http://ipmall.info/hosted\\_resources/IDEA/20.Koneru98.pdf](http://ipmall.info/hosted_resources/IDEA/20.Koneru98.pdf) (accessed on 5<sup>th</sup> April, 2015)



## CONCLUSION

Concluding, author has given a justification, and reasoning how Myriad case is in lines of well established notions of economics, as well as legal doctrines, making it a good law. However certain negative implications have also been highlighted. But from a normative point, it makes for a good understanding on the concept of economic efficiency.

