

**COMPARISON OF THE IMPLEMENTATION
OF STATUTORY PATENT ELIGIBILITY
REQUIREMENTS APPLIED TO GENE
PATENTS IN THE EUROPEAN UNION, THE
UNITED STATES, AND AUSTRALIA**

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I. INTRODUCTION

Patents grant the right to exclude others from practicing a claimed invention—not the right to preclude others from using a “power in nature . . . open to all.”² As science has advanced our understanding of the natural world, the definition of patent eligible subject matter has had to evolve to balance incentives for innovation with the greater public good.³ Under the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) Agreement, member states are left to their own devices to define patent eligible subject matter.⁴ In the European community, legislation has defined the limits on patentability and has been strictly applied.⁵ On the other hand, the evolution in the United States and Australia has primarily occurred through case law in attempts to formulate a rule for patentability.⁶

Patents are “pillars” of the modern biotechnology industry, which requires adequate protection for future

² *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853).

³ *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (stating that “patent protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention’”).

⁴ *See infra* Part III.

⁵ *See infra* Section I.A.

⁶ *See infra* Section I.B–C.

success.⁷ While steps are in process, harmonization of patentability criteria serves the goals of protection and dissemination of knowledge on an international level.⁸ This article analyzes patent statutes and case law on patent eligibility of DNA and complementary DNA (“cDNA”) in the European Union, the United States, and Australia, and the potential impact of harmonizing these three systems in the international patent community.

II. STATUTORY BACKGROUND ON PATENT ELIGIBLE SUBJECT MATTER

A. *The European Union*

The European patent system operates under the European Patent Convention (“EPC”),⁹ in which Article 52 defines patentability.¹⁰ Article 52(1) states that “European patents shall be granted for any inventions which are susceptible of industrial application, which are new, and which involve an inventive step.”¹¹ This language is analogous to the patentability requirements encompassed in

⁷ Joseph Straus, *Biotechnology and Patents*, 54 CHIMIA INT’L J. CHEMISTRY 293, 293 (2000).

⁸ OLIVER MILLS, *BIOTECHNOLOGICAL INVENTIONS: MORAL RESTRAINTS AND PATENT LAW* 81 (Ashgate Publ’g Co. 2010).

⁹ Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 270 (1973) [hereinafter EPC] (A procedural agreement that allows applicants to apply through the European Patent Office to receive multiple national patents for each member state of the EPC).

¹⁰ EPC, *supra* note 9, art. 52, at 285.

¹¹ EPC, *supra* note 9, art. 52(1), at 285.

the United States statutes for patent eligible subject matter.¹² However, the EPC statutorily narrows patentability in Article 52(2) defining mathematical models, aesthetic creations, and presentations of information as unpatentable.¹³ Furthermore, Article 53 categorically excludes from patentability “inventions the commercial exploitation of which would be contrary to ‘ordre public’ or morality,” “plant or animal varieties, or essentially biological processes,” methods for the treatment of humans or animals, and diagnostic methods practiced on humans or animals.¹⁴

B. The United States

The statutory basis for patent eligible subject matter in the United States is 35 U.S.C. § 101, which states, “[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 therefor.”¹⁵ Historically, most inventions have easily satisfied these requirements. For example, pharmaceutical compounds may be considered a composition of matter or an article of manufacture. However, fitting within these categories does not necessitate a finding of patentability. U.S. courts have struggled to answer the more difficult question of whether a particular type of invention is within Congress’s contemplation of the patent system. The Constitution dictates that patents should be granted only for

¹² See 35 U.S.C. §§ 101–103 (2015) (requiring that an invention be a process, machine, manufacture, or composition of matter that is new, useful, and non-obvious).

¹³ EPC, *supra* note 9, art. 52(2), at 285.

¹⁴ EPC, *supra* note 9, art. 53 (as in effect 2001).

¹⁵ 35 U.S.C. § 101 (2015).

inventions that are within the “useful arts,”¹⁶ and therefore, a law of nature, an abstract principle, a natural phenomenon, or a mental step is viewed as outside of the reach of this purpose.¹⁷

C. Australia

The Australian Patents Act¹⁸ defines the “essential characteristics of a ‘patentable invention.’”¹⁹ Section 18(1)(a) provides: “Subject to subsection (2), a patentable invention is an invention that, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section

¹⁶ U.S. CONST. art. I, § 8, cl. 8. (“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”).

¹⁷ See *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853) (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”); see also *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

¹⁸ Patents Act 1990 (Cth) s 18 (Austl.).

¹⁹ *N V Philips Gloeilampenfabrieken v Mirabella Int’l Pty Ltd* (1995) 183 CLR 655, 659 (Austl.).

of the *Statute of Monopolies*.^{20, 21} This section further limits patentable inventions, barring patents on “[h]uman beings, and the biological processes for their generation,” completely.²² Additionally, “plants and animals, and the biological processes for the generation of plants and animals,” are not patentable inventions;²³ however, this section does not apply if the invention is a microbiological process or is a product of that process.²⁴

III. TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT

TRIPS itself does not expressly disallow any biotechnology industry; therefore, patentability of inventions such as gene sequences and embryonic stem cells are left to the individual countries. Article 27 mandates that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field

²⁰ English Statute of Monopolies of 1623, 21 Jac. 1, c. 3 (1624)

(That any declaration before mentioned shall not extend to any letters patents and grants of privilege for the term of fourteen years or under, hereafter to be made of *the sole working or making of any manner of new Manufacturers* within this realm, to the true and first inventor and inventors of such manufacturers, which others at the time of making such letter patents and grants shall not use, so as also they be not contrary to the law nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient.) (emphasis added).

²¹ Patents Act, *supra* note 18, s 18(1)(a) (Section 18(1)(b)–(d) discusses other requirements of patentability—novelty, inventive step, usefulness, and no secret user before the priority date).

²² *Id.* s 18(2).

²³ *Id.* s 18(3).

²⁴ *Id.* s 18(4).

of technology and whether products are imported or locally produced.”²⁵ This means that all TRIPS member states must allow patents on some level for biotechnology and cannot expressly forbid them as a technological field, while participant countries can influence and control the patents issued based on national legislation and decisions by patent offices and courts of law.

The positions of the European Union, the United States, and Australia on the patentability of DNA implicate TRIPS. Because all three nations are member states to the TRIPS Agreement,²⁶ each is bound by it. The legislation in the European Union was adopted after the ratification of TRIPS in 1996²⁷ and closely mirrors the language in TRIPS, reducing the risk of violation of Article 27.²⁸ In comparison, the United States’ and Australia’s decisions on the unpatentability of DNA and cDNA raises the question of whether gene patents are being discriminated against based on the field of technology.

However, Article 27 is not without exceptions. Subsection 2 of Article 27 delineates that, “[m]embers may exclude from patentability inventions, the prevention within

²⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art. 27(1), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 33 I.L.M. 1126 (1994) [hereinafter TRIPS], http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [<https://perma.cc/UX8T-M5BZ>].

²⁶ *Members Accepting Amendment of the TRIPS Agreement*, WORLD TRADE ORGANIZATION (Oct. 2, 2015), https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [<https://perma.cc/DLX6-5XNP>].

²⁷ Directive 98/44/EC, of the European Parliament and of the Council of July 6, 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213), 13 [hereinafter Directive].

²⁸ TRIPS, *supra* note 25, art. 27(2).

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.”²⁹ Furthermore, subsection 3 permits member states to exclude from patentability “(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals” and “(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.”³⁰ Again, the TRIPS language is echoed in the European Union’s law. Furthermore, this language may relieve the tension between Article 27(1) and the United States’ and Australia’s positions on excluding DNA and cDNA as patentable subject matter.

The broad language of the TRIPS Agreement allows member states to develop their own legislation and case law to establish the patentability of genes and other biotechnological products.³¹ These disparities create legal conflicts both between member states and between patent holders and their respective governments. Additionally, under TRIPS, legal conflicts can only be challenged by individual member states, thus, precluding an individual patent holder from filing an action with the World Trade Organization, against a member state, for breach of the

²⁹ *Id.*

³⁰ *Id.* art. 27(3)(a)–(b) (Subsection (b) further provides, “[m]embers shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.”).

³¹ *See id.* arts. 27–38 (identifying the minimum standards that member-states must adhere to in order to provide sufficient patent standards).

TRIPS Agreement.³² The TRIPS Agreement only obligates member states to comply with a basic set of intellectual property rights that encourages heightened user protections at the national level.³³ But the Agreement provides no options to reduce or eliminate any of the basic TRIPS protections. The problems faced by individual member states are emblematic of issues that occur between member states as incongruent national intellectual property laws are enacted, amended, and re-codified worldwide under the wide umbrella of the TRIPS Agreement.³⁴

IV. ANALYSIS

D. The European Union's, the United States', and Australia's Implementation of Statutory Requirements of Patentability

1. The European Union—Strict Application

In an effort to harmonize European Union member

³² *Id.* art. 64 (outlining dispute settlement procedures involving member states only).

³³ *Id.* art. 27(2)–(3) (identifying permissible limitations on patentable subject matter at the national level); Rochelle Cooper Dreyfuss, *TRIPS Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21, 21 (2004) (arguing that the TRIPS Agreement encourages countries to expand patent rights, but makes them susceptible to a WTO challenge for any reduction of protections provided for in the TRIPS Agreement).

³⁴ *See, e.g.,* Q. Todd Dickinson, *Patentable Subject Matter: The Debate Reignites – Or Did It Ever Really Go Away?*, LANDSLIDE, Nov.–Dec. 2008, at 30, 35 (identifying skepticism regarding the expansion of patentable materials in India and Brazil); Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 89 (2007) (confirming that TRIPS “left ample room for national variations and approaches”).

states' laws in the area of biotechnology, the EPC adopted EU Directive 98/44/EC ("Directive") on the legal protection of biotechnological inventions.³⁵ The Directive has been implemented by all European Union member states.³⁶ As early as 1999, the EPC contracting states decided to incorporate the Directive as secondary legislation into the Implementing Regulations to the EPC.³⁷ Together with the EPC articles on substantive patent law,³⁸ these rules now provide the basis for decisions on the patentability of biotechnology applications at the European Patent Office.

In the Directive, it was expressly stated that the then-current national or European patent laws did not prohibit biological matter as patentable subject matter.³⁹ The authors of the Directive, conscientious of the controversy over gene sequences and partial sequences, were of the opinion that such patents should not be subject to criteria any different from that of any other area of technology and that patent eligibility should turn on novelty, an inventive step, and the

³⁵ Directive, *supra* note 27.

³⁶ Member States of the European Patent Organisation, EUROPEAN PATENT OFFICE (Sept. 7, 2015), <http://www.epo.org/about-us/organisation/member-states.html> [<https://perma.cc/9TST-8S3K>].

³⁷ Implementing Regulations to the Convention on the Grant of European Patents, Oct. 5, 1973, as adopted by decision of the Administrative Council of the European Patent Organisation, Dec. 7, 2006, as amended by decision of the Administrative Council of the European Patent Organization, June 27, 2012, European Patent Office (15th ed. Sept. 2013), *available at* [http://documents.epo.org/projects/babylon/eponet.nsf/0/00E0CD7FD461COD5C1257C060050C376/\\$File/EPC_15th_edition_2013.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/00E0CD7FD461COD5C1257C060050C376/$File/EPC_15th_edition_2013.pdf) [<https://perma.cc/6EE7-NYYE>].

³⁸ *See supra* Part I.A.

³⁹ Directive, *supra* note 27, art. 15.

industrial application.⁴⁰ Specifically, relating to gene patents, the Directive affirmed that isolated biological material is patentable “even if it previously occurred in nature.”⁴¹ Rule 23(e)(2) states: “An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.”⁴² It also confirmed that “plants or animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.”⁴³ Furthermore, an invention relating to gene sequences can be patented as long as “[t]he industrial application of a sequence or a partial sequence of a gene [is] disclosed in the application” and all other patentability criteria are fulfilled.⁴⁴

However, the Directive rules out the patenting of the entire human body in all its developmental phases.⁴⁵ The same rule applies to processes for cloning human beings, processes for modifying the germ-line genetic identity of human beings, and the use of human embryos for industrial or commercial purposes, *e.g.*, a genetic modification.⁴⁶ Also excluded from patentability are processes for modifying the genetic identity of animals, which processes are likely to cause suffering without any substantial medical benefit to

⁴⁰ *Id.* art. 22.

⁴¹ EPC, *supra* note 9, Rule 27(a) (as in effect 2001).

⁴² *Id.* Rule 29(2).

⁴³ *Id.* Rule 27(b).

⁴⁴ *Id.* Rule 29(3); *see also id.* Rule 30 (describing the application requirements for patenting genome sequences).

⁴⁵ EPC, *supra* note 9, Rule 29(1) (as in effect 2001).

⁴⁶ *Id.* Rule 28; Directive, *supra* note 27, ¶ 32.

man or animal.⁴⁷ These categorical exceptions to patentability are not exhaustive.⁴⁸

The European Patent Office relies heavily on the text of the Directive in determining patentable subject matter. For example, the Board of Appeal of the European Patent Office held that the EPC and the Directive support the patentability of DNA in its decision based on Myriad Genetics’⁴⁹ European patents encompassing DNA sequences and screening methods relating to genes associated with a greater risk of developing breast and ovarian cancers (“BRCA” genes).⁵⁰ Opponents in the suit⁵¹ argued that the BRCA sequences occur in nature and are therefore a discovery rather than an invention.⁵² The Board cited Rule 23(e)(2) of the EPC in determining that the sequence was an isolated element of the human body, and thus is patentable

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ See *infra* notes 79–89 and accompanying text (discussing the *Myriad* case in the United States).

⁵⁰ Case T 1213/05 - 3.3.04, Univ. Utah Research Found. v. Sozialdemokratische Partei der Schweiz (Sept. 27, 2007) (European Patent Office, Board of Appeals) (holding the subject-matter of claim 1 of European Patent No. 0,705,902, as amended, to involve an inventive step. Claim no. 1, as amended, reads: “An isolated nucleic acid which comprises a coding sequence for the human BRCA1 polypeptide . . . said coding sequence comprised in a cDNA.”), available at <http://www.epo.org/law-practice/case-law-appeals/pdf/t051213eu1.pdf> [<https://perma.cc/5F5H-S5N5>].

⁵¹ See *id.* (oppositions filed by Switzerland’s Social Democratic Party; Greenpeace Germany; the French Institut Curie; Assistance Publique-Hôpitaux de Paris; the Belgian Society of Human Genetics; the Netherlands, represented by the Ministry of Health; and the Austrian Federal Ministry of Social Security).

⁵² *Id.* ¶ 43.

subject matter and should not be excluded as a discovery.⁵³

Opponents also argued that the patent violated the “*ordre public*” or morality provision of EPC Article 53(a) because there was no proof that the donors of the cells used to identify the BRCA sequence had given informed consent.⁵⁴ The Board found that the EPC does not contain any provision requiring proof of informed consent of donors to satisfy the morality clause of Article 53.⁵⁵ Specifically, Recital 26 of the Directive states: “Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.”⁵⁶ Therefore, the legislature has not provided for a procedure of verifying the informed consent in the framework of biotechnological patents under the EPC.⁵⁷

Lastly, the Opponents argued that the Board should consider the socio-economic consequences of patenting DNA under Article 53(a).⁵⁸ Opponents pointed out that gene patenting would not only result in increased costs for

⁵³ *Id.* ¶ 45.

⁵⁴ *Id.* ¶ 47.

⁵⁵ *Id.* ¶ 48.

⁵⁶ Directive, *supra* note 27, art. 26.

⁵⁷ See Case C-377/98, *Netherlands v. Parliament & Council*, 2001 E.C.R. I-7079, <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-377/98> [<https://perma.cc/69Z5-5M5L>] (finding that the reliance on the fundamental right of human integrity was “clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products”).

⁵⁸ Case T 1213/05 - 3.3.04 ¶ 52.

patients, but would also influence the way in which diagnostics and research would be organized in the EU, claiming this effect would “be clearly to the detriment of patients and doctors.”⁵⁹ The Board rejected this argument based on the text of Article 53(a).⁶⁰ The text of Article 53 refers to the exploitation of *the invention*, not the exploitation of the patent.⁶¹ While the Board recognized the sensitivity of public health argument, it found no basis to depart from the plain language of the EPC.⁶² Looking to the resolution of the European Parliament for “Patents on Biotechnological Inventions,”⁶³ the Board determined that the Resolution contains no suggestion that the EPO is vested with the task of taking into account the socio-economic effects of the grants of patents in a specific area and restricting the field of patentable subject matter accordingly.⁶⁴ Thus, the Board strictly applied the text of the Directive in concluding that the Myriad patent claiming DNA and cDNA is patent eligible under the Article.⁶⁵

2. The United States—A Thin Line

Specifically applicable to the biotechnology

⁵⁹ *Id.*

⁶⁰ *Id.* ¶ 53.

⁶¹ *Id.*

⁶² *Id.*

⁶³ EUR. PARL. DOC. (COM P6_TA(2005)0407) ¶ 5 (2005) (“Calls on the European Patent Office and the Member States to grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other users can use and patent the same DNA sequence for other applications (purpose-bound protection).”).

⁶⁴ Case T 1213/05 - 3.3.04 ¶ 55.

⁶⁵ *Id.* ¶¶ 56–57.

industry, United States courts have long established that a product of nature, such as a chemical element or biological substance found in its natural state, is not patentable.⁶⁶ For example, the Supreme Court ruled that the discovery of properties of a bacterium is “no more than the discovery of some of the handiwork of nature.”⁶⁷ The Supreme Court in *Diamond v. Chakrabarty* held that a living, human-made microorganism was patent eligible subject matter not barred by the natural phenomenon exception because it was “a product of human ingenuity.”⁶⁸ The *Chakrabarty* Court held that § 101 should be given broad construction to effectuate patent law’s purposes.⁶⁹ Regarding products of nature, the *Chakrabarty* Court instructed that the proper analysis is between products of nature, which are unpatentable, and human-made living things, which are patentable under § 101.⁷⁰

The Supreme Court has acknowledged that inventions in the biotechnology field deserve consideration as *applications* of the laws of nature despite the § 101 statutory limitations. The Court further refined the patentability of inventions derived from nature in *Diamond*

⁶⁶ *General Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642 (3d Cir. 1928) (citing *U.S. Indus. Chem. Co. v. Theroz Co.*, 25 F.2d 387, 389 (4th Cir. 1928)).

⁶⁷ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

⁶⁸ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

⁶⁹ *Id.* at 308–09 (quoting 5 Writings of Thomas Jefferson 76 (Washington ed. 1854)); *see also* S. REP. NO. 82-1979, at 5 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2399 (demonstrating Congress’s intent that statutory subject matter encompasses “anything under the sun that is made by man”).

⁷⁰ *Chakrabarty*, 447 U.S. at 309.

v. Diehr.⁷¹ The *Diehr* Court recognized that an *application* of a law of nature or mathematical formula encompassing that law of nature to a known structure or process may well be deserving of patent protection under § 101.⁷² Noting that a mathematical formula or law of nature in the abstract cannot be the subject of a patent, the *Diehr* Court held that a claim containing a mathematical formula may nevertheless satisfy the statutory requirements of patent eligible subject matter. In particular, it held that, if a claim implements or applies a mathematical formula in a structure or process which, when considered as a whole, performs a function that the patent laws were designed to protect—*e.g.*, transforming or reducing an article to a different state or thing—then the claim satisfies the statutory requirements for patentable subject matter.⁷³

However, this deserving nature of patents cannot overtake the principle that patent law should not inhibit future discovery by “improperly tying up the future use of laws of nature.”⁷⁴ The Supreme Court in *Mayo* expressed the concern that rewarding patents to those who discover laws of nature might encourage their discovery, but because those laws and principles are “the basic tools of scientific and technological work,” there is a danger that granting patents that tie up their use will inhibit future innovation, a danger that becomes acute when a patented process is no

⁷¹ 450 U.S. 175 (1981).

⁷² *Id.* at 183–84 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787–88 (1877)).

⁷³ *Id.* at 184.

⁷⁴ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301 (2012); *see also* *Gottschalk v. Benson*, 409 U.S. 63 (1972) (equating the preemption of a mathematical law or law of nature to claiming an abstract idea).

more than a general instruction to “apply the natural law.”⁷⁵ The *Mayo* Court set forth an analysis that, to be patent eligible subject matter under § 101, a patent must do more than simply state of the law of nature with the words “apply it;” rather it must limit the scope of the patent to a particular, inventive application of the law.⁷⁶

This jurisprudence set the framework for the Supreme Court’s decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,⁷⁷ shifting the test for patent eligibility into the biotechnology field.⁷⁸ *Myriad* involved multiple patents encompassing DNA sequences and screening methods relating to the BRCA genes associated with a greater risk of developing breast and ovarian cancers.⁷⁹ The claims in dispute asserted patent rights on the DNA code that tells a cell to produce the string of BRCA amino acids⁸⁰ as well as isolated segments of the corresponding cDNA code.⁸¹ The Supreme Court noted that, if held valid, these claims would give Myriad the exclusive right to isolate an individual’s BRCA genes and to

⁷⁵ *Mayo Collaborative Servs.*, 132 S. Ct. at 1301.

⁷⁶ *Id.* at 1294, 1300.

⁷⁷ 133 S. Ct. 2107 (2013).

⁷⁸ See Stephen H. Schilling, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731, 741 (2011) (critiquing the *Myriad II* decision for failing to take into consideration the incentive-to-invent function of the patent system).

⁷⁹ *Myriad Genetics, Inc.*, 133 S. Ct. at 2112–13.

⁸⁰ U.S. Patent No. 5,747,282 (filed June 7, 1995) (Claim 1 reads: “An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.”).

⁸¹ *Id.* (Claim 5 reads: “An isolated DNA having at least 15 nucleotides of the DNA of claim 1.”).

synthetically create BRCA cDNA.⁸²

In light of *Mayo*, the Court of Appeals for the Federal Circuit found both the isolated DNA and cDNA patents eligible under § 101.⁸³ In its analysis, the Supreme Court disagreed with the Federal Circuit and stated that Myriad’s DNA claim fell within the laws of nature exception as the principal contribution was uncovering the precise location and genetic sequence of the BRCA genes.⁸⁴ The Court stressed that the company did not create or alter either the genetic information encoded in the BRCA genes or the genetic structure of the DNA.⁸⁵ The Court noted that the company found an important and useful gene, but “[g]roundbreaking, innovative, or even brilliant discovery did not by itself satisfy the § 101 inquiry.”⁸⁶ Thus, the Court held that Myriad’s DNA claim was a naturally occurring product or law of nature and not patent eligible.⁸⁷ However, the Court concluded that the claims for cDNA did not pose the same issues⁸⁸—the creation of a cDNA sequence resulted in an exon-only molecule that was not naturally occurring and is therefore patentable.⁸⁹

⁸² *Myriad Genetics, Inc.*, 133 S. Ct. at 2113.

⁸³ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1328–29 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

⁸⁴ *Myriad Genetics, Inc.*, 133 S. Ct. at 2117–19.

⁸⁵ *Id.* at 2116.

⁸⁶ *Id.* at 2117.

⁸⁷ *Id.*

⁸⁸ *Id.* at 2119.

⁸⁹ *Id.*

3. Australia—None of the Above

As codified in the Australia Patents Act,⁹⁰ Australian common law laid out the requirement for patentability that the invention must be a “manner of manufacture” within the meaning of section 6 of the *Statute of Monopolies*.⁹¹ The seminal case, “*National Research Development Corporation v Commissioner of Patents* (“NRDC”), held that the terminology of ‘manner of manufacture’ taken from s[ection] 6 of the *Statute of Monopolies* was to be treated as a concept for case-by-case development.”⁹² This analysis was set forth to allow a “widening conception of the notion [of patentable inventions —] a characteristic of the growth of patent law.”⁹³ This analysis has been narrowed to consider the economic factors inherent in granting the exclusive right of a patent⁹⁴ consistent with the objectives of Australian common law described as “the encouragement of industry, employment, and growth, rather than justice to the ‘inventor’ for his intellectual percipience.”⁹⁵ The application of a naturally occurring phenomenon to a

⁹⁰ See also Patents Act, *supra* note 18.

⁹¹ See *supra* note 20.

⁹² *D’Arcy v Myriad Genetics Inc* [2015] HCA 35 ¶ 5 (Austl.) (citing *Nat’l Research Dev Corp v Comm’r of Patents* (1959) 102 CLR 252, 269 (Austl.) [hereinafter *NRDC*]).

⁹³ *NRDC* (1959) 102 CLR at 270.

⁹⁴ See *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260, 295 (Austl.) (stating that the *NRDC* case “requires a mode or manner of achieving an end result which is an artificially created state of affairs of utility in the field of economic endeavour”).

⁹⁵ *D’Arcy* [2015] HCA 35 ¶ 26 (quotations in original) (quoting WILLIAM CORNISH ET AL., *INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADE MARKS AND ALLIED RIGHTS* § 3-05 (Sweet & Maxwell, 8th ed. 2013)).

particular use may be a manner of manufacture, if it amounts to a new process or method of bringing about an artificially created state of affairs of economic significance.⁹⁶

The Australian courts have also dealt with the question of whether DNA is patent eligible as in Myriad’s BRCA claims.⁹⁷ In this case, the Full Court of the Federal Court of Australia concluded that the isolated nucleic acids, including cDNA, had resulted in an artificially created state of affairs for economic benefit—the treatment of breast and ovarian cancers—and therefore was patent eligible as a manner of new manufacture.⁹⁸ The Full Court recognized that there is “no statutory or jurisprudential limitation of patentability to exclude ‘products of nature;’” therefore, the court determined that the Myriad patent claimed a product different to the nucleic acid sequence as it exists in nature.⁹⁹

The High Court disagreed, holding that isolated, naturally occurring DNA is not eligible for patent protection.¹⁰⁰ The High Court determined that the long term *NRDC* test for patent eligibility is to be used only as a guide

⁹⁶ *NRDC* (1959) 102 CLR at 277; see also *D’Arcy* [2015] HCA 35 ¶ 137 (Gageler and Nettle, JJ., concurring) (“[I]nsofar as the invention consists in the application of a naturally occurring phenomenon to a particular use, the inventor cannot claim to have invented the naturally occurring phenomenon as opposed to the method of use and has no claim to a monopoly over the naturally occurring phenomenon as opposed to the method of use.”).

⁹⁷ See *D’Arcy* [2015] HCA 35 ¶ 6 (stating claim 1 is in dispute). Claim 1 recites: “An isolated nucleic coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.1 . . .” Austl. Patent No. 686,004 claim 1 (filed Aug. 11, 1995).

⁹⁸ *D’Arcy v Myriad Genetics Inc* (2014) 224 FCR 479 ¶ 214 (Austl.), *rev’d*, [2015] HCA 35.

⁹⁹ *Id.* ¶¶ 207, 213.

¹⁰⁰ *D’Arcy* [2015] HCA 35 ¶¶ 94–95.

and not a rule.¹⁰¹ Moreover, the High Court indicated that a range of other factors should be considered in determining patentable subject matter:

1. Whether the invention as claimed is for a product made, or a process producing an outcome as a result of human action.
2. Whether the invention as claimed has economic utility.
3. Whether patentability would be consistent with the purposes of the [Patent] Act and, in particular:
 - 3.1. whether the invention as claimed if patentable under [section] 18(1)(a), could give rise to a large new field of monopoly protection with potentially negative effects on innovation;
 - 3.2. whether the invention as claimed, if patentable under [section] 18(1)(a), could, because of the content of the claims, have a chilling effect on activities beyond those formally the subject of the exclusive rights granted to the patentee;
 - 3.3. whether to accord patentability to the invention as claimed would involve the court in assessing important and conflicting public and private interests and purposes.
4. Whether to accord patentability to the invention as claimed would enhance or detract from the coherence of the law relating to inherent patentability.
5. Relevancy to Australia's place in the international community of nations:
 - 5.1. Australia's obligations under international law;
 - 5.2. the patent laws of other countries.
6. Whether to accord patentability to the class of invention as claimed would involve law-making

¹⁰¹ Tania Obranovich, *Patent Eligibility in Australia: The Winding Road Ahead*, LIFE SCIENCES INTELL. PROP. REV. (Oct. 22, 2015), <http://www.lifesciencesipreview.com/article/patent-eligibility-in-australia-the-winding-road-ahead> [<https://perma.cc/7GRE-JH6L>].

of a kind which should be done by the legislature.¹⁰²

These factors embody the essential requirement that the subject matter of a claim have a “quality of inventiveness which distinguishes it from a mere discovery or observation of a law of nature.”¹⁰³ Furthermore, the correct analysis for patent eligibility should “focus on the true nature of the characteristics of the invention and thereby consider the substance of the invention rather than its form.”¹⁰⁴

In applying this test to *Myriad’s* BRCA DNA claims, the High Court determined the essential element of the invention was the coding information, *i.e.*, the sequence of nucleotides which enables a polypeptide to be generated and which is diagnostic of breast cancer.¹⁰⁵ The High Court held that this information was the same, as it exists in the body and was not “made” but rather “discerned” from nature and therefore is not patent eligible.¹⁰⁶ Furthermore, the High Court held that cDNA is also patent-ineligible finding that the nucleotides of cDNA are in the same sequence as in genomic DNA and the removal of the introns is irrelevant where the sequence of exons is the same.¹⁰⁷

4. Comparison

Applying their own statutory requirements and developed jurisprudence, the European Union, the United

¹⁰² *D’Arcy* [2015] HCA 35 ¶ 28.

¹⁰³ *Id.* ¶ 131 (Gageler and Nettle, JJ., concurring).

¹⁰⁴ Obranovich, *supra* note 101.

¹⁰⁵ *D’Arcy* [2015] HCA 35 ¶ 90.

¹⁰⁶ *Id.* ¶¶ 6, 91.

¹⁰⁷ *Id.* ¶ 89 (explaining that cDNA effectively replaces a naturally occurring sequence of exons, despite the fact that exons do not naturally exist in DNA form in a continuous sequence).

States, and Australia have reached different conclusions as to the patentability of DNA. The European Union strictly applies the text of Article 53 of the EPC and the Directive in determining patent eligibility.¹⁰⁸ Unlike the European Union's Directive and resulting decisions, the United States and Australian legislature has left this determination up to the courts. This discrepancy between the United States and Australian common law in comparison to the European Union's legislation signifies the differences in how the law developed in each country, though both the United States and Australian patent laws originate from Europe.¹⁰⁹ In particular, the European Union was compelled to harmonize the patent laws of the member states of the Union, while the United States and Australia developed their jurisprudence through the decisions of their respective high courts. Therefore, it is not surprising that the European Union decided to adopt the language of TRIPS almost verbatim when establishing the EPC. Since the European Union was already obligated under TRIPS, the European member states could have no qualms with that language as it already applied to them.

In comparison, the United States' and Australian statutory requirements for patentability pre-date TRIPS. Rather than adopting explicit legislation, the United States and Australia advance their patent eligibility rules predominantly through case law. Unlike the European Union, the United States and Australia are freer to develop jurisprudence without disrupting the patentability requirements of other member states. Both the United States and Australia have ruled that isolated DNA sequences are

¹⁰⁸ *See supra* Part IV.A.

¹⁰⁹ *See generally* AMY L. LANDERS, UNDERSTANDING PATENT LAW, 2–11 (LexisNexis, 2d ed. 2012) (explaining the history and origins of the patent right).

not patent eligible.¹¹⁰ This is unsurprising as “[t]he US product of nature test and the Australian test of artificially created state of affairs are the same questions asked from different perspectives . . . [N]ature and artifice are flip sides of the same coin.”¹¹¹ Furthermore, both the United States and Australia focus on the substance of the claim over form.¹¹² In comparison, the Directive has explicitly adopted DNA as patentable¹¹³ and upholds this finding through its common law.

The succession of the decisions on Myriad’s patent in the European Union, the United States, and Australia is perhaps indicative of a modern trend toward excluding DNA and other biotechnology from patentability. Members of the Australian High Court recognized the similarities of its common law with that of the United States by examining the Supreme Court’s *Myriad* ruling closely in its decision.¹¹⁴ Again, this is unsurprising because of the similarities in the asserted claims; however, members of the High Court expressly declined to consider the Directive on the matter even when both parties argued on the basis of European Union’s practice.¹¹⁵ Arguably, even though the claim

¹¹⁰ See *supra* Parts I.A.2, I.A.3 and accompanying notes.

¹¹¹ Brad Sherman, *D’Arcy v Myriad Genetics, Inc.: Patenting Genes in Australia*, 37 SYDNEY L. REV. 135, 141 (2015).

¹¹² See *D’Arcy v Myriad Genetics Inc* [2015] HCA 35 ¶ 144 (Austl.) (Gageler and Nettle, JJ., concurring) (“The way in which a claim is drafted cannot, however, transcend the reality of what is in suit.”).

¹¹³ Implementing Regulations, *supra* note 37, Rule 29(2).

¹¹⁴ *D’Arcy* [2015] HCA 35 ¶ 79 (Austl.).

¹¹⁵ *Id.* at ¶ 170 (Gageler and Nettle, JJ., concurring) (“The structure and prescriptive detail of European patent legislation in its application to biotechnology and genetic engineering are such that the resolution of the controversy could provide little assistance in determining whether the claim is a proper subject for letters patent according to the principles

language was almost identical between the three cases, the High Court was more amenable to adopting the United States' determination because of the similarities in their jurisprudence and because of the timing of the Supreme Court's decision only a few years earlier. Notably, however, the Australian factor test articulated by the High Court is the only instance identified by this Author where TRIPS and obligations under international law were expressly considered in a patentability determination.

However, the United States and Australian jurisprudence significantly differ on the patentability of cDNA. The United States' determination that cDNA is patent eligible is more similar to the Directive adopting cDNA along with DNA as patentable subject matter. The Supreme Court in *Myriad* rejected the argument that cDNA is naturally occurring simply without the introns, or non-coding regions, of the sequence.¹¹⁶ While the Court recognized that the "nucleotide sequence is dictated by nature, not by the lab technician,"¹¹⁷ the Court determined that the removal of the introns nevertheless created something new and distinct from the DNA from which it was derived.¹¹⁸ In comparison, the Australian High Court expressly rejected cDNA as patentable on this very argument, holding that the removal of the introns failed to create a patentable invention.¹¹⁹ The High Court came to the opposite conclusion finding that the sequence of the coding

which have been developed for the application of s[ection] 6 of the *Statute of Monopolies*.").

¹¹⁶ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (Fed. Cir. 2013).

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 ¶ 89 (Austl.).

regions, *i.e.*, the exons, was the part of the genome that enabled the generation of a polypeptide and was therefore the substance of the DNA regardless of whether it was in the full sequence of DNA or truncated sequence of cDNA.¹²⁰ These decisions mark a significant divergence in United States and Australian patent law regarding patent eligibility of cDNA. Both courts tout the importance of recognizing substance over form when it comes to a patentability analysis yet come to a different conclusion on this issue; we will see which decision stands the test of time regarding the patent eligibility for products of nature.

E. Policy Considerations

While the very status of genes as valid patentable subject matter is controversial,¹²¹ the silence of TRIPS on the subject has serious consequences.¹²² Many advocate that the failure of TRIPS to expressly exclude gene patenting creates significant barriers to innovation in the biotechnology industry and furthermore injures consumers

¹²⁰ *Id.*

¹²¹ See Tania Simoncelli, *Should You Be Able to Patent A Human Gene?*, TED (Nov. 2014) http://www.ted.com/talks/tania_simoncelli_should_you_be_able_to_patent_a_human_gene [<https://perma.cc/4DFL-K8EY>]; see generally Donald J. Willison & Stuart M. MacLeod, Commentary, *Patenting of genetic material: Are the benefits to society being realized?*, 167 CAN. MED. ASS'N J. 259 (2002) (clarifying that while patenting life is a contentious idea, it is “well established in law”).

¹²² See Cydney A. Fowler, *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 AM. U. INT'L L. REV. 1073, 1088–89 (2010) (“The TRIPS Agreement’s failure to exclude genetic material from patentability thwarts research and has a detrimental effect on consumer prices for products produced using patented genes.”).

by allowing patent-created monopolies.¹²³ In addition to the continuing questions about patenting inventions derived from the human genome, the line of *Myriad* cases raises concerns about the potentially limiting effects of the patents on further research, on the development of new tests and diagnostic methods, and on access to testing. While the considerable medical benefits of the cancer screening technology are not in dispute, there are differing views about how the patent system should recognize such technology, if at all, and about how patents on such technology, once granted, should be exercised.

This line of cases demonstrates how technical grounds of patentability also act as important safeguards of the public interest, aimed at ensuring that patents are only granted on genuine advances in technology, and are not used to exclude access to material in the public domain. But these decisions also highlight the ongoing policy debate on the patenting of human genes in general and, more specifically, on the patenting of genes used in diagnostics because of fears that such patents may constrain new diagnostic methods.

Furthermore, the commercial exploitation of the still-standing patents claiming the BRCA genes and testing methods raises another ethical issue. Critics charge that *Myriad*'s licensing policy, and the high prices demanded for testing under the patented technologies, has the effect of preventing other laboratories in countries where the patent was in force from carrying out diagnostic testing.¹²⁴ The

¹²³ See *id.*; see also JOHANNA GIBSON, INTELLECTUAL PROPERTY, MEDICINE AND HEALTH: CURRENT DEBATES 182 (2009) (suggesting that pricing of products with exclusive rights is profit-driven, with little concern for the quality or benefit of the product, thus affecting developing countries and national healthcare programs).

¹²⁴ See Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76

cases raise questions as to whether, and if so how, regulators should step in to deal with concerns about licensing practices. Because of these wide reaching concerns, the Australian High Court in its recent decision recognized that this determination might be best left to the legislature rather than the courts.¹²⁵

V. CONCLUSION

The modern biotechnology industry demands clear patent protection to foster innovation and investment in new products. However, this need must be balanced with the ethical issues that accompany the expansion of technology. Harmonization of patent eligible subject matter will best foster these goals. This paper analyzes three approaches to the specific problem of DNA patenting—the European Union’s strict adoption of patentable categories of technology, the United States’ product of nature test, and Australia’s factor determined exclusion. As evidenced by the three different outcomes evaluating the same patent claims and the inconsistent guidelines formulated by the European and United States Patent Offices, these approaches do not guarantee equal patent protection. While ethical and policy considerations may drive the adoption of patent eligible subject matter from one end of the spectrum to the

N.Y.U. L. Rev. 1623, 1626 (2001) (highlighting the concerns of a University of Pennsylvania bioethicist who has “warned that [a gene patent], and [the patent holder’s] attendant right to collect royalties from subsequent researchers working on the gene, will impede others from developing therapeutics based on the gene”).

¹²⁵ *D’Arcy* [2015] HCA 35 ¶ 7 (“Where an affirmative application of a concept is likely to result in the creation of important rights as against the world, to involve far-reaching questions of public policy and to affect the balance of important conflicting interests, the question must be asked whether that application is best left for legislative determination.”).

other, the European Union's strict application approach is the most clear and most compliant with TRIPS. Therefore, this paper concludes that the United States and Australia should also develop the requirements of patentability through legislation, rather than common law, to provide clear and predictable patent protection.