

GENE-PATENTING AND ACCESS TO HEALTHCARE: ACHIEVING PRECISION

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I. INTRODUCTION

The recent *Myriad* litigation in the United States¹ has reinvigorated the debate over gene patenting.² Furthermore, the issue of access to affordable medication continues to be debated around the world,³ and many countries, including China, have recently reformed their patent laws in light of the challenges posed by the patent law and its implications for access to health care.⁴

India has struggled with patent reform in general since 1995, spawned by its international treaty obligations, but there has been little policy debate concerning gene patenting.⁵ It is critical that Indian policy makers track global developments regarding gene patenting and establish an equitable legal framework that allows for access to research and therapeutic products.

Access to efficient and affordable healthcare remains one of

1. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

2. Andrew Pollack, *Justices Send Back Gene Case*, N.Y. TIMES, Mar. 26, 2012, <http://www.nytimes.com/2012/03/27/business/high-court-orders-new-look-at-gene-patents.html> ("The [*Myriad* case] is being closely watched because it involves the ethically charged but commercially important question of whether genes can be patented"); see also Cydney A. Fowler, Comment, *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 AM. U. L. REV. 1073, 1076–77 (2010).

3. U.N. DEPT OF ECON. & SOC. POLICY, MDG GAP TASK FORCE, THE GLOBAL PARTNERSHIP FOR DEVELOPMENT: MAKING RHETORIC A REALITY, at 59, U.N. Sales No. E.12.L.5 (2012), available at http://www.un.org/en/development/desa/policy/mdg_gap/mdg_gap2012/mdg8report2012_engw.pdf.

4. See Ronald A. Cass, *Patent Reform with Chinese Characteristics: Beijing's Amended Intellectual Property Law Holds Dangers*, WALL ST. J., Feb. 10, 2009, <http://online.wsj.com/article/SB123419814824764201.html> (discussing the Third Amendment to China's patent law).

5. See Adam Chilton, *India's Evolving Patent Laws and WTO Obligations: The Rejection of Abbott Laboratories' Application for A New Kaletra Patent*, 39 J.L. MED. & ETHICS 296, 297 (2011) (explaining that India, when it joined the World Trade Organization (WTO), was obligated to adopt the WTO's TRIPS agreement concerning intellectual property).

the predominant concerns in developing countries, especially India.⁶ Health biotechnology offers the long-term possibility of providing new approaches to the prevention and management of many intractable diseases.⁷ Of the various health biotechnologies, DNA genetic engineering research carries the most potential for health solutions in developing and developed countries.⁸ The products of genetic research, such as new genetic diagnostics tests, vaccines, and drugs can be useful for not only genetic disorders, but for diseases like cancer, HIV/AIDS, and tuberculosis.⁹ The Human Genome Project,¹⁰ for example, is perceived as one of the most important developments in the recent past.¹¹

A 2005 study conducted by researchers at the University of Toronto's Joint Centre for Bioethics identifies genetics as one of the technologies most relevant to developing countries.¹² The study reports that genetically engineered vaccines would be cheaper and more effective than current vaccines, and that they offer renewed hope for fighting widespread infections like HIV/AIDS, tuberculosis, and malaria.¹³ Furthermore, genetic drugs, such as inhalants, may make drug administration safer and potentially less expensive,¹⁴ particularly in the context of

6. See Halla Thorsteinsdóttir et al., *Introduction: Promoting Global Health through Biotechnology*, 22 NATURE BIOTECH. DC1, DC3 (2004), available at <http://www.nature.com/nbt/journal/v22/n12s/pdf/nbt1204supp-DC3.pdf> (suggesting biotechnology can be used in developing countries to remedy global health problems).

7. *Id.* at DC3–DC4; see U.N. DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT 2001: MAKING NEW TECHNOLOGIES WORK FOR HUMAN DEVELOPMENT 34–35, available at <http://hdr.undp.org/en/media/completenew1.pdf> (discussing how biotechnology has impacted various aspects of human health).

8. *Id.* at 34.

9. *Id.*; *Gene Therapy for Diseases*, AM. SOC'Y OF GENE & CELL THERAPY, http://www.asgct.org/about_gene_therapy/diseases.php (last visited Nov. 12, 2013).

10. *An Overview of the Human Genome Project*, NAT'L HUM. GENOME RES. INST., <http://www.genome.gov/12011238> (last updated Nov. 8, 2012).

11. See ALLEN BUCHANAN ET AL., FROM CHANCE TO CHOICE: GENETICS & JUSTICE 5 (2000) (emphasizing that the Human Genome Project “does much to guarantee that the stream of genetic knowledge will continue to increase in volume and speed”).

12. Abdullah S. Daar et al., *Top Ten Biotechnologies for Improving Health in Developing Countries*, 32 NATURE GENETICS 229, 229–30 (2002).

13. *Id.* at 230–31.

14. *Id.* at 230.

AIDS in South Africa and tuberculosis in India.¹⁵

While the introduction of gene therapy promises to deliver a healthier future for developing countries with respect to infectious and parasitic diseases, certain legal and ethical concerns must be addressed particularly in regards to the patenting of *genetic applications*.¹⁶ There are also serious socio-cultural concerns surrounding the patenting of life forms and its moral acceptability.¹⁷ Moreover, it is important to note that the patenting of genetic applications may lead to increases in drugs and treatments created by these applications, which could limit access to these treatments for poorer populations.¹⁸ Evidence suggests that public and private laboratories may be unable to offer diagnostic tests due to costly license and royalty fees.¹⁹

This Article critically evaluates whether and to what extent there has been substantive debate on the ethical aspects of patenting genetic material in light of the widely held opinion that the association of human biological material with property rights is unethical. The ethical concerns are twofold. Some believe that patenting genetic material implies a reduction of its status to “information,” rather than acknowledging it as an integral part of human identity.²⁰ Another concern is that

15. Timothy P. Flanigan et al., *The Extraordinary Hope of Antiretroviral Therapy in South Africa (Even for Patients with Tuberculosis or Kaposi Sarcoma!)*, 191 J. INFECTIOUS DISEASES 321, 321–22 (2005); B. G. Williams et al., *The Impact of HIV/AIDS on the Control of Tuberculosis in India*, 102 PROCS. NAT'L ASS'N SCI. 9,619, 9,619–20 (2005).

16. See Daniel P. Sulmasy, *Who Owns the Human Genome?* in ETHICS AND THE NEW GENETICS: AN INTEGRATED APPROACH 123, 123–24 (H. Daniel Monsour ed., 2007) (discussing some of the moral implications of “owning” the human genes).

17. U.N. CONF. ON TRADE & DEV.-INT'L CTR. FOR TRADE & SUST. DEV. [UNCTAD-ICTSD], RESOURCE BOOK ON TRIPS AND DEVELOPMENT 379 (2005) [hereinafter RESOURCE BOOK ON TRIPS].

18. Sulmasy, *supra* note 16, at 123.

19. Aditi Mathur & Kshitij Dua, *The Maze and Haze of Gene Patenting: A Comparative Study of DNA Sequence Patenting in the USA, Europe & Japan, and Suggestions for the Course of Action for India*, CASRIP NEWSLETTER (Center for Advanced Study & Res. on Intell. Prop., Seattle, Wash.), Fall 2005, available at <http://www.law.washington.edu/Casrip/Newsletter/default.aspx?year=2005&article=newsv12i2MathurDua>.

20. See Barbara Looney, *Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 L.

genetic material is a product of nature rather than a man-made invention, and, hence, it is immoral to patent it.²¹ Garforth says that the very “language” of patent law renders it unsuitable for the patenting of higher living organisms.²² In order for higher life to fall within the ambit of patentable material, the essential ethical dilemma of reducing animate beings to objects to be owned and protected arises.²³ Furthermore, this Article evaluates whether the necessary regulatory and policy tools (such as patent laws) are available in India. These regulatory tools are needed to construct a patent policy for human-gene patenting that provides equitable and adequate access to the treatments and technologies derived from these developments. Part Two of this Article examines the legality of gene patenting in India and analyzes the Indian Patent Act, looking specifically at provisions that uphold the exclusive rights to microorganisms. This part further explores intellectual-property policies on gene patenting in other countries to draw a critical and comparative perspective. Part Three examines the concerns arising from patenting genes. Moreover, this Part will reflect on other countries facing similar concerns, including the United States, and critically evaluates the available solutions. Part Three also evaluates whether India would violate the Trade Related Intellectual Property Rights (“TRIPS”)²⁴ provisions if it sought to restrict or even limit gene-patent rights. Part Four provides recommendations gleaned from other countries’ experiences with gene patenting. Part Five offers concluding

& POL’Y INT’L BUS. 231, 237–239 (1994) (arguing the human genome represents part of humankind’s “natural” and “universal” heritage).

21. E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MED. 39, 49 (2010), available at <http://www.nature.com/gim/journal/v12/n1s/pdf/gim2010142a.pdf>.

22. See, e.g., Kathryn Garforth, *Life as Chemistry, or Life as Biology? An Ethic of Patents on Genetically Modified Organisms*, in PATENTING LIVES: LIFE PATENTS, CULTURE AND DEVELOPMENT 27, 52 (Johanna Gibson ed., 2008).

23. *Id.*

24. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]. As a member of the WTO, India is subject to the TRIPS agreement, which means that it must incorporate TRIPS standards in its intellectual property law. *Id.*

observations.

II. PATENTING GENES IN INDIA: EXPLORING THE LEGAL SPACE

Despite being a source of controversy, genes have been patented in many countries, most prominently in the United States, Canada, Japan, Germany, and France.²⁵ Notably, the patent system originally excluded the patenting of higher life forms,²⁶ but the rapid and consistent transformation of industrialization from chemical and pharmaceutical industries to the current biotechnology industry has “expanded [the] scope of patentable subject-matter to accommodate the claims of th[e]se emerg[ing] industries.”²⁷ In more recent times, the scope of patentable material has expanded greatly given the ongoing path of industrialization away from pharmaceutical industries towards biotechnology and the need to accommodate these new industries’ requirements.²⁸ The determination of what constitutes patentable subject matter has been largely a subject of judicial scrutiny rather than legislative intervention.²⁹ This is evident in *Diamond v. Chakrabarty*, wherein the U.S. Supreme Court made life forms patentable for the first time.³⁰ The patent system initially was not designed to include life forms, but rather predominantly was intended to include mechanical inventions and technology.³¹ Higher life forms were not considered to fall within the category of patentable material since they were products of nature,³² but as industrialization extended from mere mechanical inventions to endeavors of a chemical nature, and subsequently biotechnology, higher life

25. *The Human Genome Project Completion: Frequently Asked Questions*, NAT’L HUM. GENOME RES. INST., <http://www.genome.gov/11006943> (last updated Oct. 30, 2010); Gold & Carbone, *supra* note 21, at 62.

26. Ikechi Mgboeji & Byron Allen, Comment, *Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Healthcare and Biomedical Research*, 2 CAN. J.L. & TECH. 83, 85 (2003), available at http://cjlt.dal.ca/vol2_no2/pdfarticles/mgboeji.pdf.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980).

31. Mgboeji & Allen, *supra* note 26, at 85.

32. *Id.*

forms became increasingly considered patentable.³³ This expansion of the ambit of “patentable material” did not come about as the result of proactive legislative changes, but rather from inclusion by the judiciary of higher life forms within this definition.³⁴ Critics of genetic patenting argue that because chemical compounds may be recognized as composition of matter for the purpose of patenting, they constitute “discoveries” rather than “inventions,” and therefore, do not meet the criteria of patents.³⁵ But if the substance is a “[p]roduct[] of nature, [it] may not be patented.”³⁶ Various American courts have held that if an inventor isolates and purifies a substance, it becomes patentable, provided that the substance meets all other patentability criteria.³⁷ American courts also consider whether any “commercial” or “therapeutic value” has been added to an isolated and purified, naturally occurring substance when deciding whether a substance is patentable.³⁸ Subsequently, genes have been patented in various countries based on this logic.³⁹

The next section will consider two important questions: (1) whether India will be violating TRIPS if it decides to ban patenting for gene-related inventions; and, (2) how India can prevent the frivolous patenting of genes and ensure sufficient access to drugs in the case where a genetic application, diagnostic tool, or genetic drug is patented.

33. *Id.*

34. *Id.*

35. WENDY H. SCHACHT, CONG. RESEARCH SERV., RS22516, GENE PATENTS: A BRIEF OVERVIEW OF INTELLECTUAL PROPERTY ISSUES 1–3 (2008), available at http://www.ipmall.info/hosted_resources/crs/RS22516_061003.pdf.

36. *Id.*

37. See, e.g., Chakrabarty, 447 U.S. at 309–310 (qualifying a microorganism as patentable because it was a non-naturally occurring composition of matter “having a distinctive name, character and use”); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (holding a process of synthesizing rubber as patentable because it transformed and reduced an “article” to a “different state or thing”) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972)).

38. Georgios Zekos, *Patenting Biotechnology*, 2004 J. INFO. L. & TECH. 1, 14–15 (2004), available at http://www2.warwick.ac.uk/fac/soc/law/elj/jilt/2004_1/zekos/.

39. Gold & Carbone, *supra* note 21, at 62.

A. *Options for Regulating Gene Patenting vs. Banning Gene Patenting*

Although genes are being patented in many countries, it is important to critically examine whether India needs to approach the issue of gene patenting more cautiously—especially in light of the fact that recent anti-cancer drugs (mostly biotech-based drugs) are prohibitively expensive and beyond the reach of millions in India.⁴⁰ It is worth examining whether India, as a matter of policy, should ban gene patenting and whether a ban would violate India's international obligations under TRIPS. Indeed, the Indian Patent Act was amended in 2002 to incorporate the patenting of microorganisms.⁴¹ This amendment comported with India's TRIPS obligation.⁴²

The recent *Myriad* litigation in the United States, which concerns two human genes (BRCA1 and BRCA2) associated with the development of breast and ovarian cancer,⁴³ has brought attention to the debate surrounding the banning of gene patents.⁴⁴ "Myriad's patents have raised significant controversy on a global scale because the patents held by Myriad not only cover the BRCA gene mutations themselves, but also include diagnostic tests and the use of the genes for advances in predictive medicine."⁴⁵ The cost of procedures stemming from this patent are prohibitively expensive and beyond the reach of

40. *Anti-Cancer Drug Prices Hit the Roof*, DNA INDIA TIMES, Oct. 5, 2012, <http://www.dnaindia.com/mumbai/1749080/report-anti-cancer-drug-prices-hit-the-roof>.

41. The Patents (Amendment) Act, No. 38 of 2002, INDIA CODE (2002) (Section 3(j) of the Act excludes from patentability "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.").

42. See Chilton, *supra* note 5, at 297 (noting the three-stage process by which India aligned its intellectual property laws with TRIPS as required by India's membership in the WTO, which culminated in the Patents (Amendment) Act of 2005).

43. "BRCA1 and BRCA2 are human genes that produce tumor-suppressor proteins. . . . Specific inherited mutations in BRCA1 and BRCA2 increase the risk of female breast and ovarian cancers, and they have been associated with increased risks of several additional types of cancer." *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (last visited Nov. 12, 2013).

44. Pollack, *supra* note 2, at B1; Fowler, *supra* note 2, at 1076.

45. Fowler, *supra* note 2, at 1076–77.

many women around the world.⁴⁶

1. *Recent Development in the U.S. on Gene Patenting*

A recent decision by the Supreme Court of the United States concerning the patent eligibility of genetic sequences has the potential to completely revamp the biogenetic industry, as well as, the biotechnology industry as a whole.⁴⁷ The controversy in question concerned Myriad, a biotechnology company focused on human genomics, and its patent claims on certain isolated ovary and cancer-inducing genetic sequences (BRCA1 and BRCA2). Myriad had filed patent infringement suits against organizations providing diagnostic testing for BRCA from 1997 onwards.⁴⁸ Subsequently, the Association of Molecular Pathology challenged Myriad's patents, to which Myriad moved to have the case dismissed, alleging lack of standing.⁴⁹

The District Court of the Southern District of New York applied the "all the circumstances" test set forth by the Supreme Court and concluded that the plaintiffs had sufficiently established standing.⁵⁰ The District Court held that isolated DNA was not "markedly different" from DNA found in nature, and, therefore, isolated DNA would be considered "products of nature".⁵¹ Thus, isolated DNA would fall within one of the exceptions to patentable material, namely a "natural phenomenon"⁵² and would not be capable of being patented. Myriad appealed the District Court's judgment urging that the Court of Appeals find that the plaintiffs did not have sufficient

46. *See id.* at 1077 (noting Myriad's patent on BRCA has driven up costs for breast cancer tests for women).

47. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

48. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1349 (Fed. Cir. 2011).

49. *Id.* at 1341.

50. *Id.* The "all the circumstances" test is applied to decide the difference between an abstract question and a controversy, for the purposes of the Declaratory Judgment Act. The answer depends on whether the facts alleged, under all the circumstances, show that there is a substantial controversy of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

51. *Ass'n of Molecular Pathology*, 653 F.3d at 1342.

52. *Id.* at 1350 (quoting *Chakrabarty*, 447 U.S. at 309–10).

cause to challenge Myriad's patents under the Declaratory Judgment Act.⁵³ In addition, Myriad also challenged the averment of the District Court that all of the claims were in reference to "non-patentable subject matter" under 35 U.S.C. § 101.⁵⁴

The Appeals Court partly affirmed the prior judgment, and partially reversed it.⁵⁵ Turning to the process patent claims, the Court stated that they were ineligible for patenting, and held that claims which covered "comparing" or "analyzing" DNA sequences covered "mental processes" free from physical transformations.⁵⁶ Mental processes cannot be patented.⁵⁷ The only question before the Court was whether the isolated DNA sequences and the diagnostic methods for comparing the sequences would qualify as patentable subject matter under section 101,⁵⁸ keeping in mind the *Mayo* judgment and other Supreme Court holdings.⁵⁹ The Court held that the isolated DNA molecules did not equate to DNA found in nature, and are "a product of human ingenuity."⁶⁰

Upon writ of certiorari, the U.S. Supreme Court heard the case and issued a unanimous decision denying Myriad's patent claims on the ovarian and breast cancer-related genetic sequences in question (BRCA1 and BRCA2).⁶¹ The Court held that "[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring."⁶² The Court reasoned that Myriad did not deserve patent recognition in isolating BRCA1 and BRCA2, as "Myriad

53. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1308 (Fed. Cir. 2012).

54. *Id.*

55. *Id.*

56. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 232–33 (S.D.N.Y. 2010).

57. *Id.* (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

58. *Id.* at 220.

59. *Id.* at 219.

60. *Id.* at 231–32.

61. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2119–20.

62. *Id.* at 2107.

did not create anything.”⁶³ The Court relied predominantly on the language of section 101 restricting patents to “[w]hoever invents or discovers any new and useful . . . composition of matter, or any new and useful improvement thereof” to determine the criteria required by *Myriad* to obtain patents on such material⁶⁴. The Court found that merely locating these genetic sequences did not amount to the creation of something “new” under the parameters of section 101⁶⁵.

However, the Supreme Court recognized and established limits and qualifications to their holding. First, the Court held that cDNA sequences (genetic material derived from naturally occurring sequences that lack introns) are patentable⁶⁶. The Court found that because cDNA has been altered by lab technicians to be “distinct from the DNA from which it was derived” and is “not a ‘product of nature’” it is patentable under section 101.⁶⁷ Second, the Court restricted its holding to genetic material only; thus, the Court stated that the case has no bearing on new applications based on BRCA1 and BRCA2.⁶⁸ Therefore, in summary, the *Myriad* decision withholds genetic sequence patent eligibility from those sequences already found in nature (in their complete versions, including introns) but allows patents for those applications based on such sequences or for sequences that were derived from nature but are now distinct.

In *Mayo Collaborative Services, DBA Mayo Medical Laboratories et al v. Prometheus Laboratories, Inc.*, the respondent in the case, Prometheus Laboratories Inc. (“Prometheus”), was the licensee of the two disputed patents.⁶⁹ The patents pertained to the use of drugs used to treat autoimmune diseases.⁷⁰ The claims of the petitioners related to a specific process used for the purpose of calculating the correct

63. *Id.* at 2119.

64. *Id.* at 2117.

65. *Id.* at 2119.

66. *Id.* at 2107.

67. *Id.* at 2124.

68. *Id.* at 2124.

69. *Mayo*, 132 S. Ct. at 1290.

70. *Id.*

dosage of the drugs for different patients, taking into account individual differences in rates of metabolism of such drugs.⁷¹ There are three steps in such claims: (1) an “administering” step (where the doctor administers the drug); (2) a “determining” step (where metabolite levels in the blood are measured); and (3) a “wherein” step (where a range of dosages that will not harm the patient is identified, and indication of a need to increase or reduce the dosage).⁷²

The petitioners, consisting of Mayo Collaborative Services and Mayo Clinic Rochester (collectively called “Mayo”), bought and used diagnostic tests based on Prometheus’ patents.⁷³ Then, in 2004, Mayo started to market its own tests, which were similar but not identical to those of Prometheus.⁷⁴ Prometheus sued Mayo for patent infringement, and the District Court found that there was, in fact, patent infringement.⁷⁵ However, since the processes protected by the patents involved natural laws/phenomena (i.e., the correlation between metabolite levels and efficacy of thiopurine drugs), they were not patentable at all.⁷⁶ Therefore, the District Court granted summary judgment to Mayo.⁷⁷ The Circuit Court reversed this decision and found the processes to be patent eligible by applying the “machine or transformation test.”⁷⁸ After the decision in *Bilski v. Kappos*,⁷⁹ this judgment was ordered for remand on grounds that the “machine or transformation test” was not a conclusive test of patent eligibility.⁸⁰ The Supreme Court then granted a writ of certiorari.⁸¹

The Court held the claims regarding the processes used to find the correlation between human metabolites and efficacy of

71. *Id.*

72. *Id.* at 1290–91.

73. *Id.* at 1291.

74. Mayo, 132 S. Ct. at 1291.

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

80. Mayo, 132 S. Ct. at 1291.

81. *Id.* at 1289.

the drugs only described natural relations between naturally occurring substances, and nothing more.⁸² The Court stated, “if a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.”⁸³ Although the three steps of the process were “not themselves natural laws,” they were nonetheless “insufficient to transform the nature of the claims.”⁸⁴ The judgment of the Circuit Court was reversed.⁸⁵

There were three separate sets of claims in the *Myriad* case, namely: (i) *Myriad*’s product claims regarding isolated DNA sequences, which were not upheld by the Court; (ii) *Myriad*’s method claims referring to methods of screening potential cancer therapeutics, which were also upheld by the Court; and (iii) *Myriad*’s method claims regarding analysis and comparing of BRCA gene sequences, which was rejected by the Court.⁸⁶

The *Mayo* decision does not discuss isolated genes, and therefore, issue (i) in *Myriad* is not broached. *Mayo* concerned the patenting of methods and the difference between a patent-eligible method that applied the laws of nature and a non-eligible method that simply described the laws of nature.⁸⁷ The Supreme Court in *Myriad* stated that *Myriad* would have been in the favorable position to derive new patentable methods and applications from the non-patentable materials of BRCA1 and BRCA2.⁸⁸ Thus, the Court in *Myriad* did not need to address the standards for determining patent eligibility of methods. Thus, the Court wholly avoided the potential necessary discussion of the standards laid out in *Mayo*. The

82. *Id.* at 1291.

83. *Id.* at 1297.

84. *Id.* at 1291.

85. *Id.* at 1289.

86. Ass’n for Molecular Pathology, 133 S. Ct. at 2117–19.

87. *Mayo*, 132 S. Ct. at 1290 (“Although laws of nature, natural phenomena, and abstract ideas are not patentable subject matter under § 101 of the Patent Act . . . an application of a law of nature . . . to a known structure or process may deserve patent protection.”) (internal quotation marks omitted) (citing *Diehr*, 450 U.S. at 185).

88. Ass’n for Molecular Pathology, 133 S. Ct. at 2120.

Supreme Court in *Myriad* only briefly quotes *Mayo* within its dicta and in reference footnotes (even then, it is merely to do away with *Myriad*'s claim concerning its reliance interests).⁸⁹

The same *Myriad* gene was granted a patent by the European Patent Office (EPO) in 2001.⁹⁰ The EPO revoked *Myriad*'s patent in 2004⁹¹ but the patent was reinstated in 2008.⁹² In reinstating *Myriad*'s patent, the EPO's Technical Board clarified that the patent would apply to various forms of testing for the BRCA gene mutations, but the BRCA genes themselves would be excluded from the scope of the patent.⁹³

2. *Germany and Australia on Gene Patenting*

Germany has taken a rather unique approach to gene patenting and has declared that "absolute substance protection is not available for human gene sequences."⁹⁴ Germany's statute regulating the patenting of human genes is far more restrictive than the European Patent Convention and Implementing Regulations to the Convention on the Grant of European Patents.⁹⁵ It is pertinent to note, however, that if a patent holder of a European patent so desires, their patent is valid in Germany without a separate application process under the German patent statute.⁹⁶ Germany's statute places a restriction on patentability of human genetics by requiring potential patent holders to not only specify the genetic sequence at the time of patent application, but also one or more

89. *Id.* at 2121.

90. Gold & Carbone, *supra* note 21, at 43.

91. Andy Coghlan, *Europe Revokes Controversial Gene Patent*, NEWSIDENTIST (May 19, 2004), <http://www.newscientist.com/article/dn5016-europe-revokes-controversial-gene-patent.html>.

92. Philippa Brice, *Myriad European BRCA1 Patent Upheld in Amended Form*, PHG FOUND. (Nov. 26, 2008), <http://www.phgfoundation.org/news/4412>.

93. *Id.*; Fowler, *supra* note 2, at 1086.

94. Christoph Ann, *Patents as Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal with It*, 7 GERMAN L.J. 279, 286 (2006).

95. Ann, *supra* note 94, at 282; Implementing Regulations to the Convention on the Grant of European Patents, Oct. 5, 1973, available at <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ma2.html>.

96. Ann, *supra* note 94, at 288.

applications of the gene sequence.⁹⁷ The justification for these strict requirements is that the scope of protection of the gene sequence granted by the German patent will be limited to the specified application only, and is, therefore, not an absolute form of protection.⁹⁸ The reason German law differs from the Biotechnology Directive of the EU is that, in Germany, there was a debate prior to the introduction of Paragraph 1a where it was felt that the Biotechnology Directive conferred protection to gene sequences that were too extensive in nature.⁹⁹ Germany felt that such protection would not encourage innovation, since entire or partial sequences would come under patent protection regardless of what their industrial applications were.¹⁰⁰ As a result, only the German law providing for protection of gene sequences for specific uses was introduced.¹⁰¹ Such a law is aimed to encourage scientific initiatives to identify further industrial applications and uses for already patented gene sequences.¹⁰²

It is pertinent to note that in Germany the patent protection under the GPA applies only to German patents applied for through national legislation.¹⁰³ There is another mechanism to apply for patents in the EU by which member states apply for patents through the European Patent Organisation (EPO), and the provisions of the Biotechnology Directive then govern the application.¹⁰⁴ Then the patents are nationalized in different countries, including Germany. For such patents obtained through the EPO, the provisions of the GPA (basically Paragraph 1a) do not apply, and as a result, the protection of the gene sequence in question is absolute, and not limited to the

97. *Id.* at 286.

98. *Id.*

99. See Erin Bryan, Comment, *Gene Protection: How Much is Too Much? Comparing the Scope of Patent Protection for Gene Sequences Between the United States and Germany*, 9 J. HIGH TECH. L. 52, 59 (2009).

100. See *id.* at 60, 64–65 (asserting that Germany's patent protections indicate intent to prevent stagnation of research).

101. *Id.* at 59–60.

102. *Id.* at 60.

103. *Id.* at 60–61.

104. Bryan, *supra* note 99, at 56–57.

disclosed use in the patent application.¹⁰⁵ Since it is possible for patent applicants to circumvent the limitations of the GPA placed on patenting gene sequences, the GPA is not a law that dictates patents in Germany, but rather sets a “national standard” that is mandatory only for certain patents and confers an option for inventors in Germany.¹⁰⁶

While a gene may be legally patented in many countries, there remains significant social opposition to gene patenting.¹⁰⁷ Members of the Australian Parliament, for example, have lobbied for a ban on gene patenting on the belief that the practice allows the patent holder to monopolize research on particular genes.¹⁰⁸ In other words, certain members of Parliament subscribe to the view that if gene patenting is sanctioned in Australia, it will lead to a monopoly on use of patented genes by the patent holder.¹⁰⁹ This monopoly, in turn, will discourage investment in downstream genetic research by other parties, and possibly slow down scientific progress.¹¹⁰ In furtherance of this agenda, in May 2012, the Australian Government passed a bill called the “Raising the Bar Bill,”¹¹¹ targeted to assist cancer researchers in gaining access to patented genetic material owned by corporations.¹¹²

In Australia, the current position taken on the patentability of genes largely comes from the 1995 decision in the case *Kirin-Amgen, Inc. v. Board of Regents of University of*

105. *Id.* at 60–61.

106. Ann, *supra* note 94, at 288.

107. See, e.g., Looney, *supra* note 20, at 243–44 (noting gene patenting will likely inhibit research and sharing of information, as well as, result in a “gold rush” mentality that would disadvantage less developed countries).

108. Suzanne Smith, *MP Wants Second Take on Gene Patent Laws*, ABC (May 15, 2012), <http://www.abc.net.au/news/2012-05-14/mp-urges-labor-to-back-gene-patenting-overhaul/4010612>.

109. *Id.*

110. Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of the Issues Facing the Australian Industry* 53–54 (Univ. of Tasmania Ctr. for Law and Genetics, Occasional Paper No. 6, 2003), available at <http://www.lawgenecentre.org/Publication%20PDF/OccPaper%206.pdf>.

111. Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) (Austl.).

112. Smith, *supra* note 108.

Washington.¹¹³ In this decision, it was held that an isolated gene can be eligible for patent protection, as it does not have to be considered a mere discovery, but can constitute an “artificially created state of affairs.”¹¹⁴ Also, on appeal, it was said that the discovery of a gene could be compared to the discovery of a chemical compound, thus entitling the “inventor” to patent protection over the isolated gene as well as any products derived from it.¹¹⁵

The judgment and appeal sparked a heated debate in Australia over whether genes should be patentable or not.¹¹⁶ The Australian Law Reform Commission conducted a number of inquiries into gene patents,¹¹⁷ patentable subject matter in general,¹¹⁸ and the relationship between gene patenting and human health¹¹⁹ in order to review the current position with regard to patentability of genes and explore a possible ban on this provision.¹²⁰

On November 23, 2011, the Australian government issued a response to this debate, and refuted the possibility of a ban on the patenting of genes.¹²¹ The reasoning behind this response of the government was that patenting of genes is extremely important in order to encourage scientific innovation and to

113. *Kirin-Amgen, Inc. v Bd. of Regents of Univ. of Wash.* (1995) 33 IPR 557 (Austl.); David P. Simmons & Mark E. Wickham, *Gene Patents in Australia: Where Do We Stand*, 30 NATURE BIOTECHNOLOGY 323, 323 (2012).

114. *Kirin-Amgen, Inc.*, 33 IPR at 569; Simmons & Wickham, *supra* note 113, at 323.

115. *Genetics Inst., Inc. v Kirin-Amgen, Inc.* (1996) 34 IPR 513 (Austl.).

116. *See generally* Nicol & Nielsen, *supra* note 110, at 24, 28 (discussing the judgment and noting the debate over gene patenting in Australia).

117. AUSTRALIAN LAW REFORM COMMISSION, *Senate Standing Committee on Community Affairs Inquiry into Gene Patents*, Mar. 18, 2009, <http://www.alrc.gov.au/senate-standing-committee-community-affairs-inquiry-gene-patents>.

118. ADVISORY COUNCIL ON INTEL. PROP., PATENTABLE SUBJECT MATTER FINAL REPORT (Dec. 2010), *available at* http://www.acip.gov.au/pdfs/ACIP_Final_Report_Patentable_Subject_Matter_Archived.pdf.

119. AUSTRALIAN LAW REFORM COMMISSION, GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH (June 2004), *available at* <http://www.alrc.gov.au/publications/report-99>.

120. Simmons & Wickham, *supra* note 113, at 323.

121. *Id.*

promote medical and genetic research.¹²² The government also attempted to allay ethical concerns with regard to the patenting of genes, by recommending that the legislature enact certain “ethical exclusions” to patents when patenting certain genes runs contrary to community sentiments and values.¹²³

The response of the government was expected, since Australia is a signatory to TRIPS (an agreement on the Trade-Related Aspects of Intellectual Property Rights drafted by the World Trade Organisation).¹²⁴ Under TRIPS, signatory states are required to provide patent protection for biological materials.¹²⁵ If Australia had banned the patenting of genes it would have been seen as a violation of its obligation under TRIPS.¹²⁶

There have been two notable attempts in Australia to bring about the ban on patenting of isolated genes and gene sequences.¹²⁷ In 1990, during a parliamentary debate regarding the Patents Bill in Australia, Senator Coulter sought to add an amendment to the Bill by which patenting of genes, whether naturally obtained or chemically synthesized, as well as genetically engineered organisms, would be banned.¹²⁸ This amendment was rejected by the Senate Standing Committee on Industry, Science and Technology as well as by the opposition party.¹²⁹ One reason behind this was that such an amendment would restrict the patenting of antibiotics and vaccines and would hinder medical research and biotechnological innovation.¹³⁰

The second attempt to ban gene patenting was by Senator

122. *Id.*

123. *Id.*

124. *Id.*

125. Simmons & Wickham, *supra* note 113, at 323–24.

126. *Id.* at 324.

127. Nicol & Nielsen, *supra* note 110, at 26.

128. *Id.* at 25.

129. *Id.*; Cth, Parliamentary Debates, Senate, 20 Sept. 1990, 2653 (Austl.); Cth, Parliamentary Debates, House of Representatives, 16 Oct. 1990, 2945–47 (Geoff Prosser) (Austl.).

130. Nicol & Nielsen, *supra* note 110, at 25; Cth, Parliamentary Debates, House of Representatives, 16 Oct. 1990, 2945–47 (Geoff Prosser) (Austl.).

Stott-Despoja in June 1996, when he introduced an amendment to the Patents Bill as a private member of parliament.¹³¹ The amendment would have added a new section to the Bill which would have categorized naturally occurring genes, naturally occurring gene sequences, or descriptions of the base sequence of naturally occurring genes/sequences as lacking in “inventiveness” or “novelty,” thereby constraining them to the ineligible patent category of “discoveries” rather than “inventions” which are eligible for patent protection.¹³² The quality of “novelty” is required for patent protection,¹³³ and the primary way to destroy novelty with regard to a previously existing invention in Australian patent law is full disclosure of all the features of the invention to the public, prior to the application for a patent.¹³⁴ Thus, the amendment would have rendered the above three categories of genetic material ineligible for patent protection. Debate on this amendment to the Bill was continuously postponed; ultimately it lapsed without ever coming up for discussion or consideration.¹³⁵

The case of *Cancer Voices Australia v Myriad Genetics, Inc.* in the Federal Court of Australia has the potential to change Australia’s stance on the patentability of genes.¹³⁶ This case challenges the patentability of the gene BRCA1, the same genetic sequence as ruled on by the U.S. Supreme Court in *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*¹³⁷ The Federal Court of Australia heard the case until February 2012, and it issued a decision later that month.¹³⁸ The court found that, to be patentable biomaterial, the isolated nucleic genes must fit within the Statute of Monopolies requirement of “a manner of manufacture”.¹³⁹ After providing a lengthy discussion on the

131. Nicol & Nielsen, *supra* note 110, at 26.

132. *Id.* at 26–27.

133. *Id.* at 20.

134. *Id.* at 29.

135. *Id.* at 27.

136. *Cancer Voices Austl. v Myriad Genetics, Inc.* [2013] FCA 65, (Unreported, Nicholas J, Feb. 15, 2013) (Austl.); Simmons & Wickham, *supra* note 113, at 324.

137. *Ass’n for Molecular Pathology*, 133 S. Ct. at 2116.

138. *Cancer Voices Austl.* FCA 65.

139. *Id.* at 2.

scientific background of DNA (the nucleic bases DNA is constituted from, the formal structure, etc.), the court turned its attention to the patentability of the isolation of the genetic sequences in question (BRCA).¹⁴⁰ The crux of the court's decision lies in whether the isolated genes in question constitute "an artificial state of affairs."¹⁴¹ The court noted three deciding factors for their finding that such isolated genes (BRCA) constitute an artificial state of affairs for the purpose of gene patenting. First, the court notes that the definition of "an artificial state of affairs" should be interpreted broadly.¹⁴² Second, the extraction process for nucleic acids (DNA) requires human intervention and does not occur naturally.¹⁴³ Third, isolation of such genes often requires time consuming research and efforts and thus, may be worthy of patentability.¹⁴⁴ The court concludes on these bases, that the genes (BRCA) are patentable.¹⁴⁵

The court limits patentability to nucleic acids outside of the natural environment of the cell and states that "naturally occurring DNA and RNA as they exist in cell are not within the scope of any of the disputed claims and could never, at least not until they have been isolated, result in the infringement of such claim."¹⁴⁶ It is unclear, at this juncture, how the court's holding and reasoning will be applied, however, it is abundantly clear that this judgment likely determine the future patentability of genes in the Australian context.

On the basis of Australia's jurisprudence, *Cancer Voices* can and must be distinguished from that of the *Myriad* decisions at both the U.S. Federal Circuit and Supreme Court. The facts of *Cancer Voices* are strikingly similar to that of the U.S. Supreme

140. *Id.*

141. *Id.* ¶ 101.

142. *See id.* ¶ 107.

143. *Id.* ¶ 108.

144. *Id.* ¶ 109 ("It would lead to very odd results if a person whose skill and effort culminated in the isolation of a micro-organism . . . could not be independently rewarded by the grant of a patent because the isolated micro-organism . . . was held to be inherently non patentable.").

145. *See id.* ¶ 136.

146. *Id.* ¶ 77.

Court *Myriad* decision, yet the two courts come to opposite conclusions. In the *Myriad* case, the Court found that the BRCA genes (BRCA1 and BRCA2) were not patentable biological materials.¹⁴⁷ The Court reasoned that these genes could not be patented because they were naturally occurring.¹⁴⁸ However, in the *Cancer Voices* decision, the court came to the exact opposite conclusion—finding that isolated BRCA genes were patentable. Although not legally beholden to U.S. case law, the Australian court invested considerable effort to distinguishing itself from the *Myriad* Court of Appeals case (the Supreme Court decision had not yet been released at that time).¹⁴⁹ Without extensive elaboration, the court found that the *Myriad* decision had no insight to offer to the Australian court on the issue of its own gene patenting regulations for several reasons. First, the court noted that the constitutions of each country are different from one another.¹⁵⁰ Second, the court stated that the evidence presented in both cases differed.¹⁵¹ Lastly, the court noted that its own interpretation of the facts on the matter of covalent bonds was distinguishable from that of Judge Lourie's in the *Myriad* decision.¹⁵²

The last distinguishing factor listed by the Australian court lies on faulty logical grounds. The Australian court emphasized throughout its decision that merely breaking bonds is not necessarily enough to warrant patentability; rather it is the existence of the nucleic acid outside of its natural environment (the cell) as a result of human intervention that makes the genetic material patentable according to the court.¹⁵³ However, the court's attempt to distinguish its own interpretation of human intervention from that of Judge Lourie's is not self-evident. Judge Lourie did indeed, as referred to by the Australian court itself, lay emphasis on breaking covalent bonds when isolating the DNA as a factor relevant to gene

147. Ass'n for Molecular Pathology, 133 S. Ct. at 2120.

148. *Id.* at 2107.

149. *Cancer Voices Austl.* FCA 65, ¶¶ 127–35.

150. *Id.* ¶ 135.

151. *Id.*

152. *Id.*

153. *Id.* ¶ 136.

patenting.¹⁵⁴ However, the reason underlying the court's emphasis of the breaking of covalent bonds was part of the court's larger point—that such material was not naturally occurring (as required by U.S. patent law). It is, therefore, a stretch to argue that there exists such an extreme difference between Australia's requirement of human intervention and Judge Lourie's requirement that bonds break rendering the material unnatural that would warrant a finding that the *Myriad* decision could offer no guidance to the Australian court on the subject of the BRCA gene patent.

Rather, it is the Australian court's acknowledgement of the expansive and flexible language used by the Australian court in *National Research Development Corporation v. Commissioner of Patents* that holds the key to distinguishing the United States' *Myriad* case from that of Australia's.¹⁵⁵ The United States has no such similarly expansive decision to that of Australia's *NRDC*. The broad "artificial state of affairs" standard used by the court in *Cancer Voices* was gleaned from Australia's *NRDC* decision.¹⁵⁶ The court found that isolating the BRCA genes required the removal of the nucleic acid from its natural environment (the cell) and rationally concluded that a nucleic acid existing outside of the cell was an unnatural state of affairs.¹⁵⁷ Thus, under the broad language of Australia's *NRDC* decision, the court held that the biological material could be patented.¹⁵⁸

It is fascinating to note the difference in perspective and reasoning of the courts in two related but contiguous decisions on the same issue in two different jurisdictions.

B. Banning Gene Patenting in India: Violation of TRIPS?

The section of TRIPS governing patents is silent on naturally continuous occurring material and does not "exclude"

154. *Id.* ¶ 131.

155. *Nat'l Research Dev. Corp. v Comm'r of Patents* (1959) 102 CLR 252 (Austl.).

156. *See Cancer Voices Austl.* FCA 65, ¶ 103.

157. *See id.* ¶ 136.

158. *Id.*

genetic material “from patentability.”¹⁵⁹ With regard to member countries’ domestic laws, TRIPS states that “[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”¹⁶⁰ Furthermore, Article 27(3) of the TRIPS agreement allows, but does not require, member states to exclude the following from patentable subject matter: “(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.”¹⁶¹

If a country subject to TRIPS wishes to disallow gene patenting, that country will not violate TRIPS when Articles 8 and 27 are read together.¹⁶² A country can disallow genetic patenting (to the extent of diagnostic and therapeutic methods) under Article 27¹⁶³ because Article 8 gives member countries the discretion to formulate their own domestic laws “to promote public health and nutrition, and to promote the public interest.”¹⁶⁴ Therefore, if India decides to ban gene patenting, according to the above analysis, the ban will not violate India’s TRIPS obligation. The TRIPS Agreement allows, but does not require, countries to permit the patenting of microorganisms. However, TRIPS fails to provide an explicit definition for “microorganism” therein.¹⁶⁵ Thus, any member country can argue that DNA falls under TRIPS’s meaning of “microorganism,” and, at the country’s election, can exclude

159. TRIPS Agreement, *supra* note 24, arts. 27–34.

160. *Id.* art. 8(1).

161. *Id.* art. 27(3).

162. See TRIPS Agreement, *supra* note 24, arts. 8, 27 (allowing member countries to adopt specific measures as necessary, if they are consistent with TRIPS, and to exclude plants, animals, and biological processes from patentability).

163. *Id.* art. 27.

164. *Id.* art. 8(1).

165. *Id.* art. 27.

DNA from being patented. Article 8(1) of TRIPS is a provision that allows states to exercise discretion in formulating domestic laws to further public interest.¹⁶⁶ It also allows measures to be taken in order to protect public health and nutrition and to promote the public interest in sectors of “vital importance” to their socio-economic and technological development.¹⁶⁷

This Article is a basis for community intellectual rights law.¹⁶⁸ Legislation that takes advantage of this Article, and which recognizes the value of indigenous peoples and local communities, can be enacted without technically violating the provisions of TRIPS.¹⁶⁹ TRIPS will not be violated because such legislation, even if it is in contrast with Article 27(3)(b), is in consonance with the objectives of Article 7 in the agreement.¹⁷⁰ Article 7 states that the protection of intellectual property rights should contribute to technological innovation, but in a manner that is consistent with social and economic welfare.¹⁷¹ TRIPS also allows countries to reject patents for inventions whose patent protection would be against public order and morality.¹⁷² This can include certain situations in which human life, plant and animal life, and the environment need to be protected.¹⁷³ It is possible, therefore, for countries to adopt the TRIPS agreement in a way that protects community rights by enacting laws outside the agreement that nevertheless do not violate the agreement.¹⁷⁴ Therefore, it can be argued that, if Articles 8 and

166. TRIPS Agreement, *supra* note 24, art. 8(1).

167. *Id.*

168. Gurdial Singh Nijar, *Legal and Practical Perspectives on Sui Generis Options*, THIRD WORLD RESURGENCE, June 1999, at 16–17.

169. *See id.* at 17 (stating a “law to protect and further the knowledge systems of indigenous peoples and local communities would clearly contribute to the promotion of technological innovation in furtherance of the social and economic welfare” of indigenous peoples, as contemplated by Article 8).

170. *Id.* at 19 (“Article 27.3(b) states that members must provide for protection of plant varieties either by patents or by an effective *sui generis* system or by a combination of both.”).

171. *Id.* at 17.

172. *Id.* at 20.

173. Nijar, *supra* note 168, at 20.

174. *See generally* SIMON WALKER, IUCN ENVIRONMENTAL LAW CENTER, THE TRIPS AGREEMENT, SUSTAINABLE DEVELOPMENT AND THE PUBLIC INTEREST: DISCUSSION PAPER, (2001) (discussing the relationship between the TRIPS Agreement, sustainable

27 of TRIPS are read together and interpreted in a particular manner, a country can disallow gene-patenting altogether. The interpretation is as follows: If India decides to ban gene patenting without violating TRIPS obligations, it can utilize the fact that under Article 27(3)(b), TRIPS does not mandate patenting of microorganisms, but merely allows it. Also, the Indian Patent Act does not define the term “microorganisms.”¹⁷⁵ Thus, if the Indian Government formulates a definition of “microorganism” that includes genetic material, it can ban gene patenting on this ground, and rationalize the legal ban based on public interest grounds elucidated in Article 27.

C. Evolution of Patents Law in India

Patent rights can rightly be considered a form of social contract where a person gets rewarded for an innovative contribution to society.¹⁷⁶ Traditionally, the intellectual property rights system excluded patenting life forms.¹⁷⁷ But, as our society has become more capitalistic, the jurisprudence on patentability has begun to change.¹⁷⁸ The TRIPS agreement, which binds all member countries of the World Trade Organization (WTO), is particularly interesting in this regard because all member countries were directed to change their intellectual property rights to conform to TRIPS.¹⁷⁹

If one looks at the evolution of the Indian Patent Act

human development and the public interest); Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 HOUS. L. REV. 979 (2009) (discussing the origins of Articles 7 and 8 of the TRIPS Agreement and the roles that they can play in helping less-developed countries preserve the bargains of the TRIPS negotiations to balance the international intellectual property system).

175. INTELLECTUAL PROPERTY INDIA, THE PATENTS ACT, 1970, § 2 (2013), available at http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf [hereinafter THE PATENTS ACT] (compiling the Patents Act of 1970 and all subsequent amendments thereto into one document).

176. See Looney, *supra* note 20, at 240 (discussing gene patenting as a reward for human effort and invention).

177. Mgboje & Allen, *supra* note 26, at 85.

178. See Chidi Oguamanam, *Beyond Theories: Intellectual Property Dynamics in the Global Knowledge Economy*, 9 WAKE FOREST INTELL. PROP. L.J. 104, 141–43 (2009) (discussing the prioritization of the economic benefits of information over social policy considerations and the resulting impact on the patentability of genetic material).

179. TRIPS Agreement, *supra* note 24, art. 1.

post-independence, it is ironic that the very law that was responsible for the growth of the generic pharmaceutical industry in India was later changed to meet international treaty agreements.¹⁸⁰ The pre-independence Patent Act, was substantially reformed based on recommendations of two government committees, one headed by Justice Bakshi Tek Chand (1948-1950) and the other by Justice Rajagopal Iyenger (1959); these recommendations provided the basis for the Indian Patent Act enacted in 1970.¹⁸¹ One outstanding feature of the Act was that it allowed process patents to be granted for industrial goods, while it excluded sectors like pharmaceuticals and food, and shortened protection for chemical based products.¹⁸² As a result of this new patent regime, after 1970, India was able to produce drugs at reduced prices.¹⁸³

In 1995, India joined the World Trade Organization (WTO) and automatically became a signatory to the TRIPS Agreement.¹⁸⁴ As per the requirements under TRIPS, India needed to conform to the Agreement's core provisions by January 1, 2005.¹⁸⁵ TRIPS required that India expand the scope of patentable subject matter to microorganisms, include measures for compulsory licensing consistent with TRIPS provisions, increase the duration of patent protection to 20 years, cover patents on products and minimize policy discrimination between imported and local products.¹⁸⁶ From 1995 to 2005, the Indian Patent Act was amended three times.¹⁸⁷ TRIPS forced India to enact the Patents (Amendment)

180. See Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 514-18 (2007) (discussing India's reversal on its anti-TRIPS stance).

181. *Id.* at 510-12.

182. *Id.* at 505.

183. *Id.* at 513-15; Dwijen Rangnekar, *No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime* ECON. & POL. WKLY., Feb. 4, 2006, at 410, 410-11.

184. Mueller, *supra* note 180, at 518.

185. *Id.* at 518-19.

186. TRIPS Agreement, *supra* note 24, arts. 27, 33, 37; see Philippe Cullet, *Patents Bill, TRIPs and Right to Health*, ECON. AND POL. WKLY., OCT. 27, 2001, at 4049, 4049 (2001) (outlining some of the requirements that TRIPS imposed on India).

187. Mueller, *supra* note 180, at 519 (noting the three amendments to the 1970

Act in 1999, specifically including an additional Chapter IVA on exclusive marketing rights.¹⁸⁸ The second amendment, the Patents (Amendment) Act, passed in June 2002 and extended the period of protection to twenty years for all inventions.¹⁸⁹ Thereafter, an attempt was made to bring India's patent law into full conformity with the India's TRIPS obligation by inclusion of the exempted sectors—the pharmaceuticals and agro-chemicals sectors.¹⁹⁰ In April 2005, India substantially redrafted this ordinance and passed the Patents (Amendment) Act, 2005.¹⁹¹

The introduction of product patents in 2005 started the ongoing battle for access to affordable drugs.¹⁹² India, historically, has rejected product patents on pharmaceuticals to ensure production and distribution of affordable generic drugs.¹⁹³ It is time India reconsiders its international commitment and waivers towards a patent regime that ensures access to gene therapy and drugs. By passing the 1970 Indian Patent Act, the Indian government made it clear they were focused on the protection of public health and the expansion of the Indian generic manufacturing industry.¹⁹⁴

Similarly, China recently reformed their domestic patent law to ensure access to medication.¹⁹⁵ The patent law in China

Patent Act were necessary to bring India's patent law in line with TRIPS).

188. The Patents (Amendment) Act, No. 17 of 1999, INDIA CODE (1999); Mueller, *supra* note 180, at 521–22.

189. The Patents (Amendment) Act, No. 38 of 2002, INDIA CODE (2002); Mueller, *supra* note 180, at 526.

190. Mueller, *supra* note 180, at 529.

191. The Patents (Amendment) Act, No. 15 of 2005, INDIA CODE (2005); Mueller, *supra* note 180, at 529.

192. *See generally* CHERI GRACE, A BRIEFING PAPER FOR DFID: UPDATE ON CHINA AND INDIA AND ACCESS TO MEDICINE 13–18 (Dep't. for Int'l Dev. Health Res. Ctr., 2005) (discussing the impact of the Patent (Amendment) Act of 2005 on India's generic pharmaceutical industry).

193. *See* Mueller, *supra* note 180, at 512–15 (discussing the development and pharmaceutical purposes of India's Patents Act of 1970).

194. *See id.* (discussing India's intent to stimulate drug manufacturing and lower medication prices).

195. (专利实施强制许可办法) [Patent Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12 1984, effective Apr. 1, 1985, amended Dec. 27, 2008) State Intellectual Prop. Office, *available at*

was amended in late 2008 to include new grounds for compulsory licensing among other changes.¹⁹⁶ By issuing the first ever “compulsory license,” China overhauled certain parts of its intellectual property laws to allow for local drug manufacturers to make more affordable copies of lifesaving essential drugs that are under patent protection to improve access to healthcare within the Chinese population.¹⁹⁷ One of the main reasons for China’s IP reforms includes the increasing rate of HIV/AIDS amongst the Chinese population.¹⁹⁸

In China, the reforms to the existing patent laws, on May 1, 2012, allow for Beijing to issue licenses to various eligible companies to produce so-called “generic” versions of patented drugs.¹⁹⁹ These versions will be produced under certain conditions, such as during times of emergency or other unusual situations and circumstances, as well as in the general interest of the public.²⁰⁰ Such generic versions of these drugs can also be exported to other members of the WTO if it is in the interest of public health.²⁰¹

It is a matter of policy debate whether gene patenting should be banned in India or regulated strictly. If India chooses to have patents on gene applications, it is imperative to have an equitable and balanced patent regime. The next section will evaluate the legal space for this issue in India. As indicated, the purpose of the foregoing discussion was to determine how far and how well Indian law incorporates patent jurisprudence with specific reference to genetic applications.

http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html; see Tan Ee Lyn, *China Changes Patent Law in Fight for Cheaper Drugs*, REUTERS, June 8, 2012, available at <http://www.reuters.com/article/2012/06/08/us-china-medicines-patents-idUSBRE8570TY20120608> (discussing China’s overhaul of intellectual patent laws to allow the making of cheaper, generic versions of medications still under patent protection in other countries).

196. Wenqi Liu, *Approaches to Ensuring Access to Pharmaceuticals under the New China’s Patent Law*, 15 J. INTELL. PROP. RTS. 228, 230–32 (2010).

197. Lyn, *supra* note 195.

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

D. *The Indian Patent Act*

This section will examine the Indian Patent Act, 2005 to determine whether genes are patentable in India and the current patentability criteria. In order to ascertain this, it is imperative to comprehend the patentability standard in the Indian Patent Act. As per the Indian Patent Act, to receive a patent on a gene sequence, the patent application must satisfy the requirements of novelty, utility, and non-obviousness.²⁰²

In addition to novelty and the “inventive step” defined in section 2(1)(j) of the Indian Patent Act,²⁰³ India lists “industrial applicability” as a requirement of patentability, meaning that a substance must involve a new product or process involving an inventive step and is capable of industrial application.²⁰⁴ Thus, in India, industrial applicability constitutes a statutory requirement for patentability, besides novelty and inventive step. In order to comply with Article 27 of TRIPS, India amended its Patent Act in 2002.²⁰⁵ This amendment now defines “invention” as a process “capable of industrial application.”²⁰⁶

As a prerequisite for patentability, the criterion of “industrial application” has very little relevance in Indian registry practice because, from the outset, Indian patent law excluded a series of intellectual creations from the concept of “invention”: (a) discoveries, scientific theories, and mathematical methods; (b) literary and artistic works or any other aesthetic creation as well as scientific works; (c) plans, rules and methods designed for intellectual activities, for games or economic-commercial activities as well as computer programs; and (d)

202. See Mueller, *supra* note 180, at 633 (discussing the bases for revocation of a patent under the India Patents Act, as amended in 2005).

203. THE PATENTS ACT, *supra* note 175, § 2(1)(j) (“[I]nventive step’ means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art[.]”).

204. See *id.* § 2(1)(a), (c) (“[C]apable of industrial application’, in relation to an invention, means that the invention is capable of being made or used in an industry[.]”).

205. Mueller, *supra* note 180, at 549; see TRIPS Agreement, *supra* note 24, art. 27 (“[P]atents shall be available for any inventions . . . provided that they are new, involve an inventive step and are capable of industrial application.”).

206. THE PATENTS ACT, *supra* note 175, § 2(1)(j).

ways of presenting information, etc.²⁰⁷ Moreover, the patentability of methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods used on the human or animal body are also expressly excluded.²⁰⁸ These exclusions to patentability mean that the industrial requirement has very limited prominence in practice.

“Utility” is not defined in Indian patent law, but the prerequisites of an invention in the law lists usefulness as a prerequisite.²⁰⁹ The courts have also consistently held that “a patentable invention, apart from being a new manufacture, must also be useful.”²¹⁰ The Supreme Court of India observed in *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries* that “[t]he foundation of this judicial interpretation is to be found in the fact that section 26(1)(f) of the 1911 Act recogni[ze[d] lack of utility as one of the grounds on which a patent can be revoked.”²¹¹ A patentable invention, therefore, besides being a new manufacture, must also be useful.²¹² Thus, in order to bring the subject matter of patent within the scope of invention, there must be invention so applied as to “produce a new process or an improved result.”²¹³

E. Gene Patents: How Does the Indian Patent Act, 2005, Measure Up?

India’s judiciary did not clearly state its position on the patentability of microorganisms until the landmark judgment of the Calcutta High Court in *Dimminaco AG v. Controller of Patents*.²¹⁴ This case supports microorganisms as patentable

207. See Mueller, *supra* note 180, at 549–50 (discussing India’s use of “industrial application,” rather than “discoveries,” in the definition of invention); see also THE PATENTS ACT, *supra* note 175, § 3 (“Inventions Not Patentable”).

208. THE PATENTS ACT, *supra* note 175, § 3(i).

209. *Id.* § 64(1)(g).

210. *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries*, A.I.R. 1982 S.C. 1444 (India).

211. *Id.*

212. *Id.*

213. *Id.*

214. *Dimminaco A.G. v. Controller of Patents and Designs*, 2001 A.I.R. 1 (Cal.).

subject matter.²¹⁵ Here, a Swiss company called *Dimminaco* AG applied to the office of the Controller of Patents and Designs for a patent on the process for manufacturing a vaccine for infectious bursitis in poultry in 1998.²¹⁶ The Controller rejected the application on the grounds that the end product failed the living organism preclusion.²¹⁷ In April 2002, the Calcutta High Court set aside the decision of the Controller of Patents and Designs, holding that the contentions of the Controller were not justified because the law did not bar the processes ending in the creation of a living thing.²¹⁸ The world community generally accepts the landmark Indian judgment as it is in consonance with world patent practice.²¹⁹

Given that *Dimminaco* clearly states that the law allows for the patenting of microorganisms, a consideration of the statutory provisions that guarantee patenting of microorganisms becomes necessary. In order to comprehend the provisions of the Indian Patent Act, however, reference must be made to the TRIPS provisions dealing with the patentability of microorganisms. Article 27(3) of TRIPPS reads as follows:

Members may also exclude from patentability:

diagnostic, therapeutic, and surgical method for the treatment of humans or animals;

plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.²²⁰

While Article 27(3)(b) empowers WTO members to grant patents for microorganisms, member nations ultimately determine the scope of patents because TRIPS does not define “micro-organism.”²²¹ In an effort to comply with TRIPS, India

215. *Id.*

216. *Id.*

217. *Id.*

218. *Id.*

219. See Mueller, *supra* note 180, at 560 n.412 (discussing how the Indian Manual of Patent Practice and Procedure is consistent with the *Dimminaco* decision, while also comparing the *Dimminaco* decision with *Chakrabarty*, 447 U.S. 303).

220. TRIPS Agreement, *supra* note 24, art. 27(3).

221. *Id.*

joined the Budapest Treaty on the international recognition of the deposit of microorganisms for the purpose of patent procedure.²²² In 2001, India signed this treaty, which is open only to members of the Paris Convention,²²³ and amended its Patent Act the following year.²²⁴ As a result, India's Gene Bank of the Institute of Microbial Technology (IMTECH) in Chandigarh and Microbial Type Culture Collection (MTCC) officially became an "International Depositary Authority" as of October 4, 2002.²²⁵ The latest amended Indian patent statute includes patent protection for microorganisms.²²⁶

Like Article 27(3)(b) of TRIPS, section 3(j) of the Indian Patent Act excludes from its coverage: "plants and animals in whole or any part thereof other *than* microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."²²⁷ Therefore, as long as the appropriate criteria are met, it is definite that the scope of patent protection in India has been expanded to encompass microorganisms. The Calcutta High Court, in the *Dimminaco* case, acknowledged the lack of definitions for the terms "substance" and "manner of manufacture" within the Indian Patents Act. The court prescribed the use of dictionary meanings for these terms, and that these words should be attributed and accepted if the end-product is a commercial commodity.²²⁸

Thereafter, the 2002 Act modified the meaning of the term

222. M. Somasekhar, *Micro-Organism Depository in Chandigarh*, HINDU BUS. LINE, Aug. 8, 2001, <http://www.thehindubusinessline.in/2001/08/09/stories/01096702.htm>.

223. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, art. 15, Apr. 28, 1977, 17 I.L.M. 285.

224. The Patents (Amendment) Act, No. 38 of 2002, INDIA CODE (2002).

225. Budapest Notification No. 204: Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure Status, World Intellectual Property Association (2002), *available at* http://www.wipo.int/treaties/en/notifications/budapest/treaty_budapest_204.html.

226. THE PATENTS ACT, *supra* note 175, § 3(j).

227. TRIPS Agreement, *supra* note 24, art. 27(3); THE PATENTS ACT, *supra* note 175, § 3(j).

228. *Dimminaco A.G. v. Controller of Patents and Designs*, 2001 A.I.R. 1 (Cal.).

“invention” to become a “new product or process involving an inventive step and capable of industrial application.”²²⁹ Therefore, one can infer that a patentable invention must have “industrial application.” It is apparent that the 2002 Act has substantially expanded the subject matter included within “patentable invention,” taking into account the term’s modified meaning as well as the court’s views in the *Dimminaco* judgment. From this, one can infer that inventions which comprise “novel processes of production” of human genetic material (including DNA sequences and microbes with mutations) fall within the scope of patentable subject matter.

The fact that there is no widely recognized definition of “microorganism” within intellectual property has major implications on patenting. The Indian Patent Act notably contains no comprehensive meaning for this term;²³⁰ this results in the creation of a lacuna in terms of whether DNA can be considered as patentable subject matter. However, the Manual of Patent Office Practice and Procedure (as modified on March 22, 2011) clearly states that, when a genetically modified gene sequence or amino acid sequence is novel, involves an inventive step, and has an industrial application, patents on the following can be claimed: (1) A gene sequence or amino acid sequence, (2) A method of expressing the above sequence, (3) An antibody against the protein or sequence, (4) A kit made from the antibody or sequence.²³¹ Thus, it is clear that a genetically modified gene sequence is patentable.²³² Nevertheless, the Manual of Patent Office Practice and Procedure do not define what “genetically modified gene sequence” constitutes.²³³ This is another ambiguity in the law.

Further, section 3(c) of the Indian Patent Act provides that

229. The Patents (Amendment) Act, No. 38 of 2002, § 3(f), INDIA CODE (2002).

230. THE PATENTS ACT, *supra* note 175, § 2.

231. MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, THE OFFICE OF CONTROLLER GEN. OF PATENTS, DESIGNS, & TRADEMARKS, ch. 8 (2011) *available at* <http://www.ipindia.nic.in/ipr/patent/manual/main%20link.htm>.

232. N.V. Rangantha, *Patenting of Human Genes: Moral and Ethical Issues*, PRESERVE ARTICLES, <http://www.preservearticles.com/2011120618179/patenting-of-human-genes-moral-and-ethical-issues.html> (last visited Nov. 12, 2013).

233. MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, *supra* note 231, ch. 2.

“the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or nonliving substance occurring in nature” is not patentable.²³⁴ Therefore, as per section 3(c), any microorganism that exists in nature is excluded from patent protection, as identification of that microorganism amounts to mere “discovery” and not “invention.”²³⁵ The same section rejects the patentability of any naturally occurring substance, and contains the requirement of substantial human intervention before the microorganism is eligible for patent protection.²³⁶ As a result, genetically engineered or genetically modified organisms are patentable since they fulfill the criterion of substantial human intervention.²³⁷ Different jurisdictions have deliberated over this issue and examined case law and other precedents for the purpose of formulating a variable definition. Europe, for one, has emerged as a continent possessing well-developed legislation regarding gene patents.²³⁸ Chapter V, Rule 26(3) of the Convention on the Grant of European Patents (EPO) replaced the term “microorganism” with “biological material,” defined as “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.”²³⁹ Before the amendment, “microorganism” was not defined in the EPC.²⁴⁰ The Budapest Treaty of 1977 defined the term very vaguely, but over time, progressive technological advancements have resulted in a more expansive definition that includes biological elements, which are technically not microorganisms.²⁴¹

234. THE PATENTS ACT, *supra* note 175, § 3(c).

235. *Id.*

236. *See id.* §§ 2, 3 (requiring patentable inventions involve an “inventive step” while not finding microorganisms not patentable in general).

237. *Id.*

238. *See* Looney, *supra* note 20, at 259–62 (noting various ways in which Europe has developed innovative patent legislation).

239. Convention on the Grant of European Patents, *supra* note 95, Rule 26(3).

240. *Id.*

241. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure art. II, Apr. 28, 1977, 32 U.S.T. 1243.

F. Ensure Strict Patentability Criteria

While a clear definition of microorganism would easily remove the ambiguity regarding India's position on patenting genetic material, yet another concern exists in regards to genetic patenting: the criteria are lax for biological innovations vis-à-vis chemical innovations.²⁴² It is possible that these lenient rules may lead to frivolous patenting and "evergreening" of inventions.²⁴³ Thus, to avoid patents that offer little or no inventiveness and ultimately amount to only discoveries, India's legislative changes or amendments should authorize guidelines that would prevent these likely incidents. In other words, to avoid frivolous patenting, the examination guidelines must specifically address genetic patenting. Strict guidelines must apply to the examination of patent applications involving biological material from the point-of-view of substantial human intervention and utility. Strict guidelines specifically pertaining to 'substantial human intervention' as well as 'utility' must be adopted while examining patent applications that include biological substances.²⁴⁴ The general patentability criteria (i.e., novelty, non-obviousness, and utility) need to be tailored specifically for genetic patenting.

Another issue relating to streamlining the Indian Patent Act is the privatization of DNA in the context of its accessibility to its researchers.²⁴⁵ Again, it bears repeating that patentable subject matter must meet the requirements for patentability.²⁴⁶ Thus, only inventions or discoveries deemed new, useful, and non-obvious to a person skilled in the relevant trade may be

242. Richard Gold, *Gene Patents and Medical Access*, 49 INTELL. PROP. FORUM 20, 21 (2002).

243. Evergreening refers to the "strategy adopted by patentees who seek to extend their period of patent protection by applying for secondary patents over related or derivative technologies." Robert Chalmers, *Evergreen or Deciduous? Australia Trends in Relation to the 'Evergreening' of Patents*, 30 MELB. U. L. REV. 29, 29 (2006).

244. R.A. MASHELKAR ET AL., REPORT OF THE TECHNICAL EXPERT GROUP ON PATENT LAW ISSUES 3 (2006), available at http://www.naavi.org/cl_editorial_07/mashelkar_committee_report.pdf.

245. Teresa M. Summers, *The Scope of Utility in the Twenty-First Century: New Guidance for Gene Related Patents*, 91 GEO. L.J. 475, 478 (2003).

246. *Id.*

patented.²⁴⁷ But the fact that millions of genes exist renders it difficult to meet the criteria of “usefulness” and “non-obviousness”.

The “utility” criterion is particularly relevant in the context of genes, due to the inability to determine the utility of a gene at an early stage of research.²⁴⁸ One gene could conceivably encode a cure for HIV/AIDS, Cancer, and other diseases. The court in *Brenner v. Manson* noted “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”²⁴⁹ Today, however, an invention used for its intended purpose, even if controversial, can qualify for patenting.²⁵⁰

However, a major concern remains. If applicants can patent a gene without exploring its entire utility, protected ownership of the gene will likely impede further research into the gene’s untapped utility.²⁵¹ The restriction of patents to only complete gene sequences rather than for gene sequences that are only partially characterized or gene fragments, can contribute to solving this problem. A proposition for restriction is that stricter criteria for patent examination must be adopted by patent offices, and thus, the offices should award gene patents only for sequences that are previously and properly characterized with a definite utility.

The U. S. Trademark and Patent Office’s examination guidelines contain efficient “utility” criteria.²⁵² These guidelines, originally issued in January 2001 and revised in August 2012, address the criteria for patentability of gene sequences and require that to meet the “utility” criteria, an application must provide a single “specific, substantial and credible” utility for each claimed invention.²⁵³ In addition, “a person of ordinary

247. *Id.*

248. *Id.* at 478–79.

249. *Brenner v. Mason*, 383 U.S. 534, 536 (1966).

250. *Summers*, *supra* note 245, at 478–79.

251. *Id.*

252. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107 (2012) [hereinafter PATENT MANUAL] (setting forth guidelines for examination of applications for compliance with the utility requirement).

253. *Id.* § 2107

skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention.”²⁵⁴ The office determines credibility from the perspective of a person of ordinary skill in the art provided with the patent application and any relevant evidence on record including experimental data, expert opinion, and previous scientific literature.²⁵⁵ The specific and substantive utility requirement in the U.S. PTO examination guidelines intends to avoid frivolous and insubstantial uses for filling the utility requirement under section 101 of the U.S. Patents Act.²⁵⁶ Further, if “specified and substantive” utility criteria are not met, examiners must reject the application under sections 101 and 112.²⁵⁷ This places the burden on the applicant to provide further proof to “establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.”²⁵⁸ The new interpretative guidelines also contain stricter rules for the body of the patent “specification” pertaining to presenting the written description of the invention and providing the “best mode” for its replication by others knowledgeable in current technologies that utilize the invention.²⁵⁹

India should adopt guidelines that ensure a strict vigilance of the utility criteria, while preventing frivolous patenting. These guidelines would also prevent patenting of genes with unknown functions as this would encourage the aforementioned “hunting expedition”—thus, restricting downstream inventions and discoveries to a single patent-holder. India must severely enforce these guidelines as to bind the patent officers in their examination of applications of gene patenting, ensuring correct decisions.

254. *Id.* § 2107.

255. *Id.*

256. *See id.* Section 101 of the U.S. Patent Act sets forth the general requirements for a utility patent: “[w]hoever 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, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2012).

257. PATENT MANUAL, *supra* note 252, § 2107; *see* 35 U.S.C. §§ 101, 112 (2012).

258. PATENT MANUAL, *supra* note 252, § 2107(3)(ii).

259. *Id.* § 2165 (The Best Mode Requirement); *see* 35 U.S.C. § 112 (2012).

III. CONCERNS ARISING FROM GENETIC PATENTING

The aforementioned clarifications would potentially improve the law and its enforcement. Once organizations actually obtain gene patents, however, other issues such as accessibility arise. In countries like the United States and Canada, the grants of a large number of patents on genes implicating human diseases led to the downstream rights to the diagnostic tests developed for detecting the diseases.²⁶⁰ Due to the concern regarding patent infringement, many laboratories avoid offering diagnostic tests in order to continue research on these genes.²⁶¹ It can be seen that patents act as possible restrictions to scientists, inhibiting further research on patented subject matter and impeding development of cures for different diseases.²⁶² In other words, gene patents create a monopoly of gene use by the patent holders, and may very well discourage investment in research on those genes by other parties.²⁶³ It is evident that restrictions stemming from patent rights can inevitably inhibit further research and slow down the development of new cures, as non patent-holders do not invest in research and development of the patented gene.²⁶⁴ In other words, ownership of genes by one party may discourage investment in research on the same gene by another party.²⁶⁵ Evidence suggests that public and private laboratories may be unable to offer diagnostic tests due to costly license and royalty fees.²⁶⁶

This barrier to access of the patented genes for the purpose of further research can be demonstrated by the following examples. First, Athena Neurosciences Inc. holds the exclusive

260. Julia Carbone et al., *DNA Patents and Diagnostics: Not a Pretty Picture*, 28 NATURE BIOTECHNOLOGY 784, 784–85 (2010).

261. *Id.* at 788.

262. *Id.* at 785–88.

263. Fowler, *supra* note 2, at 1093 (“[A]llowing gene patenting effectively monopolizes the relevant market by granting the patent holder complete control of the market); see Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, SCIENCE, Oct. 14, 2005, at 239, 239 (noting the possibility that “over broad patents might block follow-on research”).

264. Jensen & Murray, *supra* note 263, at 239.

265. *Id.*

266. Carbone et al., *supra* note 260, at 785–86.

license for the “method” patents related to testing the apolipo-protein (APOE) gene, implicated in Alzheimer’s disease.²⁶⁷ This biotechnology company prohibits any laboratories except its own to screen for mutations in that gene. Athena Neurosciences uses gene screening to determine whether a person carries the likelihood of Alzheimer’s disease.²⁶⁸ This clearly restricts access not only for potential research purposes but for potential patients. Second, Myriad Genetics received patents for two genes related to breast cancer; namely BRCA1 and BRCA2.²⁶⁹ This United States based company holds twenty-three patents on BRCA1 and BRCA2.²⁷⁰ The company approached private sector laboratories with the intent to license its patents and offer services to public clinics having expertise in the BRCA1 and BRCA2 testing.²⁷¹ This attempt of Myriad was met with little success, and by the late 1990’s, Myriad had licensed only thirteen laboratories in the United States where single mutation testing occurred.²⁷² Some physicians claim, “Myriad’s test misses some 10% to 20% of the expected BRCA mutations, and as a result, the patent is too broad.”²⁷³ It is unclear what downstream effects this may have caused for effective screening by other non-patent holding companies who could have entered the market if given clearer and freer access to the genes.

Consistent investment of private and public funds in research is an essential requirement to develop new diagnostic and treatment methods for various diseases. It can be argued that the patenting of medicines and innovative steps acts as an

267. Katie Skeehan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer Disease*, 12 GENETICS IN MED. 71, 71 (2010).

268. *Id.* at 73–74.

269. Gold & Carbone, *supra* note 21, at 39.

270. Meredith Wadman, *Arguments Heard in High-Profile Patent Case Against Myriad Genetics*, NATURE.COM (Apr. 4, 2011), http://blogs.nature.com/news/2011/04/arguments_heard_in_patent_case.html.

271. See Gold & Carbone, *supra* note 21, at 42. (summarizing Myriad’s attempt to position itself as a leading generic testing laboratory).

272. See *id.* at 45–49 (discussing the commercialization efforts of Myriad in both the public and private sectors).

273. Steven Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT’L CANCER INST. 80, 81 (2002).

incentive for investors to obtain returns.²⁷⁴ Numerous provisions in national and international law can ensure access to essential drugs. The next section examines various recommendations that may strengthen the Indian Patent Act to improve the access to healthcare for products of technology.

IV. RECOMMENDATIONS

Various provisions in patent legislation, many included in TRIPS, provide a way to balance the right of access to investment protections. This section analyzes these provisions as possible solutions to some of the issues raised above regarding access to health care and availability of information for research. The solutions considered relate to: (a) Non-Infringement of Patent Provision, (b) *Ordre Public*, and (c) Compulsory Licensing.

A. *Non-Infringement of Patent Provision*

Many scholars are of the opinion that the possibility of patent infringement, due to absence of rules providing for a research exemption in biotechnology, detracts from basic research.²⁷⁵ “Without the space and freedom to research, patients, doctors, and society at large are at the patentee’s mercy.”²⁷⁶ Hence, it is imperative to have an exemption clause clearly outlining the limits of such an exemption in the biotechnological context.²⁷⁷ Such an exemption clause not only provides researchers with a clear understanding of their rights, but also prevents the forestalling of significant medical

274. See Jensen & Murray, *supra* note 263, at 239 (asserting “the classic argument in support of gene patenting is that strong IP protection provides incentives crucial to downstream investment . . . and the disclosure of inventions.”).

275. Maureen E. Boyle, *Leaving Room for Research: The Historical Treatment of the Common Law Research Exemption in Congress and the Courts, and its Relationship to Biotech Law and Policy*, 12 *YALE J.L. & TECH.* 269, 302–03 (2010) (noting that since researchers cannot “invent around” specific genetic sequences, “[r]esearchers who wish to work on genetic therapy or diagnostic testing related to a patented gene fragment often cannot do so without infringing the patent”).

276. *Id.* at 273.

277. See *id.* at 272–73 (discussing the importance of exemption clauses in the judicial context).

research.²⁷⁸

However, such an exemption clause can be said to have been found in the public context in Article 27(2) of TRIPS which states “Members may exclude from patentability inventions, the prevention within their territory of 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, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”²⁷⁹ However, the Article does not, on its own, provide for the research exemption for private individuals, rather it allows state laws to do the same.²⁸⁰ Article 30 of TRIPS is also a well-known exemption, titled “Exceptions to Rights Conferred”, allowing for member states to “provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”²⁸¹

The patent laws of several European countries offer examples of exemption clauses. For example, the U.K. Patent Act provides for an experimental use exemption for private and non-commercial purposes as well as “for experimental purposes relating to the subject-matter of the invention.”²⁸²

India could likewise benefit from an exemption clause in its Patent Act to encourage research in pharmaceuticals and to protect patent holders. This would not stall biotechnology development and would enhance the possibility of finding new cures.

B. Ordre Public

TRIPS provides for two possible exceptions to patentability

278. *Id.* at 273.

279. TRIPS Agreement, *supra* note 24, art. 27(2).

280. *Id.* art. 27(1)–(2).

281. *Id.* art. 30.

282. The Patents Act 1977, 2011, c. 37, § 60(5)(b) (U.K.).

based on *ordre public* and morality.²⁸³ “The implementation of the exceptions, which must be provided under national law in order to be effective, means that a WTO member may, in certain cases, refuse to grant a patent when it deems it necessary to protect higher public interests.”²⁸⁴ “The term *ordre public*, derived from French law . . . expresses concerns about matters threatening . . . the structure of civil society.”²⁸⁵ The concept of morality relates to the values prevailing in a society, making it “inadmissible that patent offices grant patents to any kind of invention” without considering morality.²⁸⁶ Patents should be discouraged where they could potentially breach public peace or social order, or seriously endanger the environment.

Article 27(2) of TRIPS allows countries to refuse patents for inventions whose commercial exploitation would be against *ordre public* or morality.²⁸⁷ This includes and extends from situations where “human, animal or plant life or health” and the environment need protection.²⁸⁸ The European Patent Office considers an invention immoral if it may potentially offend the general public.²⁸⁹

The jurisprudence of the European Patent Office (EPO) distinguishes between *ordre public* and morality.²⁹⁰ Under the Guidelines for Examination of the EPO, *ordre public* relates to security issues, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behavior.²⁹¹ Thus, under the European Guidelines, an invention likely to generate public unrest or riots violates public morality.²⁹² The European community readily applies this concept in the context of biotechnology.²⁹³ Such a clause allows a

283. TRIPS Agreement, *supra* note 24, art. 27(2).

284. RESOURCE BOOK ON TRIPS, *supra* note 17, at 375.

285. *Id.*

286. *Id.*

287. TRIPS Agreement, *supra* note 24, art. 27(2).

288. RESOURCE BOOK ON TRIPS, *supra* note 17, at 376.

289. *Id.* at 379–80.

290. *Id.* at 379.

291. *Id.*

292. *Id.* at 379–80.

293. RESOURCE BOOK ON TRIPS, *supra* note 17, at 380 n.625 (discussing an

government to withhold patents over inventions, the commercialization of which could endanger public health.²⁹⁴ In its directives, the EPO considers certain inventions immoral and hence not a subject matter of patents.²⁹⁵ Section 53 of EPO consequently excludes any commercial exploitation from patentability, which may be contrary to *ordre public* or morality, thereby protecting the sentiments of the public.²⁹⁶

In principle, the “morality” exception could be used to deny patents to microorganisms. However, this could not be possible without simultaneously prohibiting any form of commercialization of a microorganism, a result that may not fit well with a government’s policy to fuel the growth of its biotechnology industry. The general requirements for patentability, which include ‘novelty’, ‘non-obviousness’, ‘utility’ and ‘written description’ can be adjusted to apply to applications for patents relating to microorganisms.²⁹⁷ Guidelines for examination of such patent applications, for example, can go a long way in making sure that only meritorious inventions are given patent protection.²⁹⁸ India can implement a specific clause of *ordre public* to ensure that inventions that offend moral sensitivity do not receive patents.

C. Compulsory Licensing

A compulsory license is a particular license granted to an individual or an entity by its government to grant permission to produce a patented product or use a patented process without the express consent of the patent owner.²⁹⁹ It is the subject of two major provisions in the TRIPS Agreement.³⁰⁰

TRIPS permits the issuance of compulsory licenses to third

instance when the EPO evaluated the morality of allowing a patent on an invention derived from genetic material of plants).

294. *Id.* at 376, 379–80.

295. *Id.* at 379–80.

296. See Convention on the Grant of European Patents, *supra* note 95, art. 53(a).

297. MASHELKAR ET AL., *supra* note 244, at 36.

298. *Id.*

299. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG. (Sept. 2006), http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

300. TRIPS Agreement, *supra* note 24, arts. 21, 31.

parties by governments; however, it contains safeguards to protect the interest of the original patent holders.³⁰¹ Governments can issue compulsory licenses in the case of “national emergency” or when the patented materials/processes are not being used for commercial purposes.³⁰²

India issued its first Compulsory License in 2012 in the *Bayer v. Natco case* for Bayer’s patented anti-cancer drug, sorafenib tosylate.³⁰³ This drug is used commonly to treat kidney and liver cancer.³⁰⁴ Section 84 in the Indian Patent Act contains a provision for compulsory licensing, in order to prevent patent abuse through monopoly, and for greater access to drugs by the public.³⁰⁵ The provision states that any person is eligible to apply for a compulsory license provided they had obtained a patent three years earlier,³⁰⁶ and is mirrored in several other countries.³⁰⁷ Section 92 of the Indian Patent Act provides for special provisions for compulsory licensing on notification by the central government³⁰⁸. Under Section 92, the government may opt to grant a compulsory license in the event that any of the following circumstances are satisfied: (1) national emergency; (2) extreme urgency; or (3) public non-commercial use³⁰⁹. Unlike Section 84, compulsory licenses awarded under Section 92 are at the behest of the government itself and are offered regardless of whether the license would negatively impact the patentee’s interests.³¹⁰ The main rationale for employing such a provision is to lower the price of generic drugs, and improve access of the

301. *Id.* art. 21.

302. *Id.* art. 31(b).

303. K.M. Gopakumar, *India Issues Compulsory License for Anti-Cancer Medicine*, THIRD WORLD NETWORK (Mar. 15, 2012), http://www.twinside.org.sg/title2/intellectual_property/info.service/2012/ipr.info.120304.htm.

304. *Id.*

305. *Id.*

306. THE PATENTS ACT, *supra* note 175, § 84(1).

307. *See, e.g.*, Ley de la Propiedad Industrial [Industrial Property Law], as amended, arts. 70, 77, 129, Diario Oficial de la Federación [DO], 25 de Junio de 1991 (Mex.); An Act to Amend the Patent Act and the Food and Drugs Act, R.S.C. 2004, c. C-9 (Can.); The Patents Act, 1977, 2011, c. 37, §§ 48–53 (Eng.).

308. THE PATENTS ACT, *supra* note 175, § 92.

309. *Id.* § 92(1).

public to other vital tests³¹¹. For example, in 2007 the government of Thailand created compulsory licenses for government use for the drug Kaletra, used to treat AIDS.³¹² Belgium, in 2005 adopted a compulsory license for the purpose of protecting public health.³¹³ In May 2012, China issued a compulsory licensing provision that will likely improve access to affordable drugs for people living with HIV/AIDS.³¹⁴ The Chinese government has been struggling to provide newer yet affordable HIV drugs to its population, such as the drug Viread, which is manufactured by pharmaceutical giant, Gilead Sciences Inc., and which had worldwide sales of \$737.9 million, in 2011.³¹⁵

International agreements and domestic law clearly authorize the government to continue to ensure low prices for medication by ensuring generic competition.³¹⁶ The government must routinely enact compulsory license patents on essential medicines to ensure drugs continue to be priced competitively in India.³¹⁷

V. CONCLUDING OBSERVATIONS

Technology has played a significant role in human progress. Now, the field of genetic technology offers the potential for the development of new diagnostic and pharmaceutical products for diseases affecting large populations in India. To make sure that these potential health-related benefits stemming from genetic research are easily accessible to the public, it has become

311. Dipika Jain & Jonathan Darrow, *An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India*, 23 HEALTH MATRIX (forthcoming 2013).

312. Decree of Department for Disease Control, Ministry of Public Health Regarding Exploitation of Patent on Drugs & Medical Supplies by the Government on Combination Drug Between Lopinavir & Ritonavir, Jan. 29, 2007 (Thai.).

313. GEERTRUI VAN OVERWALLE & ESTER VAN ZIMMEREN, *RESHAPING BELGIAN PATENT LAW: THE REVISION OF THE RESEARCH EXEMPTION AND THE INTRODUCTION OF A COMPULSORY LICENSE FOR PUBLIC HEALTH* 5–6 (2006).

314. Measures on Compulsory Licensing for Patent Exploitation, China Patent Agent (H.K.) Ltd., art. 6 (2012); Lyn, *supra* note 195.

315. Lyn, *supra* note 195.

316. *See supra* Part III.

317. *See supra* Part IV.C.

imperative to institute bold reforms in India's patent law regime.³¹⁸ In order to ensure that health benefits from genetic research are available and easily accessible, intrepid reforms in patent law in India surface as necessities.

This paper has examined India's legal regime on gene patenting and concluded that the Indian law currently provides for patenting of microorganisms. However, to avoid frivolous patenting, the patenting procedure under Indian law could effectively institute guidelines on gene/DNA patenting that delimit the scope of patent for microorganisms and prevent such patenting at the expense of public access. There is further a need to define the term microorganisms in the Indian Patent Act and the term 'genetically modified gene sequence' in the Manual of Patent Office Practice and Procedure, 2011 to ensure that no frivolous gene patents are granted by the Indian Patent Office. With regard to accessibility, Indian law must make use of the compulsory licensing provisions, both to ensure public access to affordable pharmaceuticals and to protect investment to encourage further research. The solutions offered in this paper should help improve the shortcomings of the current legal regime.

To ensure that the benefits of technology remain available to a large group of stakeholders, it is necessary to regulate biotechnology patenting through equitable means. The Indian government must aim to create a balance between public access to the pharmaceutical inventions. A comprehensive Patent Act that makes room for accommodating both the public interest as well as the interests of patent holders will go a long way towards making this a reality.

318. *See supra* Part IV.