

**AN EXAMINATION OF THE UNITED STATES AND EUROPEAN UNION
PATENT SYSTEMS WITH RESPECT TO GENETIC MATERIAL**

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I. INTRODUCTION

Patents on genetic material are contentious to say the least. Controversies exist across the board: in how the law should view these products and processes; how people view them morally; and the economic causes and consequences of the legal and ethical decisions made about genetic material patentability. This Note will discuss these controversies through a comparative analysis of patent law in the United States and the European Union; the moral and ethical concerns that have been raised, including technological advancements that may lessen the moral outrage; and the economic impacts of accepting or denying genetic material as patent eligible. While this paper does not discuss a “correct”

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decision from a moral view, it will argue that if countries—the United States or individual Member States of the European Union—do not allow patent protection of these processes and the products discovered or produced, (including their derivatives), they will suffer economically due to investment moving to countries with greater protection, and also to the stalling of medical and technological research and advancement.

Part II will be an overview of patent law in the United States, followed by a discussion of genetic material patents in the United States in Part III. Part IV will give an overview of patent law in the European Union, followed in Part V by a discussion of patents on genetic material in the European Union. In Parts VI and VII, ethical concerns for the United States and European Union, respectively, will be raised and analyzed, as the law moves forward, responding to technological changes in the industry. An economic analysis will be presented in Part VIII. It will argue for patent protection moderate in scope, not the purpose-bound protection that was considered in the European Union, nor perhaps as broadly interpreted as the United States where recent challenges have been successfully raised, in part due to a lack of access to patented inventions on genetic material. Alternatively, it will be suggested that a solution for the problem created by a patent monopoly may be found outside the patent system. What is made clear is that the biotechnology industry relies on patent protection, and without intellectual property rights to draw in research funding and capital investment, as well as a considerable amount of necessary human capital, the industry will grow in other countries where there is sufficient protection; the biotechnology industry, medical technological advancement, and on some level the entire economy of countries without such protection, will stagnate. Without patent protection, there can be no advancement.

II. PATENT LAW IN THE UNITED STATES

“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.”¹

This is the Patent Clause of the Constitution, the beginning of the U.S. patent system. A patent is the legal title granted for an invention that has a “technical character,” if that invention is new and involves an inventive step.² Patent protection allows the owner to prevent other inventors from creating, using,

¹ U.S. CONST. art. I, § 8, cl. 8.

² *Patents*, EUR. COMM’N, http://ec.europa.eu/growth/industry/intellectual-property/industrial-property/patent/index_en.htm (last visited Feb. 27, 2015). Coincidentally, this succinct definition of a patent is from the European Union. There is another requirement for genetic patents in the EU, which is that the industrial application must be disclosed. *Id.* For further discussion on genetic material patents in the European Union, see *infra* Part V.

or selling the invention, without obtaining permission.³ The Federal Patent Act is codified in Title 35 of the United States Code.⁴

Under Title 35, § 101 begins the substantive discussion of the requirements for obtaining a patent. An invention or discovery that is “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” may be patented.⁵ However, there are several explicit exceptions in U.S. patent law where certain subject matter cannot be patented. For example, the language of § 101 excludes from patentability subjects such as laws and products of nature, physical phenomena, and abstract ideas.⁶ This is because there is a continuing goal for society to “retain access to certain basic knowledge.”⁷ As the United States Supreme Court opined long ago in 1948, in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, “laws of nature” are “free to all men and reserved exclusively to none.”⁸

The Federal Patent Act provides more comprehensive rights such as allowing the owner to prevent others from creating, using, or selling the invention, unlike the Copyright Act which, among other things, allows for far broader fair use rights.⁹ Compared to the Copyright Act, the language of the Patent Act includes a relatively narrow experimental use exemption, which allows for access to patented inventions only if that use is “reasonably related” to developing and submitting information about the regulation, manufacture, use, or sale of drugs under a Federal Law.¹⁰ The experimental use defense, constructed by case law, is narrower under the Patent Act as well, limited only to “amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”¹¹ Patent protection only lasts for twenty years from the filing date, shorter than the term of protection under copyright law, therefore offsetting the more stringent protection of patents.¹²

Section 102 discusses the conditions for patentability. The first is novelty and prior art. A patent is obtainable unless the invention was previously “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”¹³ Under this section, in any of these situations, the invention would not be eligible for a patent because of “prior art.” Section 102(a)(2) disallows a patent if it was described in a patent issued under § 151 (which merely covers

³ *Patents*, *supra* note 2.

⁴ 35 U.S.C. §§ 100-390 (2012).

⁵ *Id.*

⁶ Simone A. Rose, *Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?*, 38 AM. J. L. & MED. 113, 116 (2012).

⁷ *Id.*

⁸ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

⁹ Rose, *supra* note 6, at 116; *see* 17 U.S.C. §§ 106-15 (2012).

¹⁰ 35 U.S.C. § 271(e)(1) (2012).

¹¹ *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000)).

¹² Rose, *supra* note 6, at 116 (citing 35 U.S.C. § 271(a)); *see also* 35 U.S.C. § 154(a)(2) (2013).

¹³ 35 U.S.C. § 102(a)(1) (2012).

issuing a patent and the fees associated with doing so), or an application for a patent published or deemed published under § 122(b) (which discusses confidentiality and publication), or if the patent or the patent application names another inventor and was effectively filed before the filing date of the current claim of invention.¹⁴ This means either a published application or previously issued patent with an earlier effective filing date would essentially preempt the new patent being issued.

Under § 102(b)(1) are other exceptions, situations that do not count as prior art under the rules of § 102(a), and these therefore would not affect the patent-eligibility of the claimed invention. Disclosures, made one year or less before the effective filing date of the claimed invention, are not considered prior art if:

- (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
- (B) the subject matter disclosed had, before such disclosure, been publicly disclosed or the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.¹⁵

The above rule covers any type of disclosure. Section 102(b)(2)(A)–(B) outlines these same exceptions almost verbatim, when the disclosures appear specifically in applications or patents, as opposed to some other means.¹⁶ This means that, if within one year before the newly claimed invention, such a disclosure is not considered prior art if the applications or issued patents were created by the same inventor, or joint inventor, or someone who obtained the information from the inventors, or if it was publicly disclosed with information obtained directly, or indirectly, from the inventor or joint inventor. Further, under § 102(b)(2)(C), disclosures are not prior art if, before the effective filing date, “the subject matter disclosed and the claimed invention . . . were owned by the same person or subject to an obligation of assignment to the same person.”¹⁷ This portion serves to close potential loopholes in the case of a reassignment of rights. Section 102(c) discusses common ownership and joint research agreements, which are allowable under § 102(b)(2)(C), and are deemed to be owned by the same inventor if a joint research agreement exists.¹⁸ Section 102(d) discusses determining whether a patent or application is considered effective prior art, with

¹⁴ *Id.* § 102(a)(2).

¹⁵ *Id.* § 102(b)(1).

¹⁶ *Id.* § 102(b)(2)(A)–(B).

¹⁷ *Id.* § 102(b)(2)(C).

¹⁸ 35 U.S.C. § 102(c).

respect to several special cases of gaining an earlier filing date under other sections of the Patent Act.¹⁹

As such, patent law prevents applying for or receiving a patent for a particular invention if it could have been anticipated, or if it lacks “priority of invention.” Section 103 contains further conditions for patentability, concerning “obviousness,” sometimes called an “inventive step.”²⁰ One of the main priorities of patent law is to ensure that if a new patent is granted, the invention is “non-obvious” in light of prior art:

A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.²¹

The “inventive step” under § 103 means the new claimed invention is not merely the next step within a given science. The patent system is designed with the purpose of “promoting the progress of science,” but not necessarily for rewarding each inventor who manages to take the next “obvious” step, but instead incentivizes more of the next “leap” in a particular field.

Under § 112, the invention must also be “useful, novel, and non-obvious to one of ordinary skill” in the art.²² In essence, someone skilled in that particular area of study would not find this next step obvious in light of previous inventions, but instead, for example, it would be more like a creative leap to establish the process or create the product given what was already known in the field. However, the patent specifications and claims are required to be written in such a way that “one of ordinary skill in the art” could duplicate the invention, either under one of the exceptions, for example to satisfy idle curiosity, or after the patent expires.²³

¹⁹ *Id.* § 102(d).

²⁰ *Id.* § 103.

²¹ *Id.*

²² Rose, *supra* note 6, at 116; *see also* 35 U.S.C. § 112.

²³ Rose, *supra* note 6, at 116.

III. PATENTING GENETIC MATERIAL IN THE UNITED STATES

A. Patenting Genes: The *Myriad* Cases

Although there are things that are excluded from patentability like laws and products of nature, physical phenomena, and abstract ideas,²⁴ defining whether isolated gene sequences should be included under the description of things that occur in nature has been a difficult question. Things such as DNA could fall under this exception, and could be patentable if there was sufficient human intervention. In 2011, in the case *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, the Court of Appeals for the Federal Circuit explicitly discussed how “isolated bioproducts that undergo additional human engineering,” which alters their chemical structure and function, made them “markedly different” from the naturally occurring product.²⁵

Complimentary DNA (cDNA) is usually created using reverse transcriptase, which mirrors a messenger ribonucleic acid (mRNA), a molecule with a DNA complementary strand of amino acids, which finally produces an exact copy of the strand of the original DNA, called the “parent” strand.²⁶ The basic idea of Myriad Genetics’s invention was that they separated two genes from the rest of human DNA that, if mutated over the course of a woman’s life through natural processes, increased that individual’s susceptibility to breast cancer and ovarian cancer.²⁷ Myriad Genetics is the sole owner of patents on the processes and products involving tests for genetic markers for the increased susceptibility to breast and ovarian cancer. The genes in their isolated form are referred to as BRCA 1/2.²⁸ Because of Myriad Genetics’s sole ownership, they had not licensed any other companies to create the tests, or to disseminate results, and thus they were able to charge a high price for the BRCA diagnostic tests.²⁹ This resulted in several groups (research scientists and scientific societies, non-profit women’s organizations, and individuals) challenging the validity of the BRCA 1/2 gene sequence patents in federal court.³⁰ In the *Myriad* case, the U.S. District Court for

²⁴ 35 U.S.C. § 101 (2012).

²⁵ Rose, *supra* note 6, at 124 n.58 (citing Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad II*), 653 F.3d 1329, 1354 (Fed Cir. 2011)).

²⁶ *Id.* (citing *Myriad II*, 653 F.3d at 1354). Creating cDNA, however, might be obvious in all cases in light of the prior art. *Id.* (citing *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009) for the proposition that a patent might be denied if a “protein was previously identified and the methods for making cDNA in general were known to those skilled in the art”).

²⁷ Ass’n for Molecular Pathology v. Myriad Genetics, Inc. (*Myriad III*), 133 S. Ct. 2107, 2116 (2013).

²⁸ Rose, *supra* note 6, at 117.

²⁹ *Id.* at 117-18.

³⁰ *Id.* at 118.

the Southern District of New York, held that the patented isolated BRCA 1/2 gene sequences were biologically identical to naturally occurring DNA.³¹

This was a naturally occurring segment of DNA, and thus the court believed it was not eligible for a patent.³² The District Court reasoned that the “location and order of nucleotides existed in nature before Myriad Genetics *found* them.”³³ Myriad did not manufacture or change the structure of the DNA, and so did not *create* or *invent* anything eligible for a patent.³⁴ Rather, the principal contribution of Myriad Genetics was to uncover that the BRCA 1 gene was located on a specific portion of chromosome 17, and the BRCA 2 gene on part of chromosome 13.³⁵ The court then asked whether such naturally occurring gene sequences were patentable.³⁶ In essence, the patentee did not synthetically create or meaningfully change the composition of the DNA, but instead merely *discovered* the location and composition of a particular gene sequence that would be useful. Thus they were not patent eligible because “products of nature” are excluded under § 101 of the Patent Act and *Chakrabarty*.³⁷ The Federal Circuit recalled Dr. Chakrabarty’s “genetically engineered crude-oil-eating bacterium,” being “markedly different” because it was created to perform a different biological function and could in fact eat crude oil.³⁸ The court also pointed out that the invention must still be “novel, useful, and non-obvious.”³⁹

Things that are naturally occurring are prohibited from patent eligibility, but synthetically created things that occur in the natural world are often eligible. This could be for two main reasons. First, because it is “markedly different,” that is to say, it is different enough in the court’s view from the naturally occurring element; or, second, because it is created to perform a different function. Also, any such processes would at least be eligible for a patent, but would have to meet the other criteria for patentability; most notably for processes, it must be “non-obvious” and involve an inventive step. In *Myriad*, in 2013, the United States Supreme Court allowed the patent for *synthetically created* cDNA.⁴⁰ This cDNA contained information for protein coding that is found in naturally occurring DNA, but omitted portions within the DNA segment that did not code for proteins.⁴¹ The court ruled that this was patentable subject matter because, as the

³¹ *Id.*; see *Myriad III*, 133 S. Ct. at 2107; *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980).

³² *Myriad III*, 133 S. Ct. at 2116.

³³ *Id.* (emphasis added).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Rose*, *supra* note 6, at 118; see *Myriad III*, 133 S. Ct. at 2107; *Chakrabarty*, 447 U.S. at 303.

³⁸ *Myriad II*, 653 F.3d at 1354; see *Chakrabarty*, 447 U.S. at 309-10.

³⁹ *Rose*, *supra* note 6, at 124 n.58.

⁴⁰ *Myriad III*, 133 S. Ct. at 2107.

⁴¹ *Id.*

petitioners conceded, the “cDNA differs from natural DNA in that ‘the non-coding regions have been removed.’”⁴²

B. Challenges to the Patentability of Genetic Material Post-Myriad

Human genes are not the only bioproducts where “the public” believes they should have greater access to patents.⁴³ The need for greater access has led to challenges to the validity of other genetic material patents as well.⁴⁴ In July 2006, the Public Patent Foundation (PUBPAT) filed on behalf of the Foundation for Taxpayer and Consumer Rights (now known as Consumer Watchdog) as a non-profit consumer group, for the United States Patent and Trademark Office (PTO) to reexamine the Thompson family of patents, owned by the Wisconsin Alumni Research Foundation (WARF).⁴⁵ These consumer groups were seeking greater public access, similar to the goal in the *Myriad* case, this time to the embryonic stem cell lines.⁴⁶ They were able to persuade the PTO to reexamine the claims of the patents.⁴⁷ After reexamination, the PTO invalidated them “as obvious in light of prior art.”⁴⁸ WARF then filed a request asking the PTO to prosecute the patents again, after amending the claims of the three Thompson patents.⁴⁹

Together, the Thompson family of three patents includes rights to all of the embryonic stem cells and the methods for creating those stem cell lines.⁵⁰ PUBPAT argued that the WARF patents were obvious in light of newly brought forth prior art, lacked novelty, and thus belonged in the public domain.⁵¹ PUBPAT submitted new prior art showing that the Thompson patents were not new in their own right, and should be revoked.⁵² In September 2006, the PTO granted the PUBPAT request to reexamine the Thompson patents, and rejected

⁴² *Id.* at 2119.

⁴³ Rose, *supra* note 6, at 119.

⁴⁴ *Id.*

⁴⁵ *WARF Stem Cell Patents*, PUB. PATENT FOUND., <http://www.pubpat.org/warfstemcell.htm> (last visited Mar. 21, 2014).

⁴⁶ Rose, *supra* note 6, at 119.

⁴⁷ *Id.*

⁴⁸ *Id.* See also Found. for Taxpayer & Consumer Rights, No. 2010-001854, 2010 WL 1734377 (B.P.A.I. Apr. 8, 2010) (rejected as obvious in light of prior art under 35 U.S.C. § 103(a)); *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005) (affirming the rejection of the claims by the PTO, under § 101, where “expressed sequence tags” (ESTs) have common usage for identifying genes; the genes also lacked a known function and did not support a finding of specific utility to satisfy § 101 of the Patent Act).

⁴⁹ Rose, *supra* note 6, at 119.

⁵⁰ *Id.* at 127; see U.S. Patent No. 5,843,780 (filed Jan. 18, 1996) (issued Dec. 1, 1998); U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001); U.S. Patent No. 7,029,913 (filed Oct. 18, 2001) (issued Apr. 18, 2006).

⁵¹ *WARF Stem Cell Patents*, *supra* note 45.

⁵² *Id.*

every claim of each of the three Thompson patents on March 30, 2007.⁵³ Despite the fact that the Thompson patents were issued separately from 1996 to 2001, PUBPAT was arguing that there was relevant prior art that had either not been found, or was not presented prior in the same way to the PTO, and this required the revocation of the three patents.⁵⁴

In the Order granting reexamination of the first Thompson patent, Patent 5,843,780 ('780 Patent), the PTO stated that PUBPAT raised a "substantial new question of patentability" (SNQ) by raising prior art in the Williams et al. Patent 5,166,065,⁵⁵ the Robertson et al. (1983) and (1987) process,⁵⁶ and the Piedrahita et al. (1990) process.⁵⁷ Then in the PTO Order rejecting the '780 Patent, Number 4 stated that Claims 9–10 were rejected under 35 U.S.C § 102(b) as anticipated by Patent 5,166,065, the Williams et al. Patent.⁵⁸ The PTO stated in Number 5 of the rejection Order that Claims 1–8 and 11 were rejected under § 102(b) as anticipated, or under § 103(a) as obvious, given the same Williams et al. Patent.⁵⁹ Basically, this means the PTO was not satisfied that the '780 Patent required an inventive step from the Williams et al. Patent.

Reexamination of the second Thompson Patent, Patent 6,200,806 ('806 Patent), was granted because the newly presented "old art" created an SNQ, in very similar fashion to the above '780 Patent owned by WARF.⁶⁰ In the PTO Order rejecting the '806 Patent, Number 4 stated that Claims 1–8 and 11 were rejected, either under § 102(e) as anticipated, or under § 103(a) as obvious, in light of the Hogan Patent 5,453,357.⁶¹ WARF therefore amended its patent,

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ U.S. Patent No. 5,166,065 (filed Aug 3, 1989) (issued Nov. 24, 1992) [hereinafter Williams et al. Patent]. The Williams et al. Patent relates to the use of leukemia inhibitory factor (LIF) to maintain and derive embryonic stem cells in a culture. *Id.*

⁵⁶ The Robertson et al. (1983) and (1987) process taught, step-by-step, how to isolate "pluripotential" mammalian embryonic stem cells. Order Granting Request for *Ex Parte* Reexamination of U.S. Patent No. 5,843,780, Control No. 90/008,102, at 7 (Sept. 29, 2006), available at <http://www.pubpat.org/assets/files/warfstemcell/90008102-1granted.pdf>.

⁵⁷ The Piedrahita et al. (1990) process is a method of isolating ovine (sheep), porcine (pig), and murine (rodent) embryonic stem cells. *Id.*

⁵⁸ Office Action in *Ex Parte* Reexamination of U.S. Patent No. 5,843,780, Control No. 90/008102 (Mar. 30, 2007), available at <http://www.pubpat.org/assets/files/warfstemcell/780rejected.pdf>; Williams et al. Patent, *supra* note 53.

⁵⁹ Office Action in *Ex Parte* Reexamination of U.S. Patent No. 5,843,780, *supra* note 58; Williams et al. Patent, *supra* note 55.

⁶⁰ Order Granting Request for *Ex Parte* Reexamination of U.S. Patent No. 6,200,806, Control No. 90/008,139 (Sept. 29, 2006), available at <http://www.pubpat.org/assets/files/warfstemcell/90008139granted.pdf>. The PTO declared these were new, because not brought before the PTO prior, or not in the same light as they were currently being raised. *Id.*

⁶¹ *Id.*; see U.S. Patent No. 5,453,357 (filed Oct. 8, 1992) (issued Sept. 26, 1995) [hereinafter The Hogan Patent]. The Hogan Patent covers a "non-mouse" pluripotential

narrowing the original claims that had satisfied the PTO, and the patents were reissued.⁶² Consumer Watchdog appealed the reissuance of the patents, and the Federal Circuit Court of Appeals had scheduled oral arguments for January 2014.⁶³

At the time of Rose's article in 2012, it was hard to predict the outcome of the *Myriad* case, or the WARF patent dispute.⁶⁴ Even now, with the guidance of the Supreme Court's decision in the final *Myriad* case, it may be hard to predict the final outcome of the WARF dispute, as it moves back to oral arguments before a court, and not the U.S. PTO. Challenges like these gain publicity and momentum when they succeed on some level, just as the WARF dispute has forced a narrowing of the patent claims; this was arguably a "success" because the consumer groups who brought the action seeking greater public access have, at least, narrowed WARF's control over the products, processes, and future developments. Because an inventive step is required, narrowing the claims may prove less of a hindrance to such future developments, also increasing public access. Success then can be gained from the revocation or modification of the patents, or even from increased scrutiny on behalf of the PTO or the courts; and success is likely to cause more challenges to be raised for patents already issued, much less the uncertainty of future genetic patent applications. A byproduct of these small successes will almost certainly be an increase in the cost of prosecuting patents in front of the PTO and defending these patents in a court of law. It will also likely impact the scope of protection granted for an issued patent, or whether the new efforts at patenting similar genetic or biological material will be disallowed at the outset. Also, although a new and useful technical process seems to be more eligible for a patent, and less likely to be "naturally occurring" because of the human intervention required, processes run the risk of not taking an inventive step and thus being declared "obvious in light of prior art."

embryonic stem cell, and the process to create it (the cells have certain other properties making them valuable for research). *Id.*

⁶² *WARF Stem Cell Patents*, *supra* note 45.

⁶³ *Id.*; see *Consumer Watchdog v. Wis. Alumni Research Found.*, No. 13-1377 (Fed. Cir. Dec. 4, 2013), available at <http://www.scribd.com/doc/199064185/CW-v-WARF-Order-of-Dec-4-2013>.

⁶⁴ Rose, *supra* note 6, at 119.

IV. PATENT LAW IN THE EUROPEAN UNION

The European Union acknowledges that a patent does not allow the holder to implement the invention, but rather allows the holder “to prohibit third parties from exploiting it for industrial and commercial purposes.”⁶⁵ Additionally, the European Community and the Member States signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which requires that patent protection be available for products and processes in all areas of technology.⁶⁶ This means that all TRIPs participants must allow patents on some level for “bioproducts” 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. However, it is important to keep in mind that the EU requires the industrial application to be present and disclosed for a patent on genetic material to be issued.

Following the ratification of TRIPs, which became effective in 1996, the European Parliament and the European Council created a Directive on July 6, 1998 (The Directive), which discussed the legal protection of biotechnological inventions such as genetic material.⁶⁷ The Directive makes a point of expressing that TRIPs Article 34 binds all Member States with detailed provisions and explanations on the burden of proof required for patentability, and so it is not necessary to create or change the existing system.⁶⁸ As such, the EU has recently worked to address the desired unity among its Member States for patents overall:

⁶⁵ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, recital 14 1998 O.J. (L 213) 13, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> [hereinafter The Directive]. This is very similar to the U.S., which gives the patent holder the right to exclude others from making or using their products and processes (with limited exceptions).

⁶⁶ *Id.* recital 12.

⁶⁷ *Id.*

⁶⁸ *Id.* recital 54. The Directive notes:

the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that “further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

Id. recital 56.

In 2012 Member States and the European Parliament agreed on the “patent package”—a legislative initiative consisting of two Regulations and an international Agreement, laying grounds for the creation of unitary patent protection in the EU. The patent package implements enhanced cooperation between 25 Member States (all Member States except Italy and Spain). Following the adoption of the two Regulations in December 2012, the contracting Member States will proceed with the signature and ratification of the Agreement on a Unified Patent Court—the third and last component of the “patent package” setting up a single and specialized patent jurisdiction. Once the Agreement and the Regulations enter into force, it will be possible to obtain a European patent with unitary effect—a legal title ensuring uniform protection for an invention across 25 Member States on a one-stop shop basis, providing huge cost advantages and reducing administrative burdens.⁶⁹

This is obviously a recent development in EU patent law. However, The Directive was conscientious of the differences in national and international laws between Member States, especially with regard to biotechnological inventions, and also acknowledged that these differences can create barriers to trade along with differences in legislative and economic development. It correctly noted that greater division in the EU would only incite more disincentives to trade, to the detriment of industrial development, and both the internal and international markets.⁷⁰

V. PATENTING GENTIC MATERIAL IN THE EUROPEAN UNION

The Member States of the EU face their own challenges with respect to patents on genetic material and the scope of protection. TRIPS itself does not expressly disallow any biotechnology industry; things such as gene sequences and embryonic stem cells are left to the individual countries.⁷¹ This is similar to the United States, where the Supreme Court expressed in *Chakrabarty* that such decisions should be left to the legislative body.⁷²

Then, similar to how Rose posed the question, what should a country do for patents that are on the questionable edge of patentability, especially if they

⁶⁹ *Patents*, *supra* note 2 (emphasis omitted).

⁷⁰ The Directive, *supra* note 65, art. 7.

⁷¹ *See id.* recital 36.

⁷² *Chakrabarty*, 447 U.S. at 318. Specifically, “Congress is free to amend patent statute[s] so as to exclude from patent protection organisms produced by genetic engineering.” *Id.*

require significant research and development capital?⁷³ This is indeed a question arising daily it seems in patents for genetic material. This category of questionable patents certainly includes “‘building block’ biological materials” such as stem cells and isolated gene sequences, or partial sequences.⁷⁴ The Directive in 1998 was again looking forward to how to deal with these issues.

In The Directive, it was expressly stated that the then-current national or European patent law did not prohibit biological matter as patentable subject matter.⁷⁵ 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; patent eligibility should turn on novelty, an inventive step, and the industrial application.⁷⁶ Unique to The Directive, at least in expression, the EU requires that the industrial application for a gene sequence or partial sequence be specifically enumerated in the application for a patent.⁷⁷ The industrial application, again, is its specific use. By design, this requirement prevents the mere discovery of a gene sequence, for example, followed by the utilization of a patent to claim ownership without a specific purpose in mind (some useful advancement of medical science). This would essentially lockout a different inventor with a purpose in mind, or, perhaps more crucially, could make an inventive step harder to pursue, and a later invention would be more susceptible to being obvious in light of prior art, while the original inventor is neither using the invention to its potential, nor advancing science.

The Directive proceeded in the same direction as the most recent decisions in cases in the U.S. In another conscientious move, it specifically addressed some of the controversy within science and the law, regarding “elements isolated” from the human body:

it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment.⁷⁸

Again, possibly ahead of its time, The Directive expressed that such elements isolated from the human body, or identical products created in some

⁷³ Rose, *supra* note 6, at 117. Rose was pushing for *sui generis* protection for semiconductor chips because they seemed to fall outside of patent law. *Id.* But this question is also highly relevant for genetic material patents.

⁷⁴ *Id.*

⁷⁵ The Directive, *supra* note 65, art. 15.

⁷⁶ *Id.*

⁷⁷ *Id.* art. 5(3).

⁷⁸ *Id.* recital 20.

other way, can be eligible for patent protection.⁷⁹ The element could be produced, identified, purified, or isolated through a technical process (which would almost certainly be eligible for a patent in its own right if the conditions were met), and the element may also be patent eligible.⁸⁰ It could also be a technical process or other technique that allows the element to be reproduced outside of the human body, which again would likely be patentable.⁸¹ Only human beings are capable of such scientific discovery and performing such practices; it is something nature cannot accomplish on its own. Allowing patent protection for such processes and products is on par with the very definition, and goal, of a patent system, and encourages such scientific advancement.

The Directive rather expertly describes some very subtle differences between discovering something that occurs in nature and something that is a product of human intervention, which closely mirrors some of the distinctions drawn out in the *Myriad* case (almost fifteen years later).⁸² At the very least, human ingenuity and science are needed to discover the element, its functions, and certainly the ability to use it, and even change it or its functions. This is likely the reason that processes seem to be *more patentable*; while some material, which naturally exists within the human body, is likely not something one should *own*, the processes by which it is discovered, replicated, and put to use, deserve patent protection. There is also the synthesizing side of the science; even if the final product occurs in nature, producing (or reproducing) it outside the human body, for example should make it patent eligible.

The Directive acknowledges that the legal framework of the European Community, with respect to biotechnological inventions, includes principles such as determining whether the claim is a discovery or an invention, especially when it comes to “elements of human origin,” whether to allow it to be patented, and the scope of protection that should be granted.⁸³ The Directive seemed to predict these issues moving forward, and each has been faced in turn by the United States as well. Mere discoveries in both patent systems seem to be ineligible for patent protection, especially if they are elements of the human body, and in a broader sense as well because a patent on any such discovery does not fulfill the anticipation, non-obviousness, and inventive step requirements. Such a patent would give exclusive ownership rights to something literally “found” in nature. The other important part of the patent requirements in the EU is the industrial application.

In the EU, to comply with the industrial application requirement, when a gene sequence or partial sequence is used to create a protein, or other similar chemical form, it must be specified what is to be created, and what function it will perform.⁸⁴ This is in line with the requirements of patent applications in the

⁷⁹ *Id.* art. 5(2).

⁸⁰ The Directive, *supra* note 65, recital 21.

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.* recital 13.

⁸⁴ *Id.* recital 24.

United States as well, with the end goal to have a new and useful invention with the proper scope of protection. Similar, it seems, to recent U.S. case law, such a caveat in the biotechnological field of genetics was explicitly carved out in The Directive: “a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention.”⁸⁵ This ensures that patent protection is reserved for useful inventions, and much like the United States, promotes the progress of science. With excellent foresight, the drafters of The Directive included the idea that if a sequence overlaps with another, in parts that have nothing to do with the invention and its purpose, each sequence will be independent when considered for a patent.⁸⁶ In one of the most impressive predictions of future laws to come, that idea falls in line exactly with the U.S. Supreme Court holding in *Genetics Institute*, which was decided in 2010.⁸⁷

Under Article 3 of The Directive, an invention that concerns or contains biological material, or a process by which that product is created, used, or further processed, may be patentable if it is new, required an inventive step, and includes an industrial application.⁸⁸ Even if the particular biological material previously occurred in nature, but was isolated from that environment, or produced in some other way by a technical process, it is not preempted from patent protection.⁸⁹ However, it seems there is a carve-out for plant varieties and even for plant groupings, despite human intervention through the use of a biotechnological process.

In Article 4, plant and animal varieties themselves, and “essentially biological processes,” meaning naturally occurring processes with little or no human intervention that produce plants or animals, are explicitly not eligible for patent protection.⁹⁰ However, inventions that concern plants or animals are patentable if not confined to a particular variety. Microbiological processes, or other technical processes, meaning not “essentially biological processes” or products obtained by such biological processes, are not prejudiced by The Directive, and may be patented.⁹¹

The Directive explicitly states that plant and animal varieties are *not* excluded from patentability.⁹² However, if the invention concerns plants or animals, it can be patentable if the application of the invention is not confined to a single variety of plant or animal.⁹³ A “plant variety” is defined by legislation as

⁸⁵ The Directive, *supra* note 65, recital 23.

⁸⁶ *Id.* recital 25.

⁸⁷ *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 687 F. Supp. 2d 486, 486 (D. Del. 2010). Because the deletion ranges in the amino acids were different, and one amino chain could not anticipate the other, they were essentially different, and deserving of two separate patents. *Id.*

⁸⁸ The Directive, *supra* note 65, art. 3(1).

⁸⁹ *Id.* para. 2.

⁹⁰ *Id.* art. 4(1)(b).

⁹¹ *Id.* para. 3.

⁹² *Id.* recital 29.

⁹³ The Directive, *supra* note 65, recital 29.

its whole genome.⁹⁴ It is therefore distinguishable from other varieties, even if only a slight difference is present genetically.⁹⁵ Further, a “plant grouping” is characterized not by its entire genome, but rather by a specific gene, and is not part of the same exclusion as a “plant variety,” and thus may be eligible for a patent, “even if it comprises new varieties.”⁹⁶ The key is whether the whole genome, and therefore the plant’s “individuality,” is being patented. If an invention is merely the genetic modification of a variety of plants, and a new variety is the result, it is not patentable, even if it is a product of a biotechnological process, which requires human intervention.⁹⁷ This is an interesting distinction in The Directive, and indeed more of an exception to the exception of human intervention enabling processes and products to be patented. Before, The Directive expressed that *because* of human intervention, patents *were* obtainable to protect the investment of both money and human capital; but here, the creation of an entirely new plant, even if it was not through a purely biological process such as crossbreeding (which is obviously not patent eligible), but a biotechnological process requiring human intervention such as genetic modification, is *not* patentable in the event it creates a new plant.

Article 5 of The Directive eliminates from the scope of patent protection the human body, its stages of development and formation, and “the simple discovery” of an element of the human body.⁹⁸ Explicitly eliminated are gene sequences or partial sequences.⁹⁹ However, Article 5 *allows* a patent for an element from the human body, *including* a gene sequence or partial sequence, if it is *isolated* or *produced* through a *technical process*.¹⁰⁰ This remains true even if it is identical to the naturally occurring element.¹⁰¹ The *Myriad* case in the United States would satisfy this requirement of a technical process, and would be eligible for patent protection if it met the other requirements. Here, also in Article 5, is the language that the industrial application of a gene, partial or complete, must be disclosed in the patent application, which follows conventional patent protection in the EU under the “classic model.”¹⁰² Thus, for example, the description that the *Chakrabarty* microorganism was developed to clean up crude oil would suffice as the industrial application.

Finally, as discussed within the scope of this Note, Article 6 expressly excludes inventions “where their commercial exploitation would be contrary to ordre [sic] public or morality.”¹⁰³ In particular, the following shall be considered *not* eligible for a patent: processes for cloning human beings, processes for

⁹⁴ *Id.* recital 30.

⁹⁵ *Id.*

⁹⁶ *Id.* recital 31.

⁹⁷ *Id.* recital 32.

⁹⁸ The Directive, *supra* note 65, art. 5(1).

⁹⁹ *Id.*

¹⁰⁰ *Id.* art. 5(2).

¹⁰¹ *Id.*

¹⁰² *Id.* art. 5(3).

¹⁰³ The Directive, *supra* note 65, art. 6(1).

modifying the germ line genetic identity of human beings, use of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal.¹⁰⁴ In parallel to the exclusion of new plants created through genetic modification, animals resulting from such processes are also excluded.¹⁰⁵

Other language from the text of The Directive similarly paints the picture of crossing some arbitrary moral line: “processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability.”¹⁰⁶ The Directive emphasizes the controversy when the words chosen exclude such things as “obviously” not patentable.¹⁰⁷ However, it is notable that research is allowed on animals if there are *substantial benefits*.¹⁰⁸ Uniquely interesting is the fact that The Directive contemplated controversial research to the *detriment* of animals, as long as substantial benefits to either animals or humans would be produced.¹⁰⁹ One wonders where the moral line is drawn with regard to experiments on animals and the use of stem cells, for instance, in the pursuit of medical science, along with the right to patent such products, processes, and their derivatives under those circumstances.

In addition to The Directive, the Commission of the European Communities elected to create subsequent reports discussing The Directive, and detailing the issues that have arisen since it was written in 1998. The Report from the Commission to the Council and the European Parliament stated that, as of the end of June 2005, twenty-one Members of the EU had notified the Commission of the instruments they intended to use to implement and enforce The Directive, as was required of all Member States.¹¹⁰ Actions were taken against those Member States that had not communicated such mechanisms, or those that had not completed the transposition of The Directive over the seven years since it was published.¹¹¹

The Second Report then comments on two major issues that were identified as necessary for the Commission to address:

¹⁰⁴ *Id.* art. 6(2)(a)-(c).

¹⁰⁵ *Id.* art. 6(2)(d).

¹⁰⁶ *Id.* recital 38.

¹⁰⁷ *See id.* recital 38.

¹⁰⁸ *See* The Directive, *supra* note 65, recital 45, art. 6(2)(d).

¹⁰⁹ *See id.*

¹¹⁰ *Report from the Commission to the Council and the European Parliament: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM (2005) 312 Final, at 1.1 (Jul. 14, 2005) [hereinafter Second Report], available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52005DC0312:EN:HTML>. The entirety of the report specifically dealt with these complicated and controversial areas of patent law.

¹¹¹ *Id.*

1. For gene sequences or partial sequences that have been isolated from the human body, what is or should be the scope of patent protection?
2. Should human stem cells and any resulting stem cell lines be eligible for patent protection?¹¹²

In the concluding remarks of the first of these reports, the Commission acknowledged that it should revisit these two questions in subsequent reports after some time.¹¹³ The first question developed into whether gene or DNA sequences should be patentable according to “the classical model” of patent claims.¹¹⁴ Under the classical model, the first inventor would claim the gene sequence or partial sequence more broadly, which would include possible future uses.¹¹⁵ Alternatively, the scope of the patent could “be restricted so that only the specific use disclosed in the patent application can be claimed.”¹¹⁶ The Commission calls this “purpose-bound protection,” where current derivative uses, or further developed uses later on, are not protected by the original patent.¹¹⁷ Furthermore, as stated before, if the development is not an inventive step, or is obvious in light of prior art, it will not be eligible for protection under claims of a new patent.

The Second Report notes that Articles 8–11 of The Directive do not address how, or whether, to limit the scope of protection, but rather include that patent protection “extends to any biological material obtained from the claimed product or in which the claimed product is incorporated and the same genetic information expresses its function.”¹¹⁸ Note that it is this function that is described in the industrial application portion, and it is only that use that is protected in a limited scope, “purpose-bound” patent. The Commission itself argues over the meaning of the omission of any specific direction on this matter (in much the same way some Americans argue over the language of the Constitution).¹¹⁹ Should the omission of any limitation on the scope of protection mean it was purposefully not to be limited?¹²⁰ Or was it omitted because, despite its forward-looking creation, it was not contemplated at the time?¹²¹

The Second Report acknowledges that the intent of The Directive could have been to give broad protection, subject only to the explicitly stated exclusion of “claims to the human body in its entirety,”¹²² under Article 5(1).¹²³ However, from Article 5(3)¹²⁴ of The Directive, and also stated in Recitals 23 and 25,¹²⁵ the

¹¹² *Id.* at 2.

¹¹³ *Id.*

¹¹⁴ *Id.* at 2.1.

¹¹⁵ Second Report, *supra* note 110, at 2.1.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*; see The Directive, *supra* note 65, arts. 8-11.

¹¹⁹ Second Report, *supra* note 110, at 2.1.

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ The Directive, *supra* note 65, art. 5(1).

¹²⁴ *Id.* art. 5(3).

intention could have been to raise the possibility of purpose-bound protection, where the scope is limited to the specific industrial application that is enumerated in the patent for biological material.¹²⁶ If that is not the case, then Article 5(3) of The Directive merely repeats the normal requirements for a patent, by specifically stating again that an industrial application for genetic material patents is required,¹²⁷ as it also appears in Recital 22.¹²⁸ The best answer is a middle-of-the-road approach.¹²⁹

The first of these reports to the Commission set up a Group of Experts, with the expressed purpose of advising the Commission through examining “important issues relating to biotechnological inventions.”¹³⁰ The Group of Experts was comprised of specialists in patent law and highly qualified persons from the field of biotechnology. It was formed because the Commission thought such a group was necessary to properly examine all the issues, including legal, ethical, and economic issues, as well as possible solutions when dealing with the field biotechnology and the respective patents.¹³¹

The Group of Experts first met in March 2003 to discuss the issues surrounding the proper scope of protection granted for patents on genes and partial gene sequences.¹³² One of the main points in this first discussion was the potential of a limited scope, “purpose-bound” protection for biotechnological inventions, such as gene sequences or partial sequences. It was decided that “classic patent protection” was appropriate because the “majority of the Group felt that there were no objective reasons to create a specific regime of purpose-bound protection” in the area of patents on genes or gene sequences.¹³³ Particularly, technical and legal experts “felt there were no differences between DNA sequences and chemical substances” to justify a change in the scope of patent protection from the classical model.¹³⁴ Again this seems to be the best choice, otherwise these patents would be so severely limited to the specific purpose of the enumerated industrial application.

According to the Second Report, “as a specific field of technology becomes mature, the application of the normal patent criteria of novelty, inventive step and industrial applicability means that future patents are necessarily limited in scope because the invention claimed has to be distinguished from the vast array

¹²⁵ *Id.* recitals 23, 25.

¹²⁶ Second Report, *supra* note 110, at 2.1.

¹²⁷ *Id.*

¹²⁸ See The Directive, *supra* note 65, recital 22.

¹²⁹ There are certainly moral concerns with these questions, but more than that, there will be economic concerns, and consequences, depending on which side of the road is chosen. For further discussion on why a middle-of-the-road approach is best from the economic perspective, see *infra* Part VIII.

¹³⁰ Second Report, *supra* note 110, at 1.2.

¹³¹ *Id.*

¹³² *Id.* at 2.1.

¹³³ *Id.*

¹³⁴ *Id.*

of what is already known in the field.”¹³⁵ This supports the argument for a middle-of-the-road answer on how to limit the scope of protection for such patents. If it is too broad, it could run into previously issued patents as prior art, or, in a similar fashion, could discourage future inventions. It could also prevent the industry from taking an inventive step because so many ideas would fall under the protection of an overly broad patent. The Second Report continues on with the opinion that, because of differences in legislation across individual countries, it may also be ineffective in any significant manner to “further refine the scope of protection of gene sequence patents.”¹³⁶ The Second Report here follows the wisdom of The Directive, recognizing that each country has developed its own general patent laws, and especially with respect to a controversial topic like genetic material. Beyond this, the Commission does not take a position on choosing between a purpose-bound, limited scope of protection, and the classical model of patent protection.¹³⁷ However, allowing countries to decide for themselves based on whatever ethical and economic criteria they choose seems more appropriate than specifically limiting patents on genetic material for the entire group of the EU to “purpose-bound” protection, or, on the other end of the spectrum, protection that is too broad in scope.

The Commission believed The Directive was clear and precise, and that uncertainty was not allowed when it came to the patentability of plants, animals, and microorganisms.¹³⁸ As such, the Commission believed “there was no ambiguity regarding the patentability of material isolated from the human body.”¹³⁹ However, the Second Report introduced new considerations that are crucial to this field of patents.¹⁴⁰ The Commission stated that they did not have any *objective grounds* for limiting the scope of patent protection under the classical model of patent protection for inventions such as gene sequences or partial sequences isolated from the human body;¹⁴¹ the requirements of the patent system in place were sufficient, as was the scope of protection it granted. The difficulties of the questions of patentability, and the proper scope of protection are not lost on the European Community, as the Second Report also admits, there is not an “immediate answer” to the question of the whether embryonic, pluripotent stem cells, should be eligible for a patent.¹⁴² But, the Second Report does go so far as to say that the cells that could develop into a human being, the totipotent stem cells, should not be eligible for a patent “on grounds of human dignity.”¹⁴³ This position is strikingly similar to the Article 6(1) exception to refuse a patent

¹³⁵ Second Report, *supra* note 110, at 2.1.

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.* at 3.

¹³⁹ *Id.*

¹⁴⁰ Second Report, *supra* note 110, at 3.

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

“on grounds of ordre [sic] public or morality,” and it is likely under that moral reasoning that they would be rejected.¹⁴⁴

VI. ETHICAL CONCERNS OF GENETIC MATERIAL PATENTS IN THE UNITED STATES

Four days after fertilization, a human egg cell develops into what is called a blastocyst.¹⁴⁵ Embryonic stem cells can be collected from the inner mass of this blastocyst.¹⁴⁶ Embryonic stem cells are totipotent and could potentially develop into any organ or tissue type, except sperm and egg cells.¹⁴⁷ There is also another type of stem cell besides totipotent, known as pluripotent.¹⁴⁸ Totipotent stem cells “are capable of developing into a human being,” while pluripotent stem cells are *not*.¹⁴⁹ Obviously, this blastocyst, and in theory, the stem cells taken from that inner cell mass, if they divide normally, could develop into a human being, not just any of the different cell types. For these reasons, embryonic stem cells are largely controversial.

However, there are different types of stem cells with their own properties, advantages, and limitations, regarding their uses for research and medicine.¹⁵⁰ Human embryonic stem cells are controversial because they are collected from an unborn child, or fetus, and raise their own moral issues, as well as some that coincide with abortion. However, there are also somatic stem cells that can be isolated from adult tissue. Adult cells do not have this same versatility, usually capable of only developing into a specific type of cell.¹⁵¹ Research suggests that adult “terminally-differentiated cells,” that have reached their end stage of differentiation, i.e. a heart cell, can be converted into pluripotent cells.¹⁵² However, they have a propensity to develop into tumor cells, such as teratomas.¹⁵³ Because of these differences in capabilities, and the hurdle of adult stem cells developing into tumorous pluripotent stem cells, embryonic stem cells are (arguably) superior for use by scientists to explore treatment options for human diseases.¹⁵⁴ There are more than 200 types of cells in the human body, and

¹⁴⁴ The Directive, *supra* note 65, art. 6(1).

¹⁴⁵ Rose, *supra* note 6, at 126 (citing Jessica Reaves, *The Great Debate over Stem Cell Research*, TIME (July 11, 2001), <http://www.time.com/time/health/article/0,8599,167245,00.html>).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ Second Report, *supra* note 110, at 2.2.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ Rose, *supra* note 6, at 126.

¹⁵² *Id.* at 126 n.71 (citing Monya Baker, *Adult Cells Reprogrammed to Pluripotency, Without Tumors*, NATURE (Dec. 6, 2007), <http://www.nature.com/stemcells/2007/0712/071206/full/stemcells.2007.124.html>).

¹⁵³ *Id.*

¹⁵⁴ *Id.* at 126-27.

embryonic stem cells can develop into any of these types of cells with the proper stimulation.¹⁵⁵ Thus, embryonic stem cells are particularly interesting and valuable to researchers, as they could potentially develop into any of these types of cells *outside* of the human body, with the right stimulation.¹⁵⁶ Note that at the time of the Second Report, they were the only pluripotent stem cell that could be “isolated and grown in culture in sufficient numbers to be useful.”¹⁵⁷

The debate revolving around stem cells was encouraged in early 2004 when Korean researchers announced to the public the results of experiments that had allowed them to develop a line of pluripotent stem cells.¹⁵⁸ They used a technique called “therapeutic cloning.” This is a process that allows the development of cells with the exact same genetic material as a patient, and then which could potentially be used to treat that patient.¹⁵⁹ This basically eliminates the risk that the patient’s immune system will reject the treatment.¹⁶⁰ Such a process has broad treatment possibilities, including bone marrow and organ transplants, which are known for their risk of rejection in the host body, which is why there is considerable effort to screen and match donors and recipients. If this process could be refined, we could genetically match and create healthy tissue for each recipient, and also perhaps without risking surgery for a donor. Much of the controversy stems from how the cells are obtained, but also there is conflict over whether humans should obtain them, and further, whether we should use stem cells to advance medical science, and potentially to improve our health and save lives.

An important discovery has been made by Dr. Tony Atala of Wake Forest University, which could perhaps lessen moral outrage. In 2007, he discovered that a small amount of pluripotent stem cells are present in the amniotic fluid surrounding a fetus, and they may be a more ethical way to obtain these non-adult stem cells that are so valuable for research.¹⁶¹ In a telling example of the ethical and economic issues surrounding stem cells, Dr. Atala produced a human bladder from regenerated adult stem cells.¹⁶² Interestingly, this “invention” was a patentable bioproduct; it was novel, useful, and non-obvious.¹⁶³

¹⁵⁵ *Id.* at 126 n.2.

¹⁵⁶ Second Report, *supra* note 110, at 2.2 (emphasis added).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* (citing Helen R. Pilcher, *Cloned Human Embryos Yield Stem Cells*, NATURE (Feb. 12, 2004), <http://www.nature.com/news/1998/040209/full/news040209-12.html>).

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ Rose, *supra* note 6, at 126 (citing Paolo De Coppi et al., *Isolation of Amniotic Stem Cell Lines with Potential for Therapy*, 25 NATURE BIOTECHNOLOGY 100 (2007)).

¹⁶² *Id.* at 127.

¹⁶³ *Id.* at 127 n.76. Dr. Atala has produced several prosthetic organs that have been patented. *See, e.g.*, U.S. Patent No. 6,428,802 (filed Dec. 29, 1999) (issued Aug. 6, 2002) (artificial organ preparation by forming polylayers of different cell populations on a substrate); U.S. Patent No. 6,673,339 (filed Sept. 4, 1997) (issued Jan. 6, 2004) (creation of a prosthetic kidney and its use for treating kidney disease); *see also, e.g.*, Press Release, Wake Forest Baptist Med. Ctr., Wake Forest Physician Reports First Human Recipients of

But these research projects take a significant amount of investment, in both time and money.¹⁶⁴ This is true of the processes that are developed to reach the end stage of a synthetically created bladder, or any other such organ, and also for processes that are used to isolate human embryonic stem cells.¹⁶⁵

In the *Chakrabarty* case in 1980, the U.S. Supreme Court allowed a patent for genetically engineered bacteria that broke down crude oil.¹⁶⁶ The Supreme Court distinguished this bacterium from the naturally occurring bacteria because it was “markedly different”: it was biochemically altered and performed a different function than the natural strain of bacteria, and thus was patentable under § 101 of the Patent Act.¹⁶⁷ Then there was the challenge to Myriad Genetics’s patents in the Southern District of New York in 2009. This came about because of the company’s control over the BRCA 1/2 tests and was largely due to its heavily restrictive pricing. The District Court believed that the isolation of the genes through a biochemical process did not produce a “markedly different product from the naturally occurring genes.”¹⁶⁸ This means the isolated genes should not be patentable as they were outside the scope of § 101 because they were “products of nature.”¹⁶⁹ Under that theory, they would also fall outside of *Chakrabarty*. The District Court, with the finding that Myriad Genetics’s sequences were no different than the naturally occurring sequences, made the correct decision under

Laboratory-Grown Organs (Apr. 3, 2006), available at http://www.wakehealth.edu/News-Releases/2006/Wake_Forest_Physician_Reports_First_Human_Recipients_of_Laboratory-Grown_Organs.htm.

¹⁶⁴ Rose, *supra* note 6, at 127 n.77 (citing Declaration from Douglas A. Melton, Cabot Professor of the Natural Scis., Harvard Univ., to Gary L. Kunz, USPTO Exam’r (Apr. 18, 2006), available at <http://www.consumerwatchdog.org/resources/MeltonDecl.pdf>). Dr. Melton states in his Declaration to the PTO:

I very much believe that Dr. Thomson [sic] deserves the scientific and public recognition he has received. However, he deserves that recognition because he undertook the arduous and timely task of getting fresh and high quality human embryos to use as starting material in his work, and sufficient funding for such research, not because he did anything that was inventive. It was access to those resources, which were, and to this day still are, very difficult to obtain, that enabled Dr. Thomson [sic] to achieve his accomplishment. His perseverance and commitment deserve recognition and accolades. But I believe that had any other stem cell scientist been given the same starting material and financial support they could have made the same accomplishment because the science required to isolate and maintain human embryonic stem cells was obvious.

Declaration from Douglas A. Melton, *supra*, at para. 14.

¹⁶⁵ Rose, *supra* note 6, at 127.

¹⁶⁶ *Id.* at 118; see *Chakrabarty*, 447 U.S. at 303.

¹⁶⁷ Rose, *supra* note 6, at 118; see *Chakrabarty*, 447 U.S. at 310.

¹⁶⁸ Rose, *supra* note 6, at 118; see *Myriad III*, 133 S. Ct. at 2117.

¹⁶⁹ Rose, *supra* note 6, at 118; see *Myriad III*, 133 S. Ct. at 2114.

the law.¹⁷⁰ However, the U.S. Supreme Court disagreed with that determination, and held that they were synthetically created, and were different enough from the naturally occurring biological material.¹⁷¹ With this determination of the facts, the Supreme Court also made the correct decision according to the Patent Act and the precedent of *Chakrabarty*.

Human genes are not the only “isolated bioproducts” with limited access, which drives the public to challenge the validity of their patents.¹⁷² As discussed above, WARF owns the Thompson patents, challenged by consumer groups seeking greater public access in 2006, with the battle continuing into 2014. PUBPAT was able to persuade the PTO to reexamine them, and they were invalidated on the grounds of obviousness and prior art. The patents had already been granted (although further oral argument was scheduled), but the patents were allowing Myriad Genetics to have a monopoly on the processes and products. It was then using this exclusivity to charge a monopoly price. The best solution here seems to be outside of the world of patents. If society were to stop the patent in the first place, the test to tell if a woman is susceptible to breast cancer or ovarian cancer would not exist, and who can say what those developments in science and medical technology will lead to in the future. Scientists have been able to create a bladder outside the human body, and can now potentially obtain the cells capable of this development without embryonic stem cells from a fetus.

VII. ETHICAL CONCERNS OF GENETIC MATERIAL PATENTS IN THE EU

In the EU, the Second Report states that, according to the Group of Ethics, “there was no ethical reason for a complete ban on patenting of inventions relating to stem cells or stem cell lines,” as long as the normal requirements were met to make an invention patent eligible.¹⁷³ However, The Directive’s provisions are clear when it comes to totipotent stem cells. Article 5(1) disallows the human body at its various stages of development from being patented; thus, because each totipotent stem cell could develop into a human being, these cells and their derivatives are not patentable.¹⁷⁴

While totipotent stem cells are clearly excluded in the EU, pluripotent embryonic stem cells create a more complex situation. The Group of Experts considered the question of patent-eligibility to be closely linked to the controversial definition of an embryo.¹⁷⁵ This also affects the scope of research that would be allowed, which is dependent upon each Member State’s national

¹⁷⁰ *Myriad III*, 133 S. Ct. at 2109.

¹⁷¹ *Id.*

¹⁷² Rose, *supra* note 6, at 119.

¹⁷³ Second Report, *supra* note 110, at 2.2.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

legislation.¹⁷⁶ Under the EU framework, research funding may be available to such projects that involve embryonic stem cells, evaluated on a case-by-case basis.¹⁷⁷ As one may expect, there are differences between Member States in the acceptability of embryonic stem cell research.¹⁷⁸

Article 6(1) of The Directive, which remains law and guidance for all of the EU, affords each Member State the ability to refuse any patent “on grounds of ordre [sic] public or morality.”¹⁷⁹ As such, the Commission, in the Second Report, does not further define or provide for “further harmonization in this area,” but instead instructs that the Commission and the respective Groups will continue to monitor developments, and will take “into account both the ethical aspects and the potential impact on competitiveness.”¹⁸⁰ The Commission launched a study to examine the legal and ethical aspects of stem cell patents.¹⁸¹

Since the discussions by the Group of Experts in March 2003, new arguments have been raised. The first is a narrower question than the ones previously reiterated; whether isolated gene sequences should be treated differently from other chemical substances, not on the *objective* grounds the Group of Experts rejected, but on *ethical* grounds because they are elements of the human body that exist naturally.¹⁸² In the Second Report, the Commission notes that in France, “inventions concerning material isolated from the human body” are provided “purpose-bound protection,” as are “human/primate gene sequences” in Germany.¹⁸³ This naturally presents a further question of whether the larger European Community should create a standard, or whether it is appropriate to let each nation decide and pass legislation to regulate. The proper road again seems to be somewhere in the middle, letting each Member State decide based on their own conception of “ordre public” and human dignity. Beyond ethical concerns, the criterion upon which to decide how to limit the scope of patent protection for genetic materials also includes economic factors.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ Second Report, *supra* note 110, at 2.2.

¹⁷⁹ *Id.*; see The Directive *supra* note 65, at art. 6(1).

¹⁸⁰ Second Report, *supra* note 110, at 2.2.

¹⁸¹ *Id.*; see generally *Stem Cell Patents: European Patent Law and Ethics*, UNIV. OF NOTTINGHAM, <http://www.nottingham.ac.uk/law/StemCellProject/summary.htm> (last visited Mar. 29, 2015).

¹⁸² Second Report, *supra* note 110, at 2.1.

¹⁸³ *Id.*

VIII. INCENTIVIZING ECONOMIC GROWTH THROUGH PATENTS ON GENETIC MATERIAL

In 2007, studies indicated that there were more than 4,200 patents issued for human genes, and more than 39,000 patents issued for DNA sequences.¹⁸⁴ It was estimated that there are 25,000 genes in the human genome, and twenty percent of them were protected by patents as of 2011.¹⁸⁵ Obviously, there are many genes in the human genome that have been identified and patented, and patents for stem cells and the cell lines created are on the rise.¹⁸⁶ However, genes or DNA sequences, and stem cells, are part of different patentability battles.¹⁸⁷ The parallel gene and gene sequence battle began with the *Myriad* case, where it went to the U.S. Supreme Court to evaluate the patentability of the BRCA 1/2 gene sequences.¹⁸⁸ The battle for embryonic stem cell patentability began when the PTO reexamined the Thompson family of patents owned by WARF.

In the EU, the upcoming battles were recognized on some level way back in 1998 with The Directive. They were reiterated strongly by The Second Report and the Group of Experts. There was much discussion about the proper scope of protection for patents on genetic material, “purpose-bound protection” which limits the scope to the specifically enumerated industrial application, or “classical model protection” which will cover more derivative products down the road.

Here again, the answer seems to be a middle-of-the-road approach, which is both fortunate and unfortunate at the same time, but the compromise position makes the most sense. Neither the extreme of overly broad protection, nor that of overly narrow protection is satisfactory in practice. The unfortunate part is that there is little guidance, and much like the law in the United States, when it is created, it is not perfect. Too often in the law, people desire a test they can follow, even a bright-line rule, rather than case-by-case evaluation. So while it is unfortunate that the middle-of-the-road approach may not provide much in the way of a real answer to the scope of protection, it fortunately eliminates the extremes.

On one side of the road, broad protection is not a good solution because it would be too exclusive, protecting the gene sequence or stem cells, for example, *and* any cell lines created, or other derivative products or processes; but *also*, broad protection would protect any further development later in time, including possible unforeseen uses down the road. This creates massive problems of access (as seen in the causes for patent challenges in the U.S.) and is also strikingly

¹⁸⁴ Rose, *supra* note 6, at 126 n.67 (citing RUSSELL KOROBKIN & STEPHEN R. MUNZER, *STEM CELL CENTURY: LAW AND POLICY FOR A BREAKTHROUGH TECHNOLOGY* (2007); Karl Bergman & Gregory D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Technology Development*, 25 *NATURE BIOTECHNOLOGY* 419, 420 fig.1, 422 (2007)).

¹⁸⁵ *Myriad II*, 653 F.3d at 1335.

¹⁸⁶ Rose, *supra* note 6 and accompanying text.

¹⁸⁷ *Id.* at 126.

¹⁸⁸ *See Myriad III*, 133 S. Ct. at 2109.

similar to unjust enrichment. An inventor should get to claim rights to their innovation, and perhaps some of the other uses that they can develop for or from their invention, but overly broad protection allows the patent to protect too far down the line, things such as downstream products that were not foreseen at the time of the issued patent. Alternatively, such broad protection could prevent those products from being produced by other inventors, because the protection given to the first patent is too limiting on developments in that particular field.

On the other hand, too limited a patent will hinder, rather than promote, the progress of science, and would in fact deter investment in research and development. With very narrow patent protection, it is not likely that companies would invest such large amounts of money and human capital. This also will limit scientific advancement. An approach that is not overly broad, covering too many derivative and even unforeseen uses, but not overly narrow either, so limited to be “purpose-bound” protection, which does not reward the inventor, is in order. Some middle ground must be found, and while there is not a proper test to determine how to limit protection, a case-by-case approach to the scope of protection under a given patent is likely proper under the law with the goals of the patent system, in the E.U, and in the United States.

Indeed, the second argument that was raised after the Group of Experts met in 2003, was specifically an economic one:

is it more valuable to society to allow the first inventor a broad scope of protection so others which build on this invention should have to seek a licence [sic], or should a patent on a gene sequence be limited in scope to allow future uses of such sequences to be patented freely?¹⁸⁹

These issues are sometimes linked to “freedom of research,” even though research exceptions already exist within patent law.¹⁹⁰ However, there are certainly questions that will be answered, or will need to be, as nations decide what inventions will be eligible for patent protection and what level of protection to provide such patents. Those that elect to provide purpose-bound or similarly narrow protection will likely suffer economic consequences, including a decline in research and development from new and existing companies restricting such activities in that country while moving abroad to perform such tasks in more patent-friendly jurisdictions.

Additional economic questions concern the allowance of these patents in the first place, whether they are even patent eligible, the effect on research and development, and investment in countries with different laws and protections. “More generally it relates to the balance between investment and potential reward for the first innovator in a field compared to subsequent innovators.”¹⁹¹ Economic evidence is difficult to find; this is in part because such evidence does not link

¹⁸⁹ Second Report, *supra* note 110, at 2.1.

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

solely to gene sequence patents or stem cell patents, nor even patents on genetic material or biological matter separate from the other fields of technology.¹⁹² The Commission was able to launch a study,¹⁹³ which was organized to analyze the degree of patenting human DNA in Europe, and the “potential consequences on research and innovation.”¹⁹⁴ The Second Report recognizes that this could be another utilization of the Group of Experts, “to further the impact of the research exemption,” perhaps improving access to the inventions in the first place, and the technological innovation when improvements on old inventions can be made.¹⁹⁵ While this does not answer the question of patent-eligibility at first, it may serve to answer the scope of protection granted, and exceptions allowed, through research.

Disallowing a patent for products such as genetic material “may prove disastrous to society.”¹⁹⁶ Bioresearch patent portfolios attract venture capital to the biotechnology industry. This, in turn, generates licensing revenue and helps with the immense costs of continuing research on isolated bioproducts.¹⁹⁷ It is quite possible that a gap would result if corporate funding stops, and certainly research would stall as federal funding alone would not be enough to continue research on the same scale.¹⁹⁸ This means the government would not make up the funding gap if companies did not receive the protection they desire, and chose to invest elsewhere, either in other countries or pursue other technologies for patents. Such a gap or lack of investment would very likely stall future development in the biotechnology industry, and in turn, the economic development of countries that do not provide adequate patent protection.¹⁹⁹ While it is hard to find economic evidence to support either side on theories of economic development and research, or a lack thereof, if patents are not granted in one country versus another, there seems to be a belief from the courts and other scholars that research and development, as well as perhaps medical technology and advancements, will suffer. Companies and monies will go elsewhere if there is no protection in the United States, or similarly in the EU as a whole, or in specific Member States.

Rose believes protection in the way of patents, or a similar system, is necessary for venture capitalists to invest in bioproduct research and medicine, including genomics.²⁰⁰ This leads Rose to the point that, if some of these technologies are outside the current scope of patent protection, some sort of protection is needed to ensure further research, development, and investment in the U.S.²⁰¹ This will also be true in the EU, or in any particular Member State that

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ Second Report, *supra* note 110, at 2.1.

¹⁹⁵ *Id.*

¹⁹⁶ Rose, *supra* note 6, at 119.

¹⁹⁷ *Id.* at 119-20.

¹⁹⁸ *Id.* at 120.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 122.

²⁰¹ *See* Rose, *supra* note 6, at 123.

does not allow for such patents, or at least patent-type protection; however, this problem is not solved if the system overly broadens or limits the scope of that protection. Any Member State, or the EU as a whole, will likely suffer in the areas of research, development, and investment.

Rose was arguing for *sui generis* (of its own kind) protection of “isolated bioproducts,” such as genes or stem cells, as they were outside the scope of patent protection at the time.²⁰² This argument was supported with an analysis of semiconductor chips and the success that was had when they received *sui generis* protection from the U.S. Congress.²⁰³ This Note does not support the premise that much of these isolated bioproducts are not patentable subject matter under current laws in both the U.S. and the EU. However, what can be taken away from the *sui generis* argument is the similarity between the semiconductor market and its necessary research and development and the corresponding research and development that goes into medical or other technological advancements gained through patenting genetic material. Both semiconductors and genetic material were heavily dependent upon the protection these companies receive. Perhaps the other compelling argument Rose made (albeit for *sui generis* protection to achieve the goal) was the need to “appropriately balance access and innovation.”²⁰⁴ Remember, this was a large part of the reason for the challenge to the Myriad Genetics’s patents on the BRCA 1/2 genes and tests, and the consumer group’s challenges to the WARF owned Thompson family of patents. This is still a problem that arises from exclusivity under the patent system, but is not within the scope of this paper, and the solution may actually exist outside of the patent system itself.

Paralleling Rose’s analysis of the *sui generis* intellectual property protection granted to semiconductor chips, patent protection for these “isolated bioproducts” is the only way to ensure research, development, advancement, and a desired economic impact here in the U.S., and in the Member States of the EU. Rose pointed out that semiconductors were innovative during their time and became the backbone of consumer electronics markets in the 1970s.²⁰⁵ Then in the ten years after Congress passed the SCPA,²⁰⁶ the semiconductor industry exploded from the seventeenth largest industry in the United States, to the largest.²⁰⁷ This is comparable to the current state of the biotech industry, including gene and stem cell patents. Five years ago, it was said that “isolated bioproducts” were part of the rapidly growing biotechnology industry, and still are today.²⁰⁸ At the time of Rose’s article in 2012, it was an innovative market, and biotechnology saw growth rates between eight and ten percent for the previous

²⁰² *Id.* at 120.

²⁰³ *See id.*

²⁰⁴ *Id.* at 121.

²⁰⁵ *Id.* at 125.

²⁰⁶ *See generally* 17 U.S.C. § 906 (2012).

²⁰⁷ Rose, *supra* note 6, at 125 n.61.

²⁰⁸ *Id.*

five years.²⁰⁹ A major part of the biotech industry is continued heavy investment in research and development.²¹⁰

While there were predictions that the market would be down in 2011,²¹¹ the genomics and stem cell markets have been “bright spots for continued innovation and economic growth.”²¹² Investment by venture capitalists in startups in the field of genomics increased 23% from 2007 forward, topping out at \$261 million, despite overall biotechnology investment declining.²¹³ Analysts were predicting that the U.S. stem cell market would see a growth rate of 45% between 2011 and 2013.²¹⁴ The projection for the regenerative medicine market was \$63.8 billion by 2015.²¹⁵ Stem cells, genomics, and other regenerative medicine technologies make up most of the categories of isolated bioproducts.²¹⁶ While Rose addresses these points from a slightly different angle, urging a *sui generis* intellectual property protection,²¹⁷ they are even more relevant as economic evidence of the need for patent protection for genetic material.

When it was created, the drafters of The Directive noted that genetic engineering and biotechnology “are playing an increasingly important role in a broad range of industries.”²¹⁸ It continues on to say that protecting such biotechnological inventions will be crucial “for the Community’s industrial development.”²¹⁹ This was certainly true in 1998, and the technological boom is still expanding.

The Directive acknowledged that research and development in the field of genetic engineering requires large amounts of capital investment, even calling it high-risk, and the companies rely on patent protection to ensure their investment can be protected and profitable.²²⁰ It also takes some level of effective protection across the EU to encourage investment in the biotechnology field.²²¹ While certain questions will be left to each Member State, if there is not some uniformity in the EU, companies will go elsewhere to ensure their protection will be enforced.

One main goal of the U.S. patent system is “[t]o promote the Progress of Science and useful Arts.”²²² To the public, this means that the inventor should not

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² Rose, *supra* note 6, at 125.

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ Rose notes that a “lack of intellectual property protection . . . could deter innovation and access to knowledge in these high-growth areas.” Rose, *supra* note 6, at 125.

²¹⁸ The Directive, *supra* note 65, recital 1.

²¹⁹ *Id.*

²²⁰ *Id.* recital 2.

²²¹ *Id.* recital 3.

²²² U.S. CONST. art. I § 8, cl. 8.

receive the sole benefits (i.e. money or notoriety) from a patentable invention but rather that the *public* should reap the greater benefits and rewards of the progression of science. The challenge of the *Myriad* case arose largely because of the public's lack of access and the high price for the BRCA diagnostic test. Myriad Genetics is the exclusive licensee of the BRCA patents and they have refused to grant licenses for any "second-opinion testing."²²³ They charge as much as \$4,000 for the diagnostic test and have admitted that the BRCA tests account for 88% of the company's near \$400 million in annual revenue, with 98% of those sales occurring in the United States.²²⁴

Challenges such as the WARF dispute and the *Myriad* case are often brought because of money and access. A competitor may feel they had an earlier or better claim to an invention or process because of obviousness and prior art, or that the current patent was not an inventive step like in WARF. As in *Myriad*, the public may feel that the patent holder is monopolistic and that the public should have more access, or at least cheaper access, to the invention or process. Also, either businesses or the public may feel that the patent is too broad, which limits innovation or restricts the market and public access.

However, while the public is complaining that Myriad Genetics may be engaging in monopolistic price gouging, the fact remains that without the right to a patent, research would likely not have occurred in the first place. This type of biotechnical research requires large sums of money, and with no guarantee to reap those rewards, recoup their investment, and strive for profit, many such companies would thus not conduct the research or development which has improved our health over the last century, and improved our medical technology.²²⁵ While a broad patent can unnecessarily restrict competition, access for the public, and even innovation if the patent protects too far downstream, protection that is too narrow does not incentivize the massive funding and human capital it takes in the biotechnology industry to develop these processes and products.

The case of *Graham v. John Deere Co.* saw the U.S. Supreme Court favorably interpret the Constitution, saying that "progress" includes enhancing overall knowledge for the benefit of society, and also promoting the economy.²²⁶ Any intellectual property protection, including patents, thus should balance the promotion of innovation and public access.²²⁷ The social bargain created by patent law ensures that a valuable invention will be added to the public domain once the patent term ends.²²⁸ As the Constitution states, promoting progress should also motivate inventors; patents are intended to provide a reward for that

²²³ Rose, *supra* note 6, at 117-18.

²²⁴ *Id.* at 118 n.20 (citing John Conley et al., *How Will Myriad Respond to the Next Generation of BRCA Testing?*, GENOMICS L. REPORT (Mar. 3, 2011), <http://www.genomicslawreport.com/index.php/2011/03/01>).

²²⁵ *Id.* at 120 (citing *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 211 (S.D.N.Y. 2010), rev'd, 653 F.3d 1329 (Fed. Cir. 2011)).

²²⁶ 383 U.S. 1, 6 (1966).

²²⁷ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

²²⁸ *Sony Corp. of America v. Universal City Studios Inc.*, 464 U.S. 417, 429 (1984).

creativity, but then to allow the public to have access to “the products of their genius” after the exclusive patent right has expired.²²⁹

As the European Parliament and Commission wrote in The Directive, “the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities.”²³⁰ It is clear the EU shares a view of patents similar to that of the United States. They incentivize companies to invest and be innovative by protecting the individuals and companies investing in necessary research and development.²³¹ In 1998, The Directive made note of the progress in treating diseases because of elements isolated from the human body, and our ability to reproduce them. Technical processes that isolate these elements are perfected, and then further processes are developed so we can reproduce the product. Medical technologies such as this require immense research and development, and the patent system should encourage these valuable advancements.²³²

The Directive took note of several other interesting economic perspectives in its examination of the patent system as it relates to biotechnology. Even further, The Directive stated that the patent system is actually insufficient for research and development in biotechnology when the reward cannot be seen. Specifically it mentions rare and “orphan” diseases, believing the Member States and the European Community as a whole have a duty to respond to this incentive problem.²³³ Also, developing the biotechnology industry can be important to developing countries. It has impacts on health, epidemic and endemic diseases, and hunger across the globe.²³⁴ Thus, “the patent system should likewise be used to encourage research in these fields.”²³⁵

Genetic material, including gene sequences and partial sequences, and stem cells and the resulting cell lines, rely on patents to create venture capital to initiate the cycle, and then licensing revenue to recover the cost of such research and development.²³⁶ If there is no patent protection, it is very likely there will be a major decline in corporate investment (and not enough federal funding).²³⁷ A lack of proper patent protection will impact both the biotechnology market itself, and the economies of the United States and the EU, and also will stall valuable medical technological advancement.

²²⁹ *Id.*

²³⁰ The Directive, *supra* note 65, recital 46.

²³¹ *Patents*, *supra* note 2.

²³² The Directive, *supra* note 65, recital 17.

²³³ *Id.* recital 18.

²³⁴ *Id.* recital 11.

²³⁵ *Id.*

²³⁶ Rose, *supra* note 6, at 119-20.

²³⁷ *Id.*

IX. CONCLUSION

There is much discussion around patenting gene sequences, and especially controversial discussion surrounding human embryonic stem cells and other similar tissues. Naturally this includes questions regarding the future use and possible derivatives of these patented materials. However, despite recent judicial decisions, there is still a lack of clear guidance from the law in the United States, and The Directive from the EU does not do much better. There are still many questionable inventions today, and surely more to come in the future, in the United States, the EU, and elsewhere. Furthermore, there is no clear answer as to the proper scope of protection for bioproducts, and no clear way to resolve the concern over the need for greater access within the patent system.

This is a field that is rapidly evolving, and the corresponding laws are also in a state of constant development, responding to technological innovations, ethical concerns, and economic pressures. Genetic patents and the scope of protection within the United States and abroad will continue to be a controversial issue, from both a moral and medical stance, as well as from an economic perspective moving forward. It seems evident that many scholars, courts, and businesses believe there is economic motivation for granting patents on genetic material. It is clear that without some type of protection, we would not have reproduced a human bladder, created a prosthetic kidney, or developed the tests to see if a woman is susceptible to certain kinds of cancer. Economic evidence is hard to collect, but in the near future countries without patent protection for these types of companies, products, and processes, will suffer. Without patent protection, there will be no investment, and without funding, there can be no advancement.

