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**PATENTING HUMAN GENES:
WHEREIN LIES THE BALANCE BETWEEN PRIVATE
RIGHTS AND PUBLIC ACCESS IN INDIA AND
THE UNITED STATES?**

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ABSTRACT

This article examines the patentability of human genes by evaluating where the balance should lie between the protection of private rights and public access for the promotion of further innovation and public health. The author investigates this issue by providing a comparative study on the approaches adopted in India and the United States – two highly divergent nations that offer unique contrasts in a comparative analysis of their patent regimes. The outcome of the appraisal discerns a potential convergence in the Indian and US approaches on certain aspects of human gene patent-eligibility. This interesting result reveals that contrary to intuition, the differences in the state of economic, technological and patent law developments are not necessarily inimical to the prospect of adopting a common approach on certain facets of patent law, such as, those relating to the patent-eligibility of isolated genes. Moreover, the differences in the respective constitutional mandates

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do not inevitably constrain these two regimes to adopt dissimilar approaches to the legal treatment of issues, at least, in the context of specific aspects of human gene patenting. The article concludes by presenting that the Indian and US approaches on the patent-eligibility of isolated genomic DNA provides the better balance between granting private rights without jeopardising public access and represents a desirable departure from the current international practices.

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I. INTRODUCTION

The evolving biotechnology revolution poses immense challenges to the patent system, particularly on issues relating to the patenting of the Code of Life. Whilst genetic technologies have made significant contributions to the development and provision of medical services, they have generated much controversy. Major concerns on the grant of gene patents include the fear that it may impede further research and development and pre-empt future innovation in genetic advancement. Other concerns relate to their adverse impact on public health and access to healthcare services.

In June 2015, three notable events with significant impact on the development of biotechnology and patent law were commemorated. On the genetic technology front, it marks the 15th anniversary of the completion of the draft human genome sequence that had identified approximately 20,000 genes¹ comprised therein. With respect to patent jurisprudence, it commemorates two important events: First, the 35th anniversary of the US Supreme Court's landmark decision of *Diamond v Chakrabarty*² which ruled that human-made living matter is a patentable subject-matter. This decision has been credited as being instrumental in "spurring the creation of a dynamic and flourishing biotech industry"³ by promoting an expansive approach in which patentable subject-matter may include "anything under the sun that is made by man". Second, 2 years ago the US Supreme Court handed down another ground-breaking decision in *Association for Molecular Pathology v Myriad Genetics (AMP v Myriad)*.⁴ With remarkable unanimity, nine justices ruled that isolated genomic DNA, being "products of nature", are not patent-eligible unlike man-made complementary DNA (cDNA)⁵ which do not exist

1 See *Human Genome Project information* at http://web.ornl.gov/sci/techresources/Human_Genome/index.shtml (accessed 30 May 2015).

2 *Diamond v. Chakrabarty* 44 U.S. 303 (1980).

3 Jim Greenwood, President and CEO of Biotechnology Industry Organization quoted in Gene Quinn, "June 16, 2010: 30th Anniversary of *Diamond v Chakrabarty*" (16 June 2010) at <http://www.ipwatchdog.com/2010/06/16/june-16-2010-30thanniversary-of-diamond-v-chakrabarty/id=11268/> (accessed 29 May 2015).

4 *Association for Molecular Pathology v Myriad Genetics ("AMP v Myriad")* 133 S. Ct. 2107 (2013).

5 Man-made complementary DNA (cDNA) is used in this article to denote DNA sequences where the introns have been excised from its genomic nucleotide sequence by man to form an exon-only DNA sequence, as compared with naturally occurring exon-only DNA strands.

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naturally. The decision in 2013 marked a dramatic retreat from several decades of USPTO's "patent-happy"⁶ practice of granting thousands of patents on genes,⁷ including patents directed to isolated DNA.⁸

Building on these and related works of eminent scholars, this article will examine the issues relating to the patent-eligibility of human genes.⁹ It will engage in this discourse by evaluating where the balance should lie between the protection of private rights and public access for the promotion of further innovation and public health. Not surprisingly, the subject-matter is capable of dividing the world along ethical and policy lines and even self-interest. The author investigates this issue by providing a comparative study on the patent-eligibility of human genes in India and the United States – two highly divergent nations that offer unique contrasts in a comparative analysis of their patent regimes. Their differences on the economic, cultural and technological fronts require no further elaboration. On the legal aspect, the US patent system is well established while India is a relatively late starter having only re-introduced product patents for pharmaceuticals and chemical patents in 2005.¹⁰

The outcome of the appraisal discerns a potential convergence in the Indian and US approaches on certain aspects of human gene patentability, particularly the patent-eligibility of isolated genomic DNA. This interesting result reveals that contrary to intuition, the difference in these two regimes are not necessarily inimical to the prospect of adopting a common approach on certain facets of patent law,

6 See *per* Justice Elena Kagan who reportedly alluded to the USPTO as "patent-happy" at the US Supreme Court hearing of the *Myriad* case. See report in Jess Bravin, "Justices wary on gene patents" (April 16, 2013) *The Wall Street Journal* at <http://www.wsj.com/articles/SB10001424127887324485004578424782830965300> (accessed 26 June 2015); Rose-Ellen Lessy, "What's at stake in the Supreme Court decision in 'AMP v Myriad Genetics'" (June 5, 2013) *The Nation* ("Lessy").

7 Lessy, *ibid.*

8 See the Brief for the United States as amicus curiae in the *AMP v Myriad* (in the US Supreme Court).

9 Patent eligibility is only the first hurdle on the path to seeking patentability which requires the fulfilment of other criteria such as newness (novelty), non-obviousness (inventive step) and industrial applicability (utility).

10 Re-introduced by the Indian Patents (Amendment) Act 2005.

such as, those relating to the patent-eligibility of isolated genes. Moreover, the differences in their respective constitutional mandates do not inevitably constrain these two regimes to adopt dissimilar approaches to the legal treatment of issues at least in the context of specific aspects of human gene patent-eligibility.

Whilst diversity is generally preferred in conventional wisdom, there are instances where the benefits of convergence outweigh the cost. In the context of the patenting of human genes, it is argued that granting patents on isolated human genomic DNA would increase the potential risk of blocking research on the genes and downstream uses that may be necessary for further innovation and, more importantly, to safeguard public health.

This work begins with a short discourse on the function of patent law in biotechnology. It is followed by an introduction into the basic genetics of DNA before an appraisal of the Indian and US approaches on the patent-eligibility of human genes. A brief comparative review of the differences in the Constitutional mandates of these two nations will be highlighted. It concludes by presenting that the Indian and U.S. approaches on the patent-eligibility of isolated genomic DNA provides the better balance between granting private rights without jeopardising public access and represents a desirable departure from the current international practices.

II. FUNCTION OF PATENT LAW IN BIOTECHNOLOGY¹¹

A patent comprises a bundle of “exclusive rights” granted by a State for a limited period of time for the exploitation of an invention by the inventor in exchange for the sufficient disclosure of the invention.¹² It does not accord a right to practice the invention,¹³ neither does it confer any possessory right over the subject matter in a patented invention. In the context of a patent on human genes, the patent owner does not have *possession* over the genes that exist naturally in a human body. Rather, the patent owner has the right to prohibit its commercial exploitation, for example, by preventing others from using the genes.

11 This section is based substantially on this author’s earlier works in Elizabeth Siew-Kuan Ng, “Immoral inventions: Interaction between ethics and biotechnology patent law” (2010) 22 Singapore Academy of Law Journal 931 – 947 at 933 – 934.

The traditional role of the patent system remains true today. It seeks, *inter alia*, to incentivise activities that promote scientific progress and the creation of useful inventions which are beneficial to society. The typically large investments associated with R&D in the pharmaceutical and biotechnology industry has led to calls for a broader interpretation of the subject-matter eligibility and other validity criteria to be “guided [solely] by innovation goals”.¹⁴ Yet, an overly broad conception of subject-matter patent-eligibility may itself stifle further innovation as it could impede public access and unduly restrict the study of natural resources in the world.

At a more general level, the attitudes towards the goal of patents in biotechnology will continue to be shaped by the ongoing debate on whether patents promote or impede innovation and patient access. Some fear that granting patents too far upstream may be detrimental to the basic objectives of patent law which is to encourage downstream innovation to advance scientific progress. Not surprisingly, private enterprises maintain that patents are “the only things that matter” to a business that takes huge risks for undertaking massive investments in research.¹⁵

As we move towards a paradigm where patent “monopoly” appears to have assumed the “role of a legitimate reward for innovation”,¹⁶ it may perhaps be timely to examine the double-edged sword of patent protection. No one denies that patent exclusivity incentivises innovation and has spawned great public benefits. Yet, it

12 See, Philip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (New York: Oxford University Press, 5th Ed, 2010) at p 3; Lionel Bently & Brad Sherman, *Intellectual Property Law* (New York: Oxford University Press, 4th Ed, 2014) at p 335.

13 The freedom to practise an invention may be “limited by legislation or regulations having nothing to do with patents, or by the existence of other patents”. See Philip Grubb & Peter Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology* (New York: Oxford University Press, 5th Ed, 2010) at p 4. Note, however, section 83 of the Indian Patents Act relating to the working of patented inventions.

14 See, for example, Arti Rai, “Diagnostic patents at the Supreme Court” (2014) 18:1 Marq. Intell. Prop. L. Rev. 1 – 9 at p 2.

15 See Gene Quinn, “Emotion and Anecdotes should not drive patent policy debate” (16 June 2010) at http://www.ipwatchdog.com/2010/06/16/emotion-and-anecdotes-should-not-drive-patent-policy-debate/id=11260/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+Ipwatchdog+%28IPWatchdog.com%29 (accessed 2 July 2015).

16 Luigi Palombi, *Gene Cartels, Biotech Patents in the Age of Free Trade* (Cheltenham: Edward Elgar Publishing, 2009) at p xi.

may also impede the beneficial exchange of information necessary to spur future innovation or affordable access to patented products.¹⁷ In the context of human gene patenting, there are serious implications of increased healthcare costs on patient access. There is a need to bear in mind these competing objectives in the debate of whether genes should be patent-eligible subject-matter or ought to remain “free to all men and reserved exclusively to none.”¹⁸

III. SCIENCE OF GENETICS: A BRIEF INTRODUCTION TO GENES AND DNA¹⁹

Many of us are familiar with the “double helix” structure of the deoxyribonucleic acid (DNA) which was deciphered by Doctors James Watson and Francis Crick in 1953.²⁰ Yet, few (outside of the scientific community) may be acquainted with the DNA story of a lesser known scientist by the name of Friedrich Miescher who had in 1869 isolated “nuclein” (DNA with associated protein) and identified DNA as a distinct molecule²¹. Nearly a hundred years later, that was followed by the work of Oswald T. Avery, Colin MacLeod, and Maclyn McCarty²² who in 1944 demonstrated that it was DNA, and not protein (as was previously believed), which formed the “hereditary molecule”.²³ It was only a decade later that James Watson and Francis Crick’s well-known “double helix”²⁴ DNA structure was finally accepted.

17 See *Mayo Collaborative Servs v Prometheus Labs Inc.*, 132 S Ct. 1289 at 1305 (2012) (“*Mayo*”).

18 See *Funk Brothers Seeds v Kalo Inoculant Co.* 333 U.S. 127 (1948) at 130.

19 See generally, the Brief for the United States as amicus curiae in the *AMP v Myriad* (in the US Supreme Court); *AMP v Myriad* 133 S. Ct. 2107 (2013).

20 See J.D. Watson & F.H.C. Crick, “A Structure for Deoxyribose Nucleic Acid” *Nature*, 171 (1953), pp. 737–738.

21 See DNA from the beginning at <http://www.dnaftb.org/15/bio.html> (accessed 3 June 2015); Ralf Dahm, “Friedrick Miescher and the discovery of DNA” (2005) 278 *Developmental Biology* 274-288.

22 See O.T. Avery, C.M. MacLeod, M. McCarty, “Studies of the chemical nature of the substance inducing transformation of pneumococcal types. Induction of transformation by a deoxyribonucleic acid fraction isolated from pneumococcus type III” *J. Exp. Med.*, 79 (1944), pp. 137–158.

23 See Ralf Dahm, “Friedrick Miescher and the discovery of DNA” (2005) 278 *Developmental Biology* 274-288.

24 See J.D. Watson & F.H.C. Crick, “A Structure for Deoxyribose Nucleic Acid” *Nature*, 171 (1953), pp. 737–738.

It took nearly 150 years for the DNA to have “risen from being an obscure molecule with presumed accessory or structural functions inside the nucleus” to become the “icon of modern bioscience”²⁵ and probably the most hotly contested subject-matter in the law of patents globally.

The human genome comprises approximately 20, 000 - 22,000²⁶ genes within 23 pairs of chromosomes which form the “basis of human inheritance”.²⁷ Genes form the basic units of heredity in all living organisms. Each gene is made up of DNA and its size varies from a “few hundred DNA bases to more than 2 million bases.”²⁸ DNA controls nearly every aspect of a living organism’s physiology.²⁹ The DNA in a cell is referred to as “native” or “genomic” DNA. DNA encodes the instructions to make molecules known as proteins that are essential to cell structure and function. Its basic structure comprises two strands bound and twisted to form a double helix connected by “cross-bars”. Each cross-bar in the helix is joined by two nucleotides.

There are four standard nucleotides consisting of adenine (A), thymine (T), cytosine (C) and guanine (G) which are chemically paired so that “A” will always bind with “T”, and “C” will always bind with “G”. (See figure below). The predictable pairings of nucleotides make it possible to deduce its corresponding nucleotide sequence. The precise sequence of a DNA nucleotide generates the essential information which specifically encodes a linear sequence of amino acids that are necessary to build the proteins encoded by a given gene. Whilst some sections of a gene’s nucleotide sequence may encode for amino acids, the rest may comprise non-coding and regulatory sequences. The amino acid-coding nucleotide sequences are known as “exons” and the remaining non-coding nucleotides sequences are known as “introns”.

25 See Ralf Dahm, “Friedrick Miescher and the discovery of DNA” (2005) 278 *Developmental Biology* 274-288.

26 See *AMP v Myriad* (2013) 133 S. Ct. 2107; *AMP v Myriad* (2012) 689 F.3d 1303. See also *Human Genome Project information* at http://web.ornl.gov/sci/techresources/Human_Genome/index.shtml (accessed 30 May 2015); *Genetics Home Reference* at <http://ghr.nlm.nih.gov/handbook/basics/gene> (accessed 2 July 2015);

27 *AMP v Myriad* (2012) 689 F.3d 1303.

28 See *Genetics Home Reference*, *supra* note 26.

29 See the Brief for the United States as amicus curiae in the *AMP v Myriad* (in the US Supreme Court).

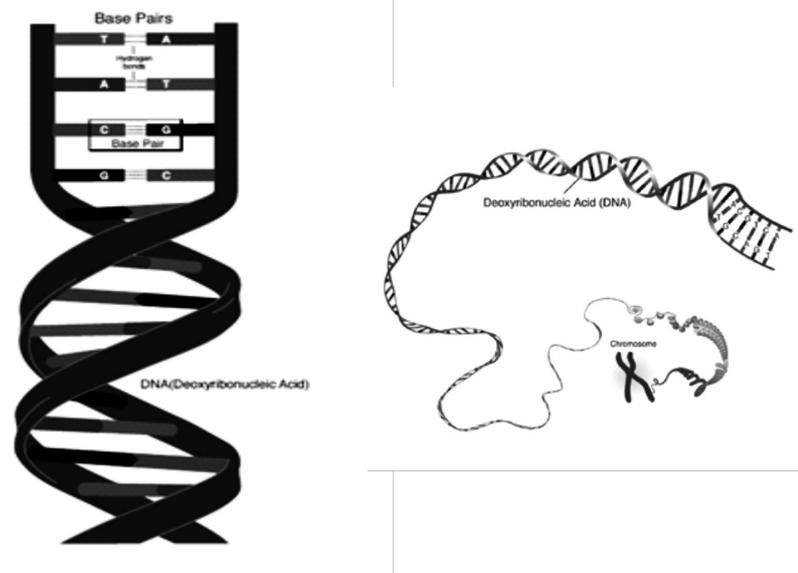


Image courtesy of Darryl Leja, NHGRI, NIH

Scientists and researchers have developed techniques to extract DNA from its natural cellular environment. The DNA that is extracted in this manner is generally referred to as “isolated genomic DNA” if the genetic sequence does not undergo any modification. Isolated genomic DNA is useful, for example, as genetic diagnostic tools and in DNA/gene sequencing.³⁰

Modifications to the isolated DNA³¹ can also be made by the scientists and researchers. This modification process will typically involve splicing and removing the non-coding introns that are generally interspersed with exon sequences in a given genetic sequence. The result is a DNA sequence made up of only exons. This resultant sequence is synthetic and is known as man-made complementary

³⁰ See, for example, Renz L Salumbre, “Genomic DNA isolation and applications (2009) at <http://www.scribd.com/doc/13890135/Genomic-DNA-Isolation-and-Applications#scribd> (accessed 29 June 2015).

³¹ Isolated DNA in this article refers to isolated genomic/”native” DNA.

DNA (cDNA)³² Due to the fact that cDNA contains only protein-coding nucleotide sequences, they can, for example, be used to express specific proteins when inserted into a cell.

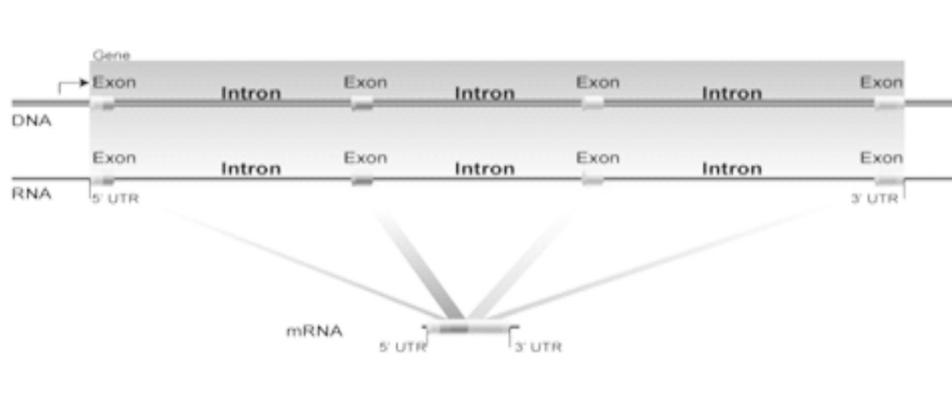


Image courtesy of NHGRI, NIH

Armed with this brief scientific background, we will now proceed to analyse the patent law issues.

IV. WHAT IS AT STAKE? IMPLICATIONS OF HUMAN GENE PATENTING

The patenting of human genes poses tremendous upstream and downstream challenges. A miscalibration may stifle innovation and unduly deprive the world of rightful opportunities to conduct further studies on genes. Where mutations of genes are correlated to diseases, an overly zealous response may have downstream adverse implications on diagnostic testing and genetic therapy. Since genetic sequences are largely derived from nature, the extent (if any) to which they should be exclusively reserved for a limited period to the inventor/investor requires careful consideration.

32 Man-made complementary DNA (cDNA) is used in this article to denote DNA sequences where the introns have been excised from its genomic nucleotide sequence by man to form an exon-only DNA sequence, as compared with naturally occurring exon-only DNA strands.

The BRCA gene saga may be illustrative. The function of the BRCA 1 gene, a tumour-suppressant, is to repair any damage to DNA. Mutation on this gene may radically increase the risk of cancer occurrence. Thus, the ability to correlate certain mutations of the BRCA gene to the increased risk of developing breast and ovarian cancer plays a vital role in prophylactic and therapeutic treatment.

This problem is compounded by the fact that breast cancer is one of the most common cancers in the US³³ as well as India,³⁴ among others.³⁵ For example, an average American woman has a 12 – 13% risk of developing breast cancer. But for women with certain genetic mutations, the breast cancer risk increases to 50 – 80% and the risk of ovarian cancer is around 20 – 50%.³⁶ Diagnostic testing of these women for the presence of mutation in the BRCA genes will play a significant part in enhancing the efficacy of clinical care and management therapy. The highly publicised case of the famous American actress and UNHCR global humanitarian ambassador Angelina Jolie Pitt is one such example.

Jolie Pitt had inherited a mutated BRCA 1 gene that carried an 87% risk of her developing breast cancer and a 50% risk of ovarian cancer.³⁷ She had lost her mother, grandmother and aunt to cancer. Armed with this knowledge, in 2013, Jolie underwent preventive double mastectomy. Two years later, she underwent a second preventive surgery to remove her ovaries and fallopian tubes.³⁸ This unique case illustrates how the discovery of the BRCA 1 gene mutation empowers some women to make choices over management of risks involving cancer associated with the BRCA mutation. The issue of whether Myriad should be conferred patent exclusivity over the BRCA genes was hotly contested globally.

33 See, for example, the US Centre for Disease Prevention & Control at <http://www.cdc.gov/cancer/breast/statistics/> (accessed 16 June 2015).

34 See Editor, “New Study shows breast cancer top killer among women, lung cancer among men in India” *The Indian Express* (29 May 2015).

35 Singapore Cancer Society at <http://www.singaporecancersociety.org.sg/learnaboutcancer/cancerfactsfigures.aspx> (accessed 16 June 2015);

36 Data is as reported in the court decisions of *AMP v Myriad* decisions, e.g. USCAFC, US Supreme Court.

37 See Angelina Jolie, “My Medical Choice” (May 14, 2013) *New York Times*.

38 See Angelina Jolie Pitt, “Angelina Jolie Pitt: Diary of a Surgery” (March 24, 2015) *New York Times*.

Whilst the BRCA 1 and BRCA 2 genes were known to exist in nature, no one had isolated them in such a manner that they could be effectively used and exploited. Myriad expended considerable effort, money and ingenuity in discovering and isolating those genes. However, the isolation techniques which they utilised were well-known and well-established. This feat has cast the spotlight on whether patents should be granted over the BRCA genes.³⁹

Some critics⁴⁰ have argued against gene patenting on the basis that the grant of patent rights on these genes will have a detrimental impact on the access to diagnostic testing, preventive and therapeutic treatment, as well as, impede future innovations in this area. It may, for example, block other diagnostic providers from offering alternative genetic tests; hinder patients' rights to second medical opinions and increase the price of diagnostic tests. Also, there are upstream implications where researchers may in certain circumstances be prevented from studying about patented genes.

The highly controversial nature of patent-eligibility for both isolated genomic DNA and cDNA is evident in the recent spate of patent lawsuits in many jurisdictions, including the United States, Australia and Canada. Indeed, at the time of writing this article, the gene patent challenge is pending before the High Court of Australia and similar lawsuits have been filed in Canada. The outcome of these litigations will determine the extent (if any) to which patent laws of different countries confer protection on the genetic sequences. Since the information encoded in a DNA sequence is necessary for the development of medical tests designed to detect certain gene mutations, the grant of patents over such a DNA sequence may adversely affect the diagnostic and treatment options available. A review of the patent law jurisprudence in India and the US may provide further illumination on this issue.

³⁹ Other reward structures may include the award of prizes.

⁴⁰ See, for example, Luigi Palombi, *Gene Cartels, Biotech Patents in the Age of Free Trade* (Cheltenham: Edward Elgar Publishing, 2009); Robert Cook-Deegan, "Gene Patents," in Mary Crowley (Ed.) *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, (Garrison, NY: The Hastings Center, 2008), 69-72.

V. DO HUMAN GENES FALL WITHIN PATENT SUBJECT-MATTER EXCLUSION ON THE GROUNDS THAT THEY ARE INHERENTLY UN-PATENTABLE? OR ARE THEY PATENT-ELIGIBLE SUBJECT-MATTER?

Before proceeding, it may be useful to re-iterate three caveats. First, it should be emphasised that whilst human gene patenting may lie at the intersection between patent law and ethics/morality, these considerations have been adequately discussed elsewhere and will not be debated here.⁴¹ Second, this article is not concerned with method patent claims, such as, those in genetic diagnostic medicine where genetic sequences or their mutations are analysed and compared. These have been dealt with in the US Supreme Court decision of *Mayo Collaborative Services v Prometheus Laboratories*⁴². Third, the focal point of discussion in this work relates only to one specific aspect of human gene patenting, namely, whether (a) isolated genomic DNA and (b) cDNA, are patent-eligible subject matter in the US and India. This eligibility analysis is merely the first condition to claim patentability. If a given genetic sequence satisfies this requirement, a patent is granted if it also satisfies the other well-established attributes of patentability, namely, new in the light of the prior art (novelty), non-obvious to the skilled addressee (inventive step)⁴³ and capable of industrial application (utility).⁴⁴

With this in mind, the US and Indian gene patenting scenarios will be explored.

41 Elizabeth Siew-Kuan Ng, 'Immoral inventions: Interaction between ethics and biotechnology patent law' (2010) 22 Singapore Academy of Law Journal 931 – 947; N.V. Rangantha, 'Patenting Human Genes: Moral and Ethical Issues' (Preserve Articles) at <http://www.preservearticles.com/2011120618179/patenting-of-human-genes-moral-and-ethical-issues.html> (accessed 13 June 2015);

42 *Mayo* 132 S. Ct. 1289 (2012). This decision was handed down one year before *Myriad*. For an excellent discussion, see ArtiRai, 'Diagnostic patents at the Supreme Court' (2014) 18:1 Marq. Intell. Prop. L. Rev. 1 – 9.

43 It is worth noting that under Indian law, inventive step and non-obviousness are two different limbs. There is a need for a step whose inventiveness is to be tested and also non-obviousness of the inventive step with reference to the skilled addressee. [Comments of anonymous referees]

44 These are the well-established patentability criteria set out in the TRIPS Agreement.

A. THE US APPROACH

1. OVERVIEW: PREQUEL TO THE MYRIAD DECISIONS

The issue of what constitutes subject-matter which may be patented under US patent law is governed by section 101 of the US Patent Act 1952 (35 USC) which provides that:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

The precise scope of this provision within the remit of the statutory goal to promote “the Progress of Science and useful Arts”⁴⁵ has been the subject of various judicial interpretations. The US Supreme Court’s landmark decision of *Diamond v Chakrabarty*⁴⁶ in June 1980 affirmed that patents were available for “anything under the sun that is made by man”. In that case, the Court held that human-made living matter is patentable subject-matter and the fact that it embraces living matter is an irrelevant consideration on the issue of patentability under patent law. The test is whether the subject-matter is the result of human intervention. The Court ruled that the “relevant distinction was not between living and inanimate things but between products of nature, whether living or not, and human-made inventions.”⁴⁷ The Court also acknowledged the longstanding precedents which affirmed implicit exceptions, namely, that “laws and products of nature, natural phenomena, and abstract ideas” are not patentable subject-matter.⁴⁸ Rather, these were “manifestations of . . . nature, free to all men and reserved exclusively to none.”⁴⁹

45 See *Diamond v Chakrabarty* 447 US 303 (1980) at 307; *JEM v Pioneer Hi-Bred* 534 US 124 (2001) at 130; Brief for the United States as amicus curiae in the *AMP v Myriad* (in the US Supreme Court) at 2.

46 *Ibid.*

47 *Ibid* at 313.

48 The US Supreme Court cited the earlier decisions of *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130(1948); *O’Reilly v. Morse*, 15 How. 62, 112-121 (1854); *Le Roy v. Tatham*, 14 How.156, 175 (1853).

49 See *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130(1948).

Yet, the US Patent and Trademark Office (USPTO) appeared to have paid little heed to these limitations on patent eligibility. Instead, it adopted an expansive approach to the issue and granted patents on a “wide range of engineered DNA molecules”.⁵⁰ In 1982, it started to issue patents that “claimed cDNA molecules in combination with other genetic materials.”⁵¹ In subsequent years, the USPTO began granting thousands of patents to “isolated DNA” on the basis that upon isolation from their natural cellular environment, they were no longer the “product of nature”. As one commentator⁵² has highlighted, the practice ignored the implicit distinction maintained in earlier judicial decisions between patent-eligible cDNA and patent-ineligible isolated genomic DNA (gDNA).⁵³

It was not until 2009 that this long standing USPTO practice was challenged by a group of medical researchers, advocacy groups, medical doctors and patients in a case relating to patents granted to Myriad for the BRCA 1 and BRCA 2 genes. It ultimately culminated in the landmark US Supreme Court decision of *AMP v Myriad* which finally reversed several decades of USPTO’s liberal practice of issuing gene patents, including those on isolated genomic DNA sequences.

2. THE MYRIAD DECISIONS: OVERTURNING THE LONG-STANDING PRACTICE OF GRANTING PATENTS CLAIMING ISOLATED DNA SEQUENCES

THE FACTS

Myriad Genetics (Myriad) made a medical breakthrough when its scientists discovered the precise location of the BRCA 1 and BRCA 2 genes on chromosomes 17 (comprising of approximately 80 million nucleotides) and 13 (comprising around 114 million nucleotides). Myriad identified the approximately 80,000 nucleotides length of each of BRCA 1 and BRCA 2 genes. On an exon-only cDNA sequence, BRCA 1 gene is only around 5,500 nucleotides long and for BRCA 2 gene, it is around 10,200. This was an immensely valuable scientific

50 See Brief for the United States as amicus curiae in the *AMP v Myriad* (in the US Supreme Court) at p 5.

51 *Ibid.*

52 See John Conley, “Myriad finally: Supreme Court surprises by not surprising” (June 18, 2013) Genomics Law Report.

53 See, e.g. *Amgen v Chugai* 927 F.2d 1200 (1991).

contribution towards the development of medical tests for detecting mutations of these two genes in patients thereby enabling an assessment to be made on their risks of developing breast and ovarian cancer. Whilst the scientific community was aware that heredity played a significant role in the risks associated with cancers, they did not know which genes were associated with these types of cancer until Myriad's breakthrough.⁵⁴

Upon this discovery, Myriad filed and obtained several patents including those related to the isolated DNA and cDNA that encodes for BRCA 1 and BRCA 2 genes. If these patents are held to be valid, they would confer on Myriad the exclusive right to isolate the BRCA 1 and BRCA 2 genes from an individual's genome, as well as, to synthetically create the BRCA cDNA. Since isolation is an essential step in conducting genetic and diagnostic testing, Myriad tried to enforce its patents against entities that were performing the BRCA testing. If the patent is upheld, Myriad will have "solidified its position as the only entity providing BRCA testing."⁵⁵ The scientific research community may have far less scope to conduct further studies on the BRCA genes since there is "no meaningful" research exemption from patent infringement in the US law.⁵⁶

THE US DECISIONS

(a) *At the US District Court (USDC) & US Court of Appeal for the Federal Circuit (USCAFC)*

It all began when Judge Sweet of the US District Court issued his bold pronouncement that Myriad's patent claims on BRCA 1 and BRCA 2 genes were patent-ineligible and invalidated them, *inter alia*, on the ground that they were not "markedly different" from products of nature. The learned judge also rejected the analogy of genetic sequences to chemical compounds which are eligible subject-matter under patent law.

54 See *AMP v Myriad* 133 S. Ct. 2107.

55 *Ibid.*

56 See Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) (2010) *Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*; John Conley, "Myriad finally: Supreme Court surprises by not surprising" (June 18, 2013) Genomics Law Report.

Not surprisingly, the case was appealed to the US Court of Appeals for the Federal Circuit (USCAFC). At the USCAFC, a divided panel reversed Judge Sweet's ruling. The judges were unanimous in ruling that man-made cDNA molecules were patent-eligible. They also held (by a delicate majority) that isolated genomic DNA was also patent-eligible. The plaintiffs appealed to the US Supreme Court. The Supreme Court vacated the USCAFC's opinion and remanded the case to the Federal Circuit for re-consideration in the light of the US Supreme Court's decision in *Mayo v Prometheus*. On remand from the Supreme Court, the same three member panel of the USCAFC basically reaffirmed its earlier decision ruling that Myriad's composite claims to isolated DNA and cDNA fell within the scope of patentable subject matter.

The central tenet of the majority decision is that the act of cleaving the DNA sequence from its cellular environment in the human body was sufficient to transform the isolated DNA into a different molecule. However, Judge Lourie and Judge Moore proffered different reasoning for their decisions:

Judge Lourie opined that isolated DNA was "markedly different" from those found in nature since the "separated portions of DNA" were non-naturally occurring new molecules (with unique chemical compositions) that never existed in that form in the human body or in nature.⁵⁷ The learned judge appeared to have adopted the chemist's viewpoint (i.e. relied on the chemical composition of the isolated DNA sequence), rather than that of a biologist which focuses on the uses (i.e. the "informational transmitting quality") of a molecule.

Judge Moore offered two main rationale for her decision. First, she expressed the view that the chemical differences highlighted by Judge Lourie alone are insufficient to support a grant. An isolated DNA could be patent-eligible only if it possesses greater utility than native genomic DNA. On this basis, she drew a distinction between shorter isolated DNA strands which may satisfy this additional utility requirement (through their use as primers and probes) as opposed to similar but longer DNA strands. Second, she assigned significant weight to the long-standing

⁵⁷ See Brief for the United States as amicus curiae in the *AMP v Myriad* (in the US Supreme Court) at p 8.

practice of the USPTO in issuing thousands of patents on such gene sequences. She was reluctant to disturb the “settled expectations and extensive property rights” that had been generated. Importantly, Judge Moore conceded that her vote might have been different if she “were deciding this case on a blank canvas.”

Isolated Genomic DNA

Judge Bryson dissented on the issue of isolated genomic DNA. He stressed that the breaking of the covalent chemical bond was inconclusive and held that isolated genomic DNA was not patent eligible as the isolated nucleotide sequence remain the same as that found in naturally occurring human genes. He proffered a “leaf analogy” as follows: merely isolating genomic DNA from the human body is not patent-eligible subject-matter in the same way that a natural leaf does not become patent eligible subject-matter just because it has been plucked from the tree. Judge Bryson opined that:

“[E]xtracting a gene is akin to snapping a leaf from a tree. Like a gene, a leaf has a natural starting and stopping point. It buds during spring from the same place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into a human-made invention ... That would remain true if there were minor differences between the plucked leaf and the fallen autumn leaf, unless those differences imparted “markedly different characteristics” to the plucked leaf.”⁵⁸

On this issue, Judge Bryson offered a kidney analogy - an isolated gene should be patent-ineligible subject-matter in the same way that a kidney which has been removed from the body is not eligible for patent protection. He stated that:

“A human kidney is a product of nature; it does not become a patentable invention when it is removed from the body, even if the patentee has developed an improved procedure for extracting the kidney, and even if the improved procedure results in some physical or chemical changes to the kidney at the points where the kidney was attached to the host body.”

58 *AMP v Myriad* (2012) 689 F.3d 1303.

The learned Judge acknowledged that the isolation of a gene involves the “alteration of a single molecule” but disputed that this alteration would be sufficient for the purpose of patentability. He concluded that it should not make a difference whether “the isolated substance is part of a single molecule, as in the case of the BRCA genes, or part of a very large aggregation of molecules, as in the case of a kidney.”⁵⁹ Judge Bryson correctly qualified that it would be an oversimplification “to say that something that can be characterized as “isolated” or “extracted” from its natural setting always remains a natural product and is not patentable.” It would depend, *inter alia*, on whether the process of isolation or extraction has resulted in a product with distinct characteristics which functions differently from the naturally-occurring state from which it was derived. Based on this analysis, the learned judge rightly concluded that:

“[N]ature has defined the genes as independent entities by virtue of their capacity for protein synthesis and, ultimately, trait inheritance. Biochemists extract the target genes along lines defined by nature so as to preserve the structure and function that the gene possessed in its natural environment. In such a case, the extraction of a product in a manner that retains the character and function of the product as found in nature does not result in the creation of a human invention.”⁶⁰

Judge Bryson’s leaf analogy was challenged by Judge Lourie (of the majority) largely on the basis that the process of isolating DNA was more difficult than simply plucking a leaf from the tree. He opined that:

“Snapping a leaf from a tree is a physical separation, easily done by anyone. Creating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort.”

With due respect to Judge Lourie, as one commentator has correctly highlighted, although the isolation of DNA may involve more skill than plucking a leaf, once the genetic sequence of the gene is known – the actual process of DNA isolation

59 *Ibid.*

60 *Ibid.*

was well-known and would not be difficult to the person skilled in the art.⁶¹ Indeed, DNA isolation processes are routinely conducted in many colleges of different countries.⁶² Moreover, the majority appeared to have focused on the skill and labour involved in the isolation process. With respect, it is submitted that this relates to the issue of non-obviousness/inventive step rather than product patent-eligibility. This is also reinforced by Judge Bryson’s kidney analogy. Although the removal of a kidney requires substantial skills and labour, no one would dispute that the surgically removed kidney cannot be patented.

The parties appealed to the highest court of the United States.

(b) The US Supreme Court decision

In June 2013, in a succinct judgment, nine Justices of the US Supreme Court accepted the position of the US Government and unanimously ruled that isolated genomic DNA are not patent-eligible subject-matter but man-made cDNA are patent-eligible.⁶³ In denying patent-eligibility to isolated genomic DNA, the Court held that Myriad had not created or altered the genetic information encoded in the BRCA 1 and BRCA 2 genes. Indeed, the order of the nucleotides in the isolated genomic sequence remained the same as that which exists in nature. In contrast, the Court was persuaded that the arrangement of the nucleotide sequence in cDNA is dictated by man rather than by nature. The Court focused on the “product of nature” exclusion and re-affirmed the implicit exception to 35 USC § 101 that laws of nature, natural phenomena and abstract ideas are not patentable.

61 See Dennis Crouch, “Gene patent debate continues: Federal Circuit finds isolated human genes patentable” (16 August 2012) Patently-O at <http://patentlyo.com/patent/2012/08/gene-patent-debate-continues-federal-circuit-finds-isolated-human-genes-patentable.html> (accessed 7 June 2015).

62 See Dennis Crouch, “Gene patent debate continues: Federal Circuit finds isolated human genes patentable” (16 August 2012) Patently-O at <http://patentlyo.com/patent/2012/08/gene-patent-debate-continues-federal-circuit-finds-isolated-human-genes-patentable.html> (accessed 7 June 2015).

63 Thomas J delivered the Court opinion, in which Roberts CJ and Kennedy, Ginsburg, Breyer, Alito, Sotomayor and Kagan JJ joined; and Scalia J concurred in part and concurred in the judgment.

The Court stressed that these are “basic tools of scientific and technological work” that lie beyond the domain of patent protection.⁶⁴ Justice Thomas (delivering the Court opinion) rightly reminded us of the importance of these exclusions when he highlighted that:

“Without this exception, there would be considerable danger that the grant of patents would “tie up” the use of such tools and thereby “inhibit future innovation premised upon them”... which would be at odds with the very point of patents, which exist to promote creation.”⁶⁵

However, the learned Justice cautioned against adopting too stringent an exclusion against patents on naturally occurring things. Since “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas, ... too broad an interpretation of this exclusionary principle could eviscerate patent law.”⁶⁶

The US Supreme Court pointed out, what this author believes to be the crux in resolving this complex issue, that in a determination of whether human genes are patent-eligible subject-matter we should not overlook the well-established rationale that patent protection must strike:

“a delicate balance between creating ‘incentives that lead to creation, invention and discovery’ and ‘impeding the flow of information that might permit, indeed spur, invention”⁶⁷ [and access for public health]⁶⁸

Although Justice Thomas did not expressly articulate the public interest/public health factor, he alluded to the fact that Myriad’s patents (if valid) would give it the exclusive right to isolate the BRCA genes which is a necessary step in conducting

64 Per Justice Thomas *AMP v Myriad* (2013) 133 S. Ct. 2107.

65 Ibid. Per Justice Thomas quoting in part from *Mayo v Prometheus* 132 S. Ct. 1289 (2012).

66 *Association for Molecular Pathology v Myriad Genetics* 133 S. Ct. 2107 (2013) at 2108.

67 Per Justice Thomas *ibid.*

68 Words in bracket inserted by this author.

genetic testing which would in turn “solidify its position as the only entity providing BRCA testing.”⁶⁹

(c) *Reactions to the Decision*

This more conservative approach of the US Supreme Court and US Government marks a significant change in the law and practice of the US patent regime.⁷⁰ Not surprisingly the reactions to this momentous court ruling were varied and intense. Some applauded the decision as a “thrilling victory for patients”⁷¹; “great news for patients, doctors and scientific researchers”⁷²; and portended that it will promote further innovation in the biotechnology industry and encourage the creation of new entities. Others (mainly from the pharmaceutical and biotechnology industry) decried it as the doomsday of innovation.⁷³ Still others were less charitable and hurled personal attacks at the Justices, likening them to “Emperor without any clothes”; and suggesting “you would have to go out of your way to find nine less qualified people to decide issues of a technological nature.”⁷⁴

Be that as it may, the US jurisprudence on the patent-eligibility of human genes is now settled. Armed with this knowledge, let us traverse to explore the Indian landscape.

69 *Per Justice Thomas AMP v Myriad* (2013) 133 S. Ct. 2107.

70 *Lessy, supra* note 6.

71 See American College of Medical Genetics and Genomics (ACMG) statement of June 13, 2013 at <https://www.acmg.net/docs/GenePatientsDecision.pdf> (accessed May 28, 2015).

72 See Lori Andrews, “US Supreme Court liberates breast cancer genes” (June 14, 2013) IIT Chicago-Kent Faculty blog at <http://blogs.kentlaw.iit.edu/faculty/2013/06/14/andrews-u-s-supreme-court-liberates-breast-cancer-gene/> (accessed May 28, 2015). Andrews L filed amici curiae briefs on behalf of several medical organisations (including the American Medical Association, American Society of Human Genetics, American College of Obstetricians and Gynaecologists).

73 See Donald Zuhn, “Reaction to Supreme Court’s decision in AMP v Myriad” (July 1, 2013) Patent Docs at <http://www.patentdocs.org/2013/07/reaction-to-supreme-courts-decision-in-amp-v-myriad.html> (accessed May 28, 2015)

74 See Gene Quinn, “Naked emperors: A Supreme Court patent tale” (May 31, 2015) IP Watchdog blog at <http://www.ipwatchdog.com/2015/05/31/naked-emperors-a-supreme-court-patent-tale/id=58110/> (accessed 3 June 2015).

B. THE INDIAN APPROACH

1. INTRODUCTION

The Indian Patents Act 1970⁷⁵ regulates the grant of patents on inventions. This Act adopts the well-established patentability criteria set out in the TRIPS Agreement.⁷⁶

Prior to 2002, the Indian Patent Office did not grant patents for inventions relating to “(a) living entities of natural or artificial origin, (b) biological materials or other materials having replicating properties, (c) substances derived from such materials and (d) any processes for the production of living substances/entities including nucleic acids.”⁷⁷

In 2002, the High Court of Calcutta in *Dimminaco AG v Controller of Patents & Designs*⁷⁸ granted patents for the processes involved in the preparation of the Bursitis vaccine where the final product of that process contained living organisms. Initially, it was rejected by the Indian Patent office on the grounds that the process for the preparation of the said vaccine could not be considered a “manner of manufacture”⁷⁹ as its end product contained a living entity and the claimed process was a natural one. That was overturned by the High Court. Justice Asok Kumar Ganguly found that there is no statutory bar against patenting the manner of manufacture notwithstanding the end product contains a living organism.

Statutory changes followed. The Patents Act was amended in 2002 to specifically permit, *inter alia*, the patenting of biotechnological and microbiological processes. In the definition of “invention”, the “manner of new manufacture” was replaced by “new product or process involving an inventive step and capable of industrial application.”⁸⁰ In 2005, a further amendment paved the way for the grant of

75 Indian Patents Act (39 of 1970) (as amended).

76 Namely, that the invention must be new, involve an inventive step and be capable of industrial application.

77 See Indian Guidelines for examination of biotechnology applications for patent (March 2013) at p2.

78 AID No. 1 of 2001 (High Court of Calcutta).

79 This was based on the definition of “invention” under the pre-Patents (Amendment) Act 2002.

80 Prior to the Patents (Amendment) Act 2002, the reference, *inter alia*, was to “manner of manufacture”, a term used under the section 6 of the English Statute of Monopolies of 1623.

product patents in any field of technology, including those in biotechnology.⁸¹ The Patents Act also expressly enumerates a list of subject-matter which are excluded from patent protection. We now turn to examine some of the provisions which are particularly relevant to gene patenting.

2. ARE HUMAN GENES EXCLUDED SUBJECT-MATTER UNDER THE INDIAN PATENTS ACT?

Section 3 of the Indian Patents Act stipulates a list of inventions which are not patentable. Of specific relevance are:

Inventions not patentable: The following are not inventions within the meaning of this Act -

3 (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

3 (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

3(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the

81 See Indian Guidelines for examination of biotechnology applications for patent (March 2013) at p 3. See also Shamnad Basheer, "India's tryst with TRIPS: The Patents (Amendment) Act 2005" (2005) 1 The Indian Journal of Law and Technology 15-46.

same substance, unless they differ significantly in properties with regard to efficacy;

3(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

3(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

The scope and impact of these sub-sections on the patent-eligibility of human genes do not appear to have been subject to any judicial consideration in India. Unlike the US, the Indian jurisprudence on the patenting of human genes has not yet been settled. Currently, the only guidance is to be found in the Indian Guidelines for Examination of Biotechnology Applications for Patents (the Indian Guidelines)⁸² and the Indian Manual of Patent Practice and Procedure (IMPPP).⁸³ It is to these that the author now turns her attention.

Before proceeding, it may be useful to highlight three main issues. First, the general ethical and moral considerations enunciated in section 3(b) of the Act will not be examined in this article as it has already received detailed treatment elsewhere.⁸⁴ Second, the author will only evaluate the impact of sections 3(c), 3(d), 3(e) and 3(j) with respect to the patent-eligibility of human genes, namely, naturally occurring DNA, isolated genomic DNA and cDNA. Third, it is unclear whether section 3(j) is applicable to human genes. We will analyse this third issue before an appraisal on its application to human gene patenting.

82 The Indian Biotechnology Guidelines were published in March 2013, just three months before the US Supreme Court released its judgment in *AMP v Myriad*. These guidelines were issued by the Indian Office of the Controller General of Patents, Designs and Trade Marks.

83 It should be noted that the IMPPP does not have the force of law. [Comments by the anonymous referees].

84 See, for example, Elizabeth Siew-Kuan Ng, "Immoral inventions: Interaction between ethics and biotechnology patent law" (2010) 22 *Singapore Academy of Law Journal* 931 - 947.

Section 3(j) Indian Patents Act

Section 3 (j) excludes from patentability any animal “in whole or any part thereof”. Its scope is ambiguous. First, it is unclear whether “animal” includes a human being. For general scientific purposes, the human species would be classified as a mammal within the animal kingdom.⁸⁵ On the other hand, this author submits that a contextual approach of section 3 suggests otherwise. A purposive interpretation of the sequence of words “human”, “animal” and “plant life” used in juxtaposition in section 3(b) would support the exclusion of human from the scope of “animal”. Furthermore, the context of the words “plant” and “animal” as they occur in section 3(j) also lend support to the conclusion.

However, for the sake of completeness, we shall proceed to evaluate the application of the section on the assumption that “any animal” includes a human. Some support for this may be found in an example provided in the Indian Guidelines which asserts that a claim for *ex vivo* educated autologous NK T cells for treating an immune-related disorder in a mammalian subject would fall within the scope of section 3(j). There is no further guidance on what constitutes a “mammal” or whether it encompasses a “human being”. Even if “any animal” were held to include humans, there is another question as to whether a genetic sequence would constitute a “part of” an animal. One commentator⁸⁶ reported that based on an interview conducted with some patent examiners of the Indian Patent Office, there appears to be an informal consensus that section 3(j) is not applicable at the molecular/cellular level involving genes. Unfortunately, no reason was enunciated for this viewpoint. It is unclear whether the interviewees were referring to the process or product at the molecular/cellular level. If it is the latter, then with due respect, this author disagrees and submits that there is nothing in the provision that requires such a restrictive interpretation. Human blood or bone marrow is as much a part

85 See Simon Nathan. ‘Collections of plants and animals - Identifying plants and animals’, TeAra - the Encyclopedia of New Zealand, at <http://www.TeAra.govt.nz/en/document/12130/classification-of-humans> (accessed 26 June 2015); See also Editor, “Classification of human species” *Factophile* at <http://www.factophile.com/show.content?action=view&pageid=3> (accessed 26 June 2015).

86 See Bhavishyavani Ravi, “Gene patents in India: Gauging policy by an analysis of the grants made by the Indian Patent Office” (2013) 18 *Journal of Intellectual Property Rights* 323 – 329 at 327.

of a human body as is a distinct organ such as a kidney. It would require overly zealous judicial activism to import distinctions based on anatomical structures, features or functions into the simple phrase, “any part” thereof.⁸⁷

It is the author’s submission that human genes are likely to fall outside section 3(j) on the grounds that an “animal” does not include a human based on the reasons enunciated above. However, in the event that the Indian courts come to an opposite conclusion, we need to consider its application to human genetic sequences.

With this in mind, we will now proceed to analyse the effects of sections 3(c), 3(d), 3(e) and 3(j) on the patent-eligibility of human genes, namely, naturally occurring DNA, isolated genomic DNA and cDNA.

(a) Naturally occurring DNA

It seems clear that the mere identification of the location of a human gene, or part of a gene, as it exists within a chromosome in nature is not patentable. It will be excluded under section 3(c) as a “discovery” of a naturally occurring living thing. This approach is largely similar to the “product of nature” exclusion under the US law.

It will also be excluded under section 3(j) as “part of an animal [human]”, if the provision applies to human genes.

(b) Isolated genomic DNA

What is less clear is whether isolated genomic DNA would fall within the scope of the exclusions under sections 3(c) and/or 3(j). Prior to 2013, the Indian Patent Office had granted patents that claim isolated genetic sequences. However, under its 2013 Indian Biotechnology Guidelines, nucleic acid sequences, proteins, enzymes, compounds etc. which are “directly isolated from nature” will be treated as a discovery and are not patentable subject-matter.⁸⁸ Based on these Guidelines, it

⁸⁷ See Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

⁸⁸ For example, a claim to an isolated *Bacillus* occurring in nature which will be treated as a discovery of a living matter occurring in nature and hence, not patentable under section 3 (c). See Indian Biotechnology Guidelines.

would seem that isolated genomic DNA which are “directly isolated from nature”⁸⁹ will also be excluded from patentable subject-matter on the basis that they are discoveries under section 3(c). However, this is not without controversy.⁹⁰ If the courts adopt the Guidelines, the legal position will seem to be aligned to the US approach.

Consideration may also be given to the impact of section 3(d) on the patent-eligibility of isolated genomic DNA. If the term “substance” includes human genes, then the genomic DNA sequence in its “isolated form” may be broadly considered as a “mere discovery of a new form of a known substance”. If this is correct, then it may be excluded under section 3(d) unless it results in the “enhancement of the known efficacy of that substance”. What constitutes “enhanced efficacy” in the context of isolated human genes is unclear? Nonetheless, since the precise arrangement of the nucleotide sequence in the isolated genomic DNA remains the same as that which occurs in nature, it may be difficult to establish that the mere act of isolating the genomic DNA is sufficient to result in the “enhanced efficacy” of the genetic sequence. Hence, it seems likely that isolated genomic DNA may be excluded from patentability for the reasons enunciated above.

Likewise, isolated genomic DNA may also be excluded under section 3(j) on the basis that an unmodified element isolated from the human body would still constitute a “part of an animal [human]” under section 3(j), if the provision applies to human genes. The mere act of isolation is insufficient to transform the unmodified isolated element into a non-human part.

If the Court accepts the outcome of the above evaluation, then the Indian approach relating to the patent-eligibility of isolated human genomic DNA may seem to be aligned to that of the US.

89 See Mrinalini Gupta, “India: Are gene patents a hindrance to innovation?” (26 June 2013) Mondaq at <http://www.mondaq.com/india/x/247166/Life+Sciences+Biotechnology/Are+Gene+pat+ents+a+hindrance+to+Innovation> (accessed June 8, 2015).

90 See Sreenivasulu N.S., *Law Relating to Intellectual Property* (2013) at p 362 where it is opined that India having ratified the TRIPS Agreement which mandates patent protection for biotechnological inventions, in India microorganisms, plants, animals, and isolated human genetic material including the products of such genetic materials such as proteins are patentable. Similarly, it is stated (at p 360) that “products of biotechnological process produced through some technical interference to natural process are non-natural hence patentable.

(c) cDNA

Turning to the more challenging issue of whether cDNA is patentable subject-matter, it may be worthwhile to repeat that we are not dealing with *naturally-occurring* short exon-only DNA sequences that exist in nature. These are likely to be excluded from patentability under sections 3(c) and 3(j). Neither are we concerned with recombinant/genetically engineered DNA sequences. Instead, we are considering an exon-only genetic sequence that is left after the introns have been removed from an isolated genomic DNA sequence by man. There seems to be a lack of useful guidance on this specific subject in the Indian Guidelines and IMPPP. The author will seek to assess this issue by analysing the exclusions set out in sections 3(c), 3(d), 3(e) and 3(j).

Section 3(c)

The Indian Guidelines provide that this section covers products that have been “*directly isolated*” from nature. It also acknowledges that modified products which do not constitute discovery of living things occurring in nature are patentable subject-matter. Beyond this, it is silent on the requisite degree of modification that would be required.

On a broad reading of section 3(c), it may be possible to argue that an artificially created exon-only sequence is no more than a “discovery” notwithstanding the human excision of the introns. After all, the precise arrangement of any nucleotide sequence of exon-only man-made cDNA has its equivalent in naturally occurring DNA sequences too.⁹¹ Indeed, the informational content encoded in the exon-only genetic sequence of the man-made cDNA would be identical to another exon sequence found in its “natural state”.

⁹¹ At the first oral argument, the US Government illustrated its position by using a “magic microscope” test. According to this test, “if an imaginary microscope could focus in on the claimed DNA molecule as it exists in the human body, the claim covers ineligible subject matter. The government thus argued that because such a microscope could focus in on the claimed isolated BRCA1 or BRCA2 sequences as they exist in the human body, the claims covering those sequences are not patent eligible. In contrast, the government contended, because an imaginary microscope could not focus in vivo on a cDNA sequence, which is engineered by man to splice together non-contiguous coding sequences (i.e., exons), claims covering cDNAs are patent eligible.” See *Lourie J in AMP v Myriad (USCAFC)* at p 41.

On a narrower construction of the word “discovery” in section 3(c), an argument could be advanced that a given strand of man-made cDNA is not a discovery *per se* since it is not “directly isolated” from nature. Rather it is a product artificially derived by man from work done on a naturally occurring substance. Indeed, cDNA may be more accurately referred to as a product that has been indirectly derived from a product directly isolated from nature. Based on this interpretation the excision of the introns may be said to have transformed the subject of the “discovery” into an invention. Thus, it would appear that the human modification may suffice to take cDNA out of the scope of section 3 (c). This may also be consistent with one of the illustrative examples in the Guidelines which intimates that an isolated peptide that is structurally equivalent to a cupredoxin or cytochrome protein would fall under section 3 (c) if a claim does not clearly indicate what “modifications/alterations/deletions” had been made to the wild-type native peptides. No guidance is provided on the extent of modification required. Similarly, another illustrative example (albeit under “industrial application”) suggests that a “polypeptide in *substantially* isolated form comprising ...” may be patentable if the claim is sufficiently enabled and its use properly established”. Again, it does not provide any elucidation, for example, on what is the distinction between a “*directly* isolated” product and a “*substantially* isolated” one.

Section 3(d)

Another provision which may be applicable in the context of the patent-eligibility of cDNA is section 3(d). If this provision applies to human genes, then cDNA may be excluded from patentability if it constitutes a “mere discovery of a new form of a known substance which does not result in the enhancement of the know efficacy of that substance”. Several factors may be worth considering. First, does cDNA constitute a “new form” of a known genomic DNA sequence? Second, is the excision of the introns to artificially create an exon-only cDNA sequence considered as a “mere discovery”? Even if these two questions are answered in the affirmative, the issue of whether cDNA will be excluded from patentability under this provision will also be contingent on whether it results in “enhanced efficacy”. In the context of human gene patentability, it is unclear what constitutes “enhanced efficacy”. For example, would the creation of an exon-only cDNA where the

precise arrangement of its nucleotide sequence has its equivalent in the genomic DNA sequences as it occurs in nature (without any modification) result in “enhanced efficacy”? Moreover, it should also be highlighted that merely establishing a “new use” for the known sequence is not sufficient to fall outside this exclusionary provision since “new use for a known substance” is also excluded from patentability under section 3(d).

Section 3(e)

This provision deals, *inter alia*, with substances obtained by a “mere admixture resulting only in the aggregation of the properties of the components thereof”. According to the Indian Biotechnology Guidelines, this provision “reflects the legislative intent on the law of patenting of combination inventions in the field of chemical as well as biotechnological sciences.” If this provision is applicable to human genes, then several issues are worth emphasising. First, it is unclear whether cDNA constitutes a substance that is obtained by a “mere admixture”. On a broad reading, it may be possible to consider the creation of an exon-only cDNA through the excision of the introns from the genetic sequence as a “mere admixture” of genetic sequences. Second, even if it can be regarded as a “substance obtained by a mere admixture”, it will only be excluded under section 3(e) if it results only “in the aggregation of the properties of the components thereof”. To put it another way, if the “mere admixture” results in some “synergistic properties”, then it may fall outside the section 3(e) exclusion. This interpretation is supported by the Indian Biotechnology Guidelines which provides that the “mere placing side by side of old integers so that each performs its own proper function independently of any of the others is not a patentable combination, but that where the old integers when placed together has some working interrelation producing a new or improved result, then there is patentable subject matter in the idea of the working inter relations brought about by the collocation of the integers.”⁹²

Section 3(j)

Equally challenging is the issue of whether cDNA will fall within the section 3(j) exclusion, if the provision applies to human genes.

92 See Indian Biotechnology Guidelines at p 13.

Although an example in the Indian Guidelines asserts that educated autologous NK T cells would fall within the scope of section 3(j), this may be of limited utility. It does not elucidate the extent of alteration required for it to fall outside the scope of section 3(j).

Similarly, although the IMPPP contains a reference to permissive claims directed at genetically modified sequences,⁹³ there is no further guidance on what constitutes “genetic modification” or the extent of modification required. For example, would the mere excision of introns from the genomic DNA sequence constitute sufficient “genetic modification”? The IMPPP also contains another reference to the fact that where a patent application discloses “sequence listing of nucleotides and/or amino acid’ it shall be filed in electronic form.⁹⁴ To the extent that this procedural provision implicitly confirms that genetic sequences are not *per se* excluded from patentability, it adds little.

In view of the dearth of guidance on this issue, the author will attempt to analyse it from two perspectives.

First, on a broader interpretation of section 3(j), it may be argued that cDNA sequence would not be patentable as it still forms “a part of an animal” albeit in modified state. Although it may have been artificially constructed by man, in the sense that man had excised the introns from the genomic DNA to form an exon-only DNA strand, this man-made exon-only cDNA strand is nonetheless still a “part of an animal” since the information transmitting qualities of this exon-only strand remains the same as its exon counterpart in nature. Another way of looking at this is to say that, the human intervention of excising the introns from the genomic DNA strand is not sufficient to transform it into a “non-human part”.

Second, a narrower construction of section 3(j) would yield a different conclusion. Based on this narrower interpretation, it may be argued that “a part of an animal” under section 3(j) should be confined to a “part of an animal” as it exists in nature,

93 See Indian Manual of Patent Practice and Procedure (2011) para 08.03.07 stating that “a genetically modified Gene Sequence/ Amino Acid Sequence claims may be directed to a Gene sequence / Amino Acid sequence, a method of expressing the sequence, an antibody against that protein / sequence, a kit containing such antibody / sequence.” This part appears under the topic of “unity of invention” (instead of patentability).

94 See Indian Manual of Patent Practice and Procedure (2011) para 03.04.06.

i.e. in its naturally existing or predominantly unaltered state. Under this narrower interpretation, man-made cDNA where the introns have been excised by man would no longer form a “part of an animal” since it does not exist in that state in nature. Rather it has been created artificially by man.

(d) Summary

Based on the outcome of the appraisal above, this author submits that naturally occurring human DNA and isolated human genomic DNA are likely to be excluded subject-matter under section 3 of the Indian Patents Act. If the Indian courts choose to adopt this approach, then there would surprisingly appear to be some commonality in the Indian and US approaches in this dialogue on human gene patent-eligibility. To test the veracity of this possible outcome, an evaluation of the Indian case-law and Constitutional mandate may provide further illumination

3. INDIAN CASE-LAW

Whilst there does not appear to be any case-law dealing directly with this issue, two cases may be worth highlighting.

The first is the decision of the High Court of Delhi in *J. Mitra v Kesar Medicaments*.⁹⁵ That case involved a patent infringement suit over a diagnostic kit for detecting antibodies to Hepatitis C virus (HCV) in human serum and plasma. The patent was challenged on the grounds that it lacked novelty, inventive step, patent-eligibility, and sufficiency of patent specification. The Court found that a *prima facie* case of infringement had been made out by the plaintiff and granted a temporary injunction on the basis of a balance of convenience. Although the full merits of the issues including the patent eligibility issue was not fully addressed, the claim involving diagnostic devices was not contested. It would seem that the patent-eligibility of medical devices presents less controversy in India.

The second decision is *Emergent Genetics India v Shailendra Shivam*.⁹⁶ The case deals, *inter alia*, with copyright issues pertaining to genetic sequence information

⁹⁵ *J. Mitra v Kesar Medicaments* (2008), CS(OS) No. 2020/2006

⁹⁶ *Emergent Genetics India v Shailendra Shivam* (2011) (47) PTC 494 (Del).

of hybrid seeds. Although it did not directly address the patenting of genetic sequences, the High Court of Delhi's judgment did allude to gene patents and may be instructive of its general approach to IP issues in genes. Justice Bhat (in that case) rejected the plaintiff's claim for copyright infringement on the grounds, *inter alia*, that the gene sequence lacked originality. The learned judge opined that the genetic sequence was "not an "original" expression of ideas but mere reproduction of something found in nature." Justice Bhat emphasised that:

"The microbiologist or scientist involved in gene sequencing "discovers" facts ... Such scientists merely copies – from nature-genetic sequence that contains codes for proteins ... So long as a researcher constructs a DNA sequence based on a sequence discovered in nature, there is no independent creation, no minimum creativity and thus no originality."

Whilst these pronouncements were made in the context of copyright law, some inference may be drawn in relation to patent law.⁹⁷ For example, would a discovery of a genetic sequence or its "construction" based on a sequence as exists in nature - which does not involve any "independent creation" nor "minimum creativity" - be sufficient to constitute an "invention" under patent law? Based on Justice Bhat's elucidation, it would seem likely to be insufficient.

Interestingly, Justice Bhat also alluded to section 3(j) of the Patents Act 1970, when he articulated that the originality of genetic sequence has:

"[T]o be seen from the background that the *process* by which those gene sequences are created, or isolated, or an improved or unique variety is developed, *does not receive any intellectual property protection, and is expressly denied patent ... protection* by reason of Section 3 (j) of the Patents Act 1970 . If the process – despite its novelty and industrial application, and other attributes of patentability - is denied patent protection, *it is inconceivable that the observation and compilation of the consequence of that process, which*

⁹⁷ It should be stressed that there are differences between the concepts of "originality" under copyright law and "invention" under patent law.

is a natural consequence, can receive an extremely wide protection as a “literary” work.” [Emphasis added]

It bears re-emphasising that Justice Bhat was not dealing with the patent-eligibility of genes in that case. Yet, the learned judge’s reference to “process” seems to indicate that he may have been referring to the exclusion in section 3(j) on “essentially biological processes for the production of plants and animals” and extending it to the consequences or compilation resulting from that process. It may be useful to re-state section 3(j):

3 (j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

If this assumption is correct, then it would appear that the learned judge may have treated the processes by which genes are created, isolated or modified as one involving a *biological* process (rather than a micro-biological process) which is excluded from patenting by virtue of section 3(j). If this argument is followed through, then it may lend some support to this author’s earlier observation that section 3(j) may apply to gene sequences, contrary to the viewpoint expressed by one commentator that it does not apply to molecular/cellular level involving genes⁹⁸.

Of greater applicability for present purpose, may be Justice Bhat’s articulation based on policy and constitutional arguments. Although these were articulated in relation to the important agricultural industry in India, they may act as useful beacons in the biotechnology patent law context. After acknowledging that an “inventor or innovator undoubtedly should be provided a fair regime which protects his creative efforts and rewards him,” the learned judge cautioned that we should not lose sight of the broader perspective that:

“The Courts, are enjoined to interpret the law and the Constitution ... By Article 39(1) the State ... is enjoined to ensure: “(b) that the ownership and control of the

98 See Bhavishyavani Ravi, “Gene patents in India: Gauging policy by an analysis of the grants made by the Indian Patent Office” (2013) 18 *Journal of Intellectual Property Rights* 323 – 329 at 327.

material resources of the community are so distributed as best to subserve the common good”.⁹⁹

The learned judge clarified that Parliament enacted section 3(j) of the Patents Act to ensure that the people of India were not subjected to one kind of intellectual property monopoly, i.e. patents in relation, *inter alia*, to “method of agriculture”. The judge also proffered examples of material resources, such as, water and rivers; petroleum and natural gas; forests; essential commodities and foodstuffs; electricity generation and distribution. These have all been held by the Indian Supreme Court to be of public importance and to which the State has to “assure equitable access and availability to the greatest numbers.”¹⁰⁰

Another Constitutional provision of importance which enjoins the Indian State “to reflect identical concerns, and guides state policy in that direction” is Article 47. It requires the State to “regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties”¹⁰¹

In conclusion, Justice Bhat warned of the dangers in the Court’s acceptance of a “ritualistic enforcement of intellectual property” approach which can potentially “implicate access to vital material resources ... which is vastly detrimental to public and national interest.”

The author finds Judge Bhat’s dicta to be a very timely reminder of the need to interpret the Indian Patents Act, in particular the list of exclusions set out in section 3, in accordance *inter alia* with the directive principles of the Constitution. It emphasizes the need to ensure that ownership and control of material community resources are distributed for the common good which includes access to the greatest numbers, particularly where it may impact on public health.

A more detailed examination of these directive principles enshrined in the Indian Constitution may cast further light on this.

99 *Emergent Genetics* at para 38.

100 *Ibid.*

101 *Ibid.*

4. CONSTITUTIONAL MANDATE

In this section, a brief comparative review of the constitutional mandate in India and the US may provide useful guidance in approaching this controversial issue relating to gene patenting. Whilst the patent regimes of both countries have constitutional bases, there appears to be variations in their orientation and mandate.

First, under the U.S. Constitution there is a specific mandate for the grant of intellectual property rights to promote the progress of Science and the useful Arts. The Constitution of the US provides under Article I (section 8) that:

The Congress shall have the Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

Although there is no specific reference to intellectual property under Article I (section 8) of the US Constitution, it is the long established basis for authorising copyright and patent protection for authors and inventors.¹⁰²

In contrast, the Constitution of India presents intellectual property rights in the Union List “devoid of an express vision”¹⁰³ on its role and mandate. The relevant provisions are set out as follows:

Article 245 (1) Subject to the provisions of this Constitution, Parliament may make laws for the whole or any part of the territory of India, and the Legislature of a State may make laws for the whole or any part of the State.

Article 246. (1) ... Parliament has exclusive power to make laws with respect to any of the matters enumerated in List I in the Seventh Schedule (in this Constitution referred to as the “Union List”).

List I – Union List in the Seventh Schedule incorporates:

(49) Patents, inventions and designs; copyright; trade-marks and merchandise marks.

¹⁰² See the Constitution of the United States, Article I section 8, explanatory note.

¹⁰³ [Comment of the anonymous referees].

Second, the US Constitution appears to lean more towards a pro-economic innovation stand by stressing the importance of promoting “progress of science and the useful arts”. There seems to be no specific mention in the US Constitution of “improvement of public health” for its people other than a reference to “general welfare” in the Preamble of the US Constitution that:

We the people of the United States, in order to form a more perfect union, establish justice, insure domestic tranquility, provide for the common defense, promote the general welfare, and secure the blessings of liberty to ourselves and our posterity, do ordain and establish this Constitution for the United States of America.

This can be contrasted with the Indian Constitution which seems to tilt towards public welfare and the promotion of “socioeconomic justice”¹⁰⁴. Moreover, the Indian Constitution also provides, *inter alia*, for Directive principles which seem to play an important role in judicial interpretation. These were alluded to by the learned judge in the *Emergent Genetic* case. For completeness, a brief discussion will be made on them.

Indian Constitution: Directive principles

The important role of the Directive principles in judicial interpretation was enunciated succinctly by the Supreme Court of India in *Suresh Kumar & Dalmia Cement (Bharat) Ltd. v. Union of India*¹⁰⁵, where the Court held that:

“The Directives would serve the court as a beacon light to interpretation. Fundamental Rights are rightful means to the end, viz., social and economic justice provided in the Directives and the preamble. The Fundamental Rights and the Directives establish the trinity of equality, liberty and fraternity in an egalitarian social order and prevent exploitation.”

The importance of these principles were also succinctly articulated in the Supreme Court of India’s landmark decision in *Kesavananda Bharati v. State of Kerala*

104 See *Dalmia Cement (Bharat) Ltd. v. Union of India*, (1996) 10 SCC 104 where “justice” is used “in broad spectrum to harmonise individual rights with the general welfare of the society.”

105 (1996) 10 SCC 104.

which described Part III (fundamental rights) and Part IV (directive principles) of the Indian Constitution as the “conscience of the Constitution”¹⁰⁶ which direct the State to build a welfare state.¹⁰⁷

Indeed in the *Emergent Genetic* case, the learned judge alluded to the importance of two Directive principles which may impact on intellectual property interpretation, namely, Articles 39 and 47, under Part IV of the Indian Constitution.¹⁰⁸ These set out the State policy as follows:

Article 39 stipulates several policy principles, more specifically subsection (b) provides that the “State shall, in particular, direct its policy towards securing ... that the ownership and control of the material resources of the community are so distributed as best to subserve the common good”.

Article 47 then imposes a duty on the State to improve public health by specifying that the “State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties”

The term “material resources of the community” under Article 39(b) has been interpreted broadly to mean “all things which are capable of producing wealth for the community”¹⁰⁹ and encompasses “everything of value or use in the material world”¹¹⁰ whether public or privately owned. Although the Courts do not appear to have suggested specifically that intellectual property rights constitute a “material resource”, nonetheless there seems to be some indication in the dicta of Justice Bhat in the context of section 3(j) of the Patents Act, that the Parliamentary intent was to ensure that the people of India were not subjected to one kind of intellectual property monopoly, i.e. patents in relation, *inter alia*, to “method of agriculture”.

Be that as it may, it has been highlighted that one should not presume, without further investigation, that these Directive principles may necessarily be used as a

106 See *KesavanandaBharati v. State of Kerala*, AIR 1973 SC 1461, (1973) 4 SCC 225 at para 1058.

107 *Ibid.* para 634.

108 Part IV of the Indian Constitution is entitled “Directive Principles of State Policy”.

109 *Sanjeev Coke Mfg. Co. v. Bharat Coking Coal Ltd.*, (1983) 1 SCC 147, AIR 1983 SC 239

110 *State of Karnataka v. Ranganatha Reddy*, AIR 1978 SC 215, (1977) 4 SCC 417.

tool of statutory interpretation in the context of determining whether “a certain subject-matter enjoys property rights”¹¹¹. This issue is no doubt an important one, but unfortunately this is not the place to debate them.

At the end of the day, the author submits that a careful consideration on the most appropriate balance to be struck between private rights and public access would fulfil the Constitutional mandate of both countries. This approach was also commended by the Supreme Court of India when it cited with approval¹¹² the conclusions of Granville Austin in his book *The Indian Constitution: Cornerstone of a Nation* as follows:

“By establishing these positive obligations of the state, the members of the Constituent Assembly made it the responsibility of future Indian governments to find a middle way between individual liberty and the public good, between preserving the property and the privilege of the few and bestowing benefits on the many in order to liberate the powers of all men equally for contributions to the common good.”¹¹³

Indeed, this question of balance or finding of the “middle way” forms the crux of the gene patenting issue.

VI. STRIKING THE BALANCE: WHEREIN LIES THE MOST APPROPRIATE BALANCE BETWEEN PRIVATE RIGHTS AND PUBLIC ACCESS?

The issue of whether and to what extent (if any) should human genes be patent eligible subject-matter is a complex one for which there is no global consensus.

Many developed countries appear to treat human genes as patent eligible subject-matter. Take, for example, Europe (including the UK), Australia (subject to reversal by the High Court of Australia in an appeal that was pending at the time of writing this article), Japan and Canada among others. Indeed, the European

111 [Comments of the anonymous referees]

112 See *Kesavananda Bharati v. State of Kerala*, AIR 1973 SC 1461, (1973) 4 SCC 225 at para 1375.

113 Granville Austin, *Indian Constitution: Cornerstone of a Nation* (1966, Clarendon) at p 52.

Biotechnology Directive expressly permits patent eligibility of genes by stating that:

“An element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”.¹¹⁴

Yet, a contrary approach seems to be emerging in the US (and possibly India) that isolated genomic DNA sequences are not patent eligible subject-matter. This position stands in stark contrast to that of other developed jurisdictions.

Why have different jurisdictions taken divergent positions in this struggle to resolve the human gene patent conundrum? Perhaps a review of the arguments for and against patents on genetic materials may illustrate this difficult challenge.

A. PROPONENTS OF GENE PATENTING

Proponents of gene patenting may mount several convincing arguments including:

1. Incentive theory by alluding to the importance of patent protection to incentivise research and development and investment therein. The reward conferred by the patent exclusivity spurs further investments in research as it offers investors a secure manner to recoup costs and to offset the risks associated with the research and commercialisation.¹¹⁵ It has often been cited¹¹⁶ that investors will only provide sustainable funding of the huge investment in this field if patents are available and able to offer sufficient exclusivity and security to investors.
2. A restrictive approach towards, or a prohibition against, gene patenting may drive investing companies to seek trade secrets protection instead.

114 See the European Biotechnology Directive 98/44/EC of 6 July 1998 which was passed by the European Parliament and enacted in the Implementing Rules of the European Patent Convention (EPC): Rule 23(e)(2) EPC.

115 See Centre for International Economics *Final Report: Economic Analysis of the Impact of Isolated Human Gene Patents* May 2013

116 See, for example, T.R. Sivaramjani & Samir K. Brahmachari, “Human genome studies and intellectual property rights: Whither national interest?” (1997) 72 (10) *Current Science* 708-716.

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The secrecy engendered by this option will be detrimental to innovation or increase the risks associated with the lack of accountability. Worse, it may inhibit progress and development in this fast changing area of technology. Hence, patent exclusivity in exchange for the disclosure of information is the better way forward.

3. Any public health concerns arising from lack of access due to the high cost of diagnostics and the inability of other researchers to conduct studies on the patented subject-matter are often caused by factors that are external to the patent system. These external factors include exclusive licensing strategies, complexity of the technology involved and the business development aspect of the patented product.¹¹⁷
4. Many developed countries recognise the patent-eligibility of isolated gene sequences and hence, a consistent and harmonized approach should be adopted.¹¹⁸
5. Genes are basically chemical compositions and hence, its patent eligibility should be treated no differently from other chemical compounds which are generally regarded as patent-eligible subject-matter. Hence, genes can be patented so long as they fulfil the other criteria of patentability, namely, novelty, non-obviousness and utility/usefulness.¹¹⁹

B. A REPLY

1. No one denies that the patent owner deserves to be rewarded for the extensive investment and effort in research and development. Indeed, the enormous effort of Myriad's scientists in mapping the BRCA 1 and BRCA 2 genes to their chromosomal locations have been highlighted in the discussion above. The author acknowledges the importance of the role the incentive theory plays in spurring innovation and investment.

117 See Centre for International Economics *Final Report: Economic Analysis of the Impact of Isolated Human Gene Patents* May 2013.

118 *Supra* note 111.

119 See, for example, MalathiLakshmikumaran, "Patenting of Genetic Inventions" (2007) 12 *Journal of Intellectual Property Rights* 45-56 where there it is argued that the protection of 'genetic inventions will foster development and will augur well for the society because it is the society which will ultimately reap the benefits of genetic inventions."

2. Yet, patent law cannot be called upon to underwrite the risks of extensive effort and investment. Justice Thomas in the *Myriad* case rejected relevance of extensive research efforts in patent-eligibility determination and rightly ruled that “extensive efforts alone is insufficient”.¹²⁰ There is neither sound basis nor support for the argument that subject-matter that is the product or process of extensive investment and effort is *per se* patent-eligible. Patent law does not (and should not) embrace “discoveries” as patent eligible subject-matter no matter how costly the discovery process may be. The patentability of a subject matter is a question of law and fact. This would appear to lend support to the suggestions by some commentators that other reward structures, such as, prizes,¹²¹ may be more appropriate for such discoveries.
3. The question of whether genetic sequences should be considered as chemical compositions; or whether the focus should be on its information-transmitting qualities based on its nucleotide arrangements is the subject of a long standing debate that is unlikely to abate. There are supporters and detractors for both views. The US Supreme Court has alluded that the answer may be dependent on what is being substantively claimed in the patent. Does it claim the informational content or the specific chemical composition of the genetic sequence? Whilst the claims would no doubt be of primary importance, we should heed the caution which has been repeatedly sounded by the US Supreme Court that patent-eligibility should not turn on “clever drafting” or camouflage.¹²² Indeed, the Supreme Court

120 See *AMP v Myriad* (2013) 133 S. Ct. 2107. . The learned Justice also reinforced the concept that “ground-breaking, innovative, or even brilliant discovery does not by itself satisfy” the patent-eligibility inquiry. This would appear to lend support to the suggestions by some commentators that other reward structures, such as, prizes

121 Take, for example, Joseph Stiglitz who proposed that the prize system (which basically offers a prize to the person who makes a discovery then widely disseminates that knowledge, using the power of the market to reap the benefits) would have major advantages without the inequality-increasing disadvantages of the intellectual property system; see Joseph Stiglitz, “The Great Divide: How Intellectual Property Reinforces Inequality” (July 14, 2013) *The New York Times* (The Opinion pages). See also Thomas Pogge, Matthew Rimmer and Kim Rubenstein (Eds.), *Incentives for Global Public Health: Patent Law and Access to Medicines* (Cambridge University Press, 2010).

122 See, for example, *AMP v Myriad* 133 S. Ct. 2107 (2013).

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of India (albeit in a non-patent law case)¹²³ has also issued a similar caution that clever drafting that create “illusions” should be “nipped in the bud”.

Although the distinction between chemical composition and informational content may be useful in informing this debate on gene patenting, it should not be over-emphasised as it is only “one factor” in the complex gene patenting calculus. The US Supreme Court has acknowledged the existence of information content in both isolated genomic DNA and cDNA. Yet, as one commentator has correctly highlighted, this may be of limited utility as the Court concluded that only cDNA was patent eligible without proffering sufficient elucidation on this issue.¹²⁴

4. Ethical and moral debates¹²⁵ against the patenting of human genes are also persuasive. As human genes are the common heritage of mankind and humanity, the common viewpoint is that private ownership threatens to jeopardise the dignity and integrity of man. This argument finds support in the Universal Declaration on the Human Genome and Human Rights (1997), particularly by Articles 1 and 4 which stipulates that:

Article 1 - The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 4- The human genome in its natural state shall not give rise to financial gains.

123 See, for example, *T. Arivandandamvs T. v. Satyapal & Another* 1977 AIR 2421, 1978 SCR (1) 742

124 See Arti Rai, “Diagnostic patents at the Supreme Court” (2014) 18:1 Marq. Intell. Prop. L. Rev. 1 – 9.

125 See, for example, Elizabeth Siew-Kuan Ng, “Immoral inventions: Interaction between ethics and biotechnology patent law” (2010) 22 Singapore Academy of Law Journal 931 – 947; T.R. Sivaramjani & Samir K. Brahmachari, “Human genome studies and intellectual property rights: Whither national interest?” (1997) 72 (10) Current Science 708-716; Matthew Rimmer, “The Empire of Cancer: Gene Patents and Cancer Voices” (2012-2013) 22(2) Journal of Law, Information and Science 18-55.

Based on this notion of “common heritage and common ownership”, it is contended that human genes should not be patent-eligible. Although gene patenting was not specifically dealt with in the TRIPS Agreement,¹²⁶ nonetheless Article 27.2 permits member states to exclude from patentability inventions “the commercial exploitation of 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”. Some countries, including India, Singapore, Europe, have incorporated such exclusions in their patent legislation¹²⁷. However, there is a lack of consensus on moral standards. For example, in Europe, the arguments advanced based on the immorality of gene patenting was rejected by the Board of Appeal of the European Patent Office in a patent case relating to the genetic sequence of the H2-Relaxin gene.¹²⁸ This approach has been seemingly confirmed by the European Biotechnology Directive (as discussed above).¹²⁹

5. At least some proponents of gene patenting have conceded that the patenting of genetic materials may pre-empt future research¹³⁰ by blocking access to knowledge required for future innovations, as well as, access of diagnostic genetic tests and therapies for public health. It bears repeating that the issue of access is a multi-factorial one which has a public health, as well as, pro-innovation facet:

126 See the WTO Agreement on Trade related aspects of intellectual property rights (TRIPS Agreement) which was negotiated under the auspices of GATT/WTO and is binding on WTO members.

127 Take, for example, section 3(b) Indian Patents Act which excludes from patentability any invention “the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment”.

128 See Relaxin/Howard Florey Institute T0272/95 (23 October 2002).

129 See the European Biotechnology Directive 98/44/EC of 6 July 1998 which was passed by the European Parliament and enacted in the Implementing Rules of the European Patent Convention (EPC): Rule 23(e)(2) EPC.

130 This point was re-iterated by the US Supreme Court in *Mayo Collaborative Services v Prometheus Laboratories* 132 S. Ct. 1289 (2012). For an insightful discussion, see Arti Rai, “Diagnostic patents at the Supreme Court” (2014) 18:1 Marq. Intell. Prop. L. Rev. 1 – 9

First, the prohibition of gene patenting may be viewed as being supportive of innovation since access to the disclosed genetic information will allow other scientists and researchers to utilise the genetic materials and its information-transmitting qualities to spur future innovations. Indeed, one commentator has succinctly argued that the US Supreme Court's *Myriad* decision could be explained from a pro-innovation perspective.¹³¹ She argues that since the patenting of isolated genomic DNA could potentially interfere with a "broad range of downstream uses", permitting patent-eligibility for cDNA where the claim involved a "narrower application specific to therapeutic development" could thereby promote innovation in the form of worked around "for other purposes".

Second, access to genetic sequences is needed to ensure that alternative and/or better genetic diagnostic tests can be developed and made available to the rich and poor patients alike for the promotion of public health for the public good. As Joseph Stiglitz has rightly emphasised "The right to life should not be contingent on the ability to pay."¹³² The grant of patents on human genes will have implications on the patentability of downstream diagnostics and their public access. This will pose potential impediment for patient access to alternative testing options utilising isolated genomic sequences. The importance of access to second medical opinions and alternative tests has been illustrated in the example of Angelina Jolie Pitt where preventive measures could be taken based on genetic testing. Indeed, as one commentator has rightly highlighted, the "upshot of the [US Supreme Court] decision is that certain patents generally associated with diagnostic medicine (gDNA) are invalid, but patents typically associated with therapeutics (cDNA) are valid."¹³³

131 See Arti Rai, "Diagnostic patents at the Supreme Court" (2015) (18:1) *Marq. Intell. Prop. L. Rev.* 1-9.

132 See Joseph Stiglitz, "The Great Divide: How Intellectual Property Reinforces Inequality" (July 14, 2013) *The New York Times* (The Opinion pages).

133 See Arti Rai, "Diagnostic patents at the Supreme Court" (2015) (18:1) *Marq. Intell. Prop. L. Rev.* 1-9.

The discourse above illustrates the difficulties in resolving the gene patenting conundrum. A clear delineation (whether expressed by statute or implicit in long-standing precedents) on the scope of excluded patent subject-matter and the other criteria of patentability¹³⁴ will be vital in providing greater certainty to the various stakeholders, such as, businesses, researchers, and healthcare providers, of the biotechnology patent system.

Moving forward, this author submits that where the line should be drawn may be premised on where the most appropriate balance lies between providing the incentive through grant of private rights on one hand, and public access to promote knowledge dissemination, future innovation and public health, on the other.¹³⁵

Whilst there is no one answer that will fit all nations, this author submits that in the context of the patent-eligibility of naturally occurring DNA and isolated genomic DNA, the potential convergence in the approaches adopted in the US and India gleaned from this appraisal may serve as a good guide. That two highly divergent nations with different constitutional orientations may have adopted a possible common approach, at least in relation to the patent-eligibility of naturally occurring DNA and isolated human genomic DNA, is illuminating – even though this postulation¹³⁶ is weakened by a lack of judicial consideration in India.

Be that as it may, the author contends that there are several avenues for addressing this issue of balance in human gene patenting generally, including:

- a. Implementing express or implied subject-matter exclusions to clearly demarcate the subject-matter that is eligible for patenting;

134 Namely, newness (novelty), non-obviousness (inventive step) and industrial applicability (utility).

135 See, for example, Matthew Rimmer, “The Empire of Cancer: Gene Patents and Cancer Voices” (2012-2013) 22(2) *Journal of Law, Information and Science* 18-55 at <http://www.austlii.edu.au/au/journals/JLInfoSci/2012/28.pdf> (accessed 13 June 2015); Elizabeth Siew-Kuan Ng, “Balancing Patents and Access to Medicine” (2009) 21 *Singapore Academy of Law Journal* 457-484; see generally, Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patent Law and Access to Medicines* (Cambridge University Press, 2010).

136 The appraisal is based on the author’s statutory interpretation of certain provisions of section 3 of the Indian Patents Act, the Indian Biotechnology Guidelines and the IMPPP.

- b. Developing a robust standard of patentability criteria, such as, novelty, non-obviousness, utility.¹³⁷ Critics against gene patenting posit, *inter alia*, that genes are not novel as they are naturally occurring; and cannot fulfil the non-obviousness criteria as they utilise well established techniques in gene isolation. Also, gene patents may lack the requisite level of specificity of function to satisfy the utility or usefulness attribute of patent law;
- c. Consideration may also be given to carefully craft the scope of such patents. One possibility is to confer limited purpose-bound patents where the protection is restricted to the specific use disclosed in the patent application.¹³⁸ Alternatively, as one commentator¹³⁹ has rightly suggested, such genetic sequences could be considered under a narrow interpretation of a “product-by-process claim”.¹⁴⁰
- d. Instituting adequate safeguards, in the form of defences and exceptions, such as, research exemptions, compulsory licences etc.¹⁴¹ These would also mitigate the incidence of undesirable patent enforcement, for example, patent trolling as was seen in some of the information technology cases.¹⁴² The Myriad case may serve as another timely reminder.¹⁴³ If Myriad had

137 See, for example, Dipika Jain, “Gene-patenting and access to healthcare: Achieving precision” (2014) 36 *Houston Journal of International Law* 101-146.

138 See, for example, Report from the Commission to the Council and the European Parliament - Development and implications of patent law in the field of biotechnology and genetic engineering (SEC (2005) 943) COM (2005) 312. Note, however, that India does not grant “use” claims. [Comments of anonymous referees]

139 See Justine Pila, “Patents for genes and methods of analysis and comparison” (2010) 126 *Law Quarterly Review*.

140 See, for example, *Biogen v Medeva* [1997] R.P.C. 1 where Lord Hoffmann treated a “recombinant product is a product-by-process in contrast to a product”. See Justine Pila, “Patents for genes and methods of analysis and comparison” (2010) 126 *Law Quarterly Review*. Such claims would generally be regarded as product claims in many jurisdictions including India.

141 These safeguards have already been instituted in some countries, including India. For more details, see Elizabeth Siew-Kuan Ng, “Balancing Patents and Access to Medicine” (2009) 21 *Singapore Academy of Law Journal* 457-484; see generally, Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patent Law and Access to Medicines* (Cambridge University Press, 2010).

142 See, for example, Elizabeth Siew-Kuan Ng, “Patent Trolling: Innovation at Risk” [2009] *European Intellectual Property Review* 593-608.

143 Other situations where the US Supreme Court has taken a strong stance against such undesirable patent enforcement strategies can be seen in patent trolling scenarios.

won, and adopted an aggressive and undesirable patent enforcement strategy, it would have retained sole control on access to the BRCA genes. This would have prevented other medical service providers from conducting research and/or offering alternative diagnostic testing which would impact on public health. Women, especially the poor and those who were not covered by medical insurance for the expensive Myriad BRCA tests, would be denied the opportunity to access cheaper alternatives and/or be prevented from obtaining second and subsequent medical opinions on the test results.

Where this balance should be struck between the competing interests of the various stakeholders would depend on the national and public interests of each nation. Some countries, such as, the United Kingdom and Australia, appear to have veered more towards instituting safeguards through “back-end” mechanisms coupled with a relatively robust standard of patentability. Others, like the US, appear to rely on implied exceptions to patent-eligibility coupled with an increasingly more robust standard of patentability criteria. Still others, such as India, appear to have adopted a multi-prong approach based on many of the avenues suggested above. Indeed, the Supreme Court of India issued a timely reminder when it wisely opined that:

“Law is the manifestation of principles of justice, equity and good conscience. Rule of law should establish a uniform pattern for harmonious existence in a society where every individual would exercise his rights to his best advantage to achieve excellence, subject to protective discrimination. The best advantage of one person could be the worst disadvantage to another. Law steps in to iron out such creases and ensures equality of protection to individual as well as group liberties ... [and] endeavour needs to be made to harmonise the individual interest with the paramount interest of the community keeping pace with the realities of ever changing social and economic life of the community envisaged in the constitution.”

VII. CONCLUSION

This article has sought to investigate the patenting of human genes from the perspective of subject-matter exclusion. Whilst the effect of the Myriad decision on public access to the BRCA gene patents is limited,¹⁴⁴ its implications on the patent-eligibility of isolated DNA will continue to ripple within the US and perhaps beyond its shores.

Interestingly, right after the US Supreme Court decision, some countries that have been more liberal in granting patents on human genes are beginning to see legal challenges to the validity of some gene patents. There are two cases in point. One is the recent gene patent challenge filed in Canada by the Children's Hospital of Eastern Ontario to invalidate the gene patents held by the University of Utah in relation to the Long QT syndrome (a rare heart disorder). The other is the Myriad gene patent case currently pending before the High Court of Australia.¹⁴⁵

In this nascent field of genetics, there is merit in diversity of approaches on how the balance should be struck between the need to incentivise innovation and maximising public access to promote further innovation and the interests of public health. Yet, the benefits of convergence on specific aspects of human gene patenting cannot be discounted. A concurrence based on the delineation of clear limits informed by doctrinal and policy considerations is preferable to one that adopts a *de minimis* conception on the nature of inventions.¹⁴⁶ The latter has been said to have failed to fully appreciate the important role that the requirement of invention plays in patent law.¹⁴⁷ As the secrets of the Code of Life are still largely an unexplored territory, the risk of impeding research and downstream uses for future innovation, as well as, patient access is both grave and real. It is important that isolated genomic DNA that form the Code of Life should remain "free for all men and reserved exclusively to none". Therefore, achieving consensus on this specific aspect of human gene patenting merits consideration.

144 BRCA1 and BRCA2 genes are set to expire in August 2015 and December 2015 respectively; see Hunt & Hunt, "Patentability of genetic materials – where does it stand today?" Australian Intellectual Property Law Bulletin (newsletter) (2013) 26:3.

145 See Riley Sparks, "5 things to know about the Canadian gene patent case" (November 3, 2014) The Toronto Star Newspaper.

146 See, for example, the European Patent Office. See also Justine Pila, "Patents for genes and methods of analysis and comparison" (2010) 126 Law Quarterly Review.

Whilst the patent regimes of many jurisdictions in the developed world uphold the patent eligibility of isolated genomic DNA,¹⁴⁸ this author submits that the better approach is that adopted by the US Supreme Court and that of the Indian Office of the Controller General of Patents, Designs and Trade Marks. That these two contrasting nations seem to have come down on the same side in this balance between competing objectives is remarkable. This potential unity between a developed nation (that has consistently adopted pro-economic & innovation stance in tailoring its patent system) and a developing nation (that has constantly emphasised the importance of promoting public welfare) gives further credence to this author's view that their approach indeed strikes the better balance between granting private rights without jeopardising public access.

Like the Lion,¹⁴⁹ India has laudably persisted in tailoring a patent regime that is best suited to its national interest and yet compliant with its international obligations. Similarly, Judge Sweet, Circuit Judge Bryson and the nine US Supreme Court Justices were not only not overwhelmed by several decades of patent practice but showed admirable aplomb to overturn it when the merits deserve a change.

Will any other nation stand with them in adopting this better approach?

147 *Ibid.*

148 See, for example, E Richard Gold and Julia Carbone, 'Myriad Genetics: In the Eye of the Policy Storm' (2010) 12 *Genetics in Medicine* S39; Matthew Rimmer, "The Empire of Cancer: Gene Patents and Cancer Voices" (2012-2013) 22(2) *Journal of Law, Information and Science* 18-55.

149 India's official emblem.