
**GENE PROTECTION: HOW MUCH IS TOO MUCH?
COMPARING THE SCOPE OF PATENT PROTECTION FOR GENE
SEQUENCES BETWEEN THE UNITED STATES AND GERMANY**

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I. Introduction

The drive to map the human genome and identify genes led to the establishment of the Human Genome Project (“HGP”).¹ The HGP estimates that the human genome consists of 20,000 to 25,000 genes.² The U.S. Patent and Trademark Office (“USPTO”) issues thousands of patents for human genes identified by HGP and it is reasonable to believe that this trend will continue as the HGP isolates and identifies more human genes.³ This increase in intellectual property protection for human genes is not only evident in the United States, but also is found in many other countries, and in the European Union (“EU”).⁴ In the EU, disputes arise as to the extent of protection given for human genes mainly due to the belief that living matter does not qualify for patent protection.⁵

This Note explores the patentability requirements for human genes in the United States, the EU, and Germany. The first part of this Note sets forth background information on deoxyribonucleic acid (“DNA”) and human genes.

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1. http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml archived at <http://www.webcitation.org/5WCQFr0j8>.

2. *Id.*

3. Lynne C. Tyler, *Genes and 35 U.S.C. §101: Are DNA Sequences Corresponding to Genes Patentable Subject Matter?*, 19 NO. 6 INTELL. PROP. & TECH. L.J. 16 (2007). Scientists estimate that through 2005 the USPTO issued over 2,000 patents covering approximately one-fifth of all human genes. *Id.* at 16. See also Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239 (2005) (examining arguments for the patentability of human genes). Along with the increasing numbers of patents on protein encoding genes, there is also an increase in the number of patents for non-protein encoding genes. *Id.* at 239.

4. See Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AIPLA Q.J. 193, 196 (2007) (describing rapid expansion of intellectual property for biotechnology).

5. Ingrid Schneider, *Civil Society Challenges Biopatents in the EU*, PROPEUR NEWSL. (Prop. Reg. Eur. Sci., Ethics & L. Project, Birmingham, U.K.), Summer 2005 at 3. Germany and France both expressed reservations with regard to the EU legislation on patenting biotechnology. *Id.*

The second part examines the relevant patent laws of the United States, the EU, and Germany. The final two parts of this Note explore the differences between Germany and the United States regarding general and limited protection of DNA sequences, and present arguments for why Germany's national law presents a better model to follow when providing intellectual property protection based on the extent of patent protection provided for genes.

II. DNA Background

Understanding how DNA functions is essential for understanding the human genome and applying that knowledge to the study of various human afflictions. DNA forms the shape of a double helix, which is comprised of chains of sugars and phosphates and the bases adenine, thymine, cytosine, and guanine.⁶ Particular DNA sequences form genes, which then code for a unique protein.⁷ The process for making proteins from genes is known as gene transcription.⁸

Gene transcription occurs when the double helix of the DNA is unwound and one strand makes messenger RNA ("mRNA").⁹ The genes that encode for the proteins copy onto the mRNA strand, which allows for the production of the proteins after a translation process.¹⁰ There are one start and three stop codons that turn translation on and off, and there are an additional sixty-four possible codons that exist, representing a total of twenty amino acids bound together to make proteins.¹¹

Along a strand of DNA, the coding regions for genes, called exons, may be spread out and not connected with one another.¹² The areas in between the exon regions are areas of non-coding material called introns.¹³ Because the coding regions are spread out along the DNA strand, the actual identification of

6. 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 N.Y.U. L. REV. 1623, 1632 (2001) (providing a scientific background of DNA and genes).

7. See Tyler, *supra* note 3, at 17 (describing the background of DNA and proteins); Gitter, *supra* note 6, at 1633 (providing a scientific background of DNA and genes). Scientists believe there are roughly 30,000 to 40,000 genes coded for on DNA chains. *Id.*

8. Tyler, *supra* note 3, at 17.

9. Jameson, *supra* note 4, at 205; Tyler, *supra* note 3, at 17. RNA is similar to DNA, but uracil substitutes for adenine and ribose substitutes for deoxyribose. *Id.*

10. Jameson, *supra* note 4, at 205; Tyler, *supra* note 3, at 17. Translation occurs when the ribosome reads the mRNA bases in sets of three (referred to as a codon) which then code for one amino acid. *Id.* mRNA specifies the order in which amino acids bond forming proteins. *Id.*

11. Jameson, *supra* note 4, at 205-06; Tyler, *supra* note 3, at 18. Due to there only being twenty amino acids and sixty-four codons, repetition exists for certain amino acids with different possible codon sequences. *Id.*

12. Tyler, *supra* note 3, at 18; see also Gitter, *supra* note 6, at 1632-33 (describing the genome "Book of Life" analogy and what role the exons and introns play in the genome).

13. Tyler, *supra* note 3, at 18. In total, exons only comprise three percent of a gene sequence while the lengthy intron portions make up the remaining ninety-seven percent. Gitter, *supra* note 6, at 1633.

genes is very difficult.¹⁴ To combat this difficulty, new developments use Expressed Sequence Tags (“ESTs”) in the identification of genes.¹⁵

ESTs are DNA sequences that contain only exons - the regions that express genes - and do not contain any introns.¹⁶ They are portions of complementary DNA (“cDNA”) produced from mRNA.¹⁷ Multiple options exist to utilize these portions of cDNA. One option is that a scientist may place the cDNA in a public library for other researchers to use to produce certain genes.¹⁸ Alternatively, a scientist may manipulate the cDNA so that it binds back onto the original DNA strand and matches the complementary location where that specific gene is located, thereby identifying the location on the DNA strand of the gene.¹⁹

Once a gene is known and characterized, researchers utilize functional genomics to try to determine the function of that gene.²⁰ There are various ways that researchers may attempt to derive the function, one being comparing the gene sequence to genes that are similar whose functions are already known.²¹ Another possible way is to turn off specific genes in mice and observe the mice for resultant changes in their health and activities.²²

Currently there is a race in the biotechnology industry to identify and patent a gene’s basic sequence.²³ Some in the industry believe that patents should not be granted for mere knowledge of the gene’s sequence. Rather, the applicant also must identify a specific function.²⁴ The scope of patent protection in both Europe and the United States has favored the view that patents may be awarded for identifying DNA sequences for different genes, so long as some *possible* function is known.²⁵

14. Tyler, *supra* note 3, at 18-19. In addition to the coding regions being spread out along the DNA strand, the DNA is wrapped and packed in various ways which can contribute to difficulties in decoding genes. *Id.*

15. Jameson, *supra* note 4, at 206.

16. Jameson, *supra* note 4, at 206. ESTs are DNA sequences of 200-500 nucleotides sequenced from the ends of an expressed gene. Tyler, *supra* note 3, at 19.

17. Tyler, *supra* note 3, at 19; *see also* Jameson, *supra* note 5, at 206 (explaining the possible uses of cDNA).

18. Jameson, *supra* note 4, at 206 (describing the possible uses of a cDNA library).

19. Tyler, *supra* note 3, at 19 (providing the benefits of using cDNA to identify genes in a specific location, such as learning what triggers the expression of certain genes).

20. Gitter, *supra* note 6, at 1634-35. “Functional genomics is the study of genes, their resulting proteins, and the role played by the proteins [in] the body’s biochemical processes.” Webster’s New World Medical Dictionary, definition of functional genomics, *archived at* <http://www.webcitation.org/5b5GGM3q9>.

21. Gitter, *supra* note 6, at 1635.

22. Gitter, *supra* note 6, at 1635. Mice engineered with certain genes deleted (“turned off”) are termed “knock out” mice, and scientists can predict the function of those specific genes based on how the mice react. Nicholas Wade, *Reading the Book of Life; Now, the Hard Part: Putting the Genome to Work*, N.Y. TIMES, June 27, 2000, at F1, *archived at* <http://www.webcitation.org/5e16cQL3z>.

23. Gitter, *supra* note 6, at 1631.

24. Gitter, *supra* note 6, at 1631 (summarizing the position of the HGP and the Celera Genomics Group, two groups working towards sequencing the entire human genome).

25. Gitter, *supra* note 6, at 1643-48. Commissioner John Doll of the USPTO describes the United States’

III. History

Various legal issues exist regarding the patentability of DNA sequences, which the United States, Germany, and the EU confront in different ways. Both the United States and Germany have their own legal frameworks for reviewing and granting gene patents on a national level, while the EU has distinct policies that individual countries within the EU implement. In addition, international agreements exist between the parties that also play a role in what is patentable for biotechnology.²⁶

A. U.S. Law

U.S. patent law arises from the U.S. Constitution, Article I, section 8, clause 8.²⁷ Further, the Patent Act of 1952²⁸ provides that certain requirements must be met in order to obtain a patent.²⁹ The item for which the patent is being sought must meet stated levels of novelty, utility, and nonobviousness.³⁰ In *Diamond v. Diehr*,³¹ the Supreme Court looked to the legislative history of the 1952 Patent Act to determine how extensive patent protection was and found that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”³² The Court, however, stated that it will apply

patent examination standard: “in order for isolated DNA sequences to be distinguished from their naturally occurring counterparts, which cannot be patented, the patent application must state that the invention has been purified or isolated or is part of a recombinant molecule.” John Doll, *Biotechnology: The Patenting of DNA*, 280 SCIENCE 689, 689 (1998). The EU standard evolved to be “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.” Council Directive 98/44, On the Legal Protection of Biotechnological Inventions, 1998 O.J. (L213) 13 (EC) at art. 5.2 [hereinafter Biotech Directive]. The EU goes further and requires that an “industrial application of a sequence or a partial sequence of a gene be disclosed in the patent application.” *Id.* at art. 5.3. Both standards recognize that DNA sequences are patentable even though they may be identical to naturally occurring sequences, but the EU standard is more rigorous. It requires applicants to identify a specific application in order for a patent to be granted. *Id.*

26. The various international intellectual property agreements that exist between the EU and the United States are beyond the scope of this note. For copies of these agreements, refer to F. SCOTT KIEFF & RALPH NACK, INTERNATIONAL, UNITED STATES, AND EUROPEAN INTELLECTUAL PROPERTY (Aspen Publishers 2006).

27. 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”).

28. 35 U.S.C. § 101 (2006).

29. 35 U.S.C. §§ 101-103. Statutory requirements for patentability include: satisfying patentable subject matter and utility (§ 101); novelty (§ 102); and nonobviousness (§ 103). *Id.*

30. 35 U.S.C. §§ 101-103. Patents are obtainable for an invention or discovery for a machine, process, manufacture, or composition of matter, as long as it is new and useful. § 101. Additionally, an invention must be novel, meaning it has not been invented and made available to the public previously. § 102. Finally, an invention must be nonobvious, meaning that various aspects of the invention were not already available to the public in a way that one skilled in the art would combine them to create the invention being patented. § 103.

31. 450 U.S. 175 (1981) (examining the scope of the statutory subject matter provision).

32. *Id.* at 182. The Supreme Court has additionally held that it will not restrict the language of the Patent Act without the express intent of Congress. *Id.* See also *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)

certain subject matter restrictions under section 101.³³

The statutory patentability requirements are applied to biotechnology, including DNA sequences, in the same way as they are to any invention.³⁴ The courts have allowed, based on *Diamond v. Chakrabarty*, the patenting of DNA sequences corresponding to certain genes when the sequences are purified, meaning that the sequence has been isolated from how it would otherwise exist in nature, showing some characteristic that is different from the natural sequence.³⁵ In addition to DNA sequences, patent protection is also extended to Expressed Sequence Tags and Single Nucleotide Polymorphisms (“SNPs”).³⁶

B. EU Law

The European Patent Convention (“EPC”),³⁷ national laws, and EU directives govern intellectual property rights in the EU.³⁸ The European Patent Organisation currently consists of thirty-four member countries.³⁹ The

(holding that living matter can satisfy the patent requirements of § 101). In holding that living matter may be patented, the Court took notice that it “should not read into the patent laws limitations and conditions which the legislature has not expressed.” *Id.* at 308 (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933)).

33. *Diehr*, 450 U.S. at 185. The Court identified three areas in which patents will not be granted: laws of nature, natural phenomena, and abstract ideas. *Id.* For example, the Court described the discovery of a new mineral in the earth, noting that it would not be patentable subject matter due to being a “manifestation of nature.” *Id.* In order to distinguish between natural phenomena and compositions of matter, the Court applies many different types of tests. Tyler, *supra* note 3, at 20. One such test comes from *Chakrabarty*, where the Court found that the composition of claimed matter had different characteristics from those found in nature, making it an invention and not part of nature. 447 U.S. at 310.

34. See Jameson, *supra* note 4, at 201 (acknowledging that the patentability standards applied to biotechnology are similar to those applied to all other inventions except that there may be a lower non-obvious standard and stricter written description requirement).

35. See, e.g., *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 1989 WL 169006, 13 U.S.P.Q.2d (BNA) 1737 (D. Mass. 1989), *aff’d in part, rev’d in part, vacated in part*, 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (recognizing the patentability of a DNA sequence for a gene). The court distinguished between a complete DNA sequence of a natural gene, which is considered a natural phenomenon, and a “purified and isolated,” and thus patentable DNA sequence that codes for a specific gene. *Id.* at 32. See also *Chakrabarty*, 447 U.S. at 310.

36. See John Murray, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI-KENT L. REV. 231 (1999) (discussing disputes over the patentability of DNA sequences in the United States). DNA sequencing is assisted by ESTs, which are fragments corresponding to only part of a gene. *Id.* at 236-37. In order to identify genes with a given disease, scientists may utilize SNPs, which are small variations in the genetic code. *Id.* at 241-42. A main element of the debate against patentability of both ESTs and SNPs is that the information should be available publicly for research purposes. *Id.* at 239-42.

37. Convention on the Grant of European Patents, art. 52, Oct. 5, 1973, 1065 U.N.T.S. 254 [hereinafter EPC].

38. Lydia Nenow, *To Patent or Not to Patent: The European Union’s New Biotech Directive*, 23 HOUS. J. INT’L L. 569, 572-73 (2001).

39. European Patent Office, Member States of the European Patent Organisation, Aug. 8, 2008, *archived* at <http://www.webcitation.org/5WLAYh2tJ>. Twenty-one countries formed the EPO based on the EPC in 1973. Nenow, *supra* note 38, at 583.

European Patent Office (“EPO”) established an independent application and examination process for the granting of patents.⁴⁰ After a patent is granted through the EPO it is nationalized in individual countries designated by the applicant.⁴¹ The enforcement of a patent in each individual country is governed by national law.⁴²

Each country has its own national patent laws and once a patent is granted through the EPO and nationalized in an individual country, it is then subject to that country’s individual laws.⁴³ Because each country has individual patent laws and enforcement mechanisms, there is a lack of uniformity among the countries.⁴⁴ The EU sets minimum standards for patent protection by issuing directives that member states must implement into their national law.⁴⁵

The European Parliament and the Council of the European Union together approve EU directives that address certain patentability requirements.⁴⁶ In 1998, the European Union issued a directive on the patentability requirements of biotechnology.⁴⁷ The EPO readily adopted the biotechnology patentability requirements specified in the Biotech Directive.⁴⁸ The Biotech Directive is important because it clarifies that biotechnological inventions are considered for patent protection based on the standards applied to any other area of technology.⁴⁹ In addition, the Biotech Directive specifies what is considered

40. See Nenow, *supra* note 38, at 583-84. The application and examination process consists of an application being filed, reviewed, and countries designated, through the EPO. European Patent Office, How to Apply for a European Patent, April 2008, *archived at* <http://www.webcitation.org/5b5H1TIG5>.

41. Nenow, *supra* note 38, at 584. During the nationalization process the EPO grants a patent, which the inventor then files translations for in designated countries along with a filing fee. See also Christopher Ann, *Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal With It*, 7 GERMAN L.J. 279, 289 (2006) (describing the nationalization process of EPC patents).

42. Ann, *supra* note 41, at 289. The nationalization process allows an inventor to select those European countries in which he desires patent protection; once nationalization is complete, the resulting patent is subject to the national patent law as if that country had granted the patent. *Id.* See also European Patent Office, Request for Grant of a European Patent, April 2008, *archived at* <http://www.webcitation.org/5b4z28P6Q>.

43. See, e.g., Nenow, *supra* note 38, at 584; Ann, *supra* note 41, at 289.

44. Nenow, *supra* note 38, at 596-97.

45. See, e.g., Nenow, *supra* note 38, at 606; Christian Kilger, et al., *The Erosion of Compound Protection in Germany: Implementation of the EU Directive on the Legal Protection of Biotechnological Inventions – The German Way*, 87 J. PAT & TRADEMARK OFF. SOC’Y 569, 571.

46. See Jameson, *supra* note 4, at 198. Intellectual property directives have included areas such as software and biotechnology. *Id.*

47. Biotech Directive, *supra* note 25, at 13; Jameson, *supra* note 5, at 198. The EU had two goals when passing the Biotech Directive; the first was to clarify the protection allowed to biotechnological inventions, and the second was to provide some sort of harmonization between the different member states on the patentability of biotechnology. Jameson, *supra* note 4, at 200.

48. Jameson, *supra* note 4, at 198-99. The EPO did not have to adopt the Biotech Directive because the European Patent Organisation is independent from the EU, but the EPO implemented the Biotech Directive because it reflected past EPO decisions. *Id.* Although the EPO adopted the Biotech Directive, individual states have not implemented it as willingly. *Id.*; see also Schneider, *supra* note 5, at 3.

49. Biotech Directive, *supra* note 25, at art. 1(1); Jameson, *supra* note 4, at 200. The Biotech Directive clearly states that “no prohibition or exclusion exists in national or European patent law which precludes a priori the patentability of biological matter.” Biotech Directive, *supra* note 25, at ¶ 15. In the EU, what

patentable, such as biological material that has been isolated from its environment, and what is not patentable, such as plants and animals or processes that would produce plants or animals.⁵⁰ The Biotech Directive also provides a morality exception stating that any invention that contravenes public policy or morality is not patentable.⁵¹

Member states were required to implement the Biotech Directive into their national law by July 30, 2000.⁵² Some countries delayed implementation and the European Court of Justice (“ECJ”) subsequently found them in violation of their obligations under EU law.⁵³ Norway, the Netherlands, and Italy filed a collective action at the ECJ to have the Biotech Directive invalidated, but the ECJ dismissed the action and used the opportunity to restate the underlying principles of the Biotech Directive, specifically to unify biotechnology patent law.⁵⁴

C. German Law

Each state in the EU has its own national patent laws separate from EU policies, which interact with and sometimes conflict with EU laws.⁵⁵ German intellectual property law is governed by both national legislation, the German

separates the intellectual property protection of biotechnology from other areas of technology is the inclusion of the morality requirement (manifested in the EPC) and the specific processes that do not gain protection. *See* Nenow, *supra* note 38, at 584-86 (highlighting EPC *ordre public* and morality exceptions to biotechnology patents).

50. Biotech Directive, *supra* note 25, at art. 3(2) and art. 4(1). The Biotech Directive clearly states that non-patentable subject matter includes: processes for human cloning, human germ cells, use of human embryos, creation of human or animal chimeras, and processes for modifying the germ line of humans. Nenow, *supra* note 38, at 593.

51. Biotech Directive, *supra* note 25, at art. 6. The addition of a morality requirement in the Biotech Directive is consistent with international law but differs from United States law, which does not include such an exception. Jameson, *supra* note 4, at 201-02. The Biotech Directive states that *ordre public* and morality correspond to specific ethical or moral principles that are held by each individual member state. Biotech Directive, *supra* note 25, at ¶ 39.

52. Biotech Directive, *supra* note 25, at art. 15(1). Various countries delayed incorporating the Biotech Directive into national law due to disagreements with certain provisions of the Biotech Directive. Schneider, *supra* note 5, at 3.

53. Ann, *supra* note 41, at 280 (identifying the limited patent protection available for human gene sequences). The ECJ found France, Austria, Belgium, and Luxembourg in violation of their duty to implement the Biotech Directive. Kilger, *supra* note 45, at 572.

54. *See* Kilger, *supra* note 45, at 572 (describing the reservations that various countries had against implementing the Biotech Directive). Particular areas of contention included: ethical questions; the boundaries of patentability, such as what level of patent protection elements isolated from the human body should get; and the fear of stalling innovation, particularly with regards to DNA sequence patents. *Id.* *See also* Commission of the European Communities, *Report from the Commission to the European Parliament and the Council: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM (2002) 545 final at 8 (summarizing the court proceedings brought regarding the Biotech Directive).

55. *See* Nenow, *supra* note 38, at 572-73 (noting the disagreements amongst the EU’s various sources of patent law.)

Patent Act (“PatG”),⁵⁶ as well as any directives issued by the EU, such as the Biotech Directive.⁵⁷ When Germany finally implemented the Biotech Directive into the PatG, the resulting legislation was more restrictive than the terms of the Directive, particularly with regard to DNA sequences.⁵⁸

The amended PatG contained a new paragraph in its first section describing which inventions would gain protection.⁵⁹ In addition, a section 1a was added after section 1, which specified that sequences or partial sequences of genes constitute patentable subject matter even if the structure is the same as that existing in nature.⁶⁰ Finally, section 1a also clearly states that if the invention is a sequence or partial sequence of a gene, the use of that sequence must be clearly identified.⁶¹

Germany’s amendment to the PatG with implementation of the Biotech Directive was delayed due to an internal debate over the absolute protection provided under the Biotech Directive for biotechnology patents and the belief that it was too extensive.⁶² There was also debate surrounding the morality clauses.⁶³ After being found in violation of its duties by the ECJ, the German Parliament compromised and implemented the Biotech Directive, but provided more restricted protection for human DNA sequence patents, keeping the same broad protection for plant and animal DNA sequences as provided in the Biotech Directive.⁶⁴

The uniqueness of the PatG, amended in 2005, is that it does not grant absolute protection for human DNA sequences.⁶⁵ Instead, when the applicant

56. German Patent Act 21/06/1976 No. 32 [hereinafter PatG].

57. See, e.g., Franz-Josef Zimmer & Svenja Sethmann, *Act Implementing the Directive on the Legal Protection of Biotechnological Inventions in Germany*, 24 BIOTECHNOLOGY L. REP. 561, 561-62 (2005); Kilger, *supra* note 46, at 570. EU member countries are governed both by their individual national legislation, which applies only in that country and is territorial in nature, as well as by any EU directives issued, which are usually attempts at harmonization between all member countries. DANIEL C.K. CHOW & EDWARD LEE, *INTERNATIONAL INTELLECTUAL PROPERTY: PROBLEMS, CASES, AND MATERIALS* 17, 65 (Thomson/West 2006). EU directives do not supersede national law, but instead must be implemented by the member state into its national legislation. *Id.* at 66; see also *supra* notes 44-49 and accompanying text.

58. See, e.g., Zimmer, *supra* note 57, at 562 (describing the changes to the PatG after the Biotech Directive was passed); Kilger, *supra* note 45, at 570-72 (describing the differences between the PatG and the EPC). In 2003, the German Parliament began drafting an implementation of the Biotech Directive, but it was not until February 28, 2005 that the Biotech Directive was adopted into the PatG. *Id.* at 573.

59. Zimmer, *supra* note 57, at 563. Paragraph 2 states that patents may be granted to inventions that are composed of biological material. *Id.*

60. Kilger, *supra* note 45, at 573 (providing a rough English translation of section 1a of the PatG).

61. Kilger, *supra* note 45, at 573. This subparagraph was the major distinction from the Biotech Directive because it did not provide absolute protection for a sequence, but instead limits protection to that application claimed. Ann, *supra* note 41, at 286.

62. See, e.g., Zimmer, *supra* note 57, at 561 (describing the public debate in Germany over absolute product protection after the Biotech Directive was passed); Kilger, *supra* note 45, at 572-73 (identifying the multiple drafts of the implementation of the Biotech Directive).

63. Kilger, *supra* note 45, at 572-73.

64. See PatG, *supra* note 56, § 1a(4); Zimmer, *supra* note 58, at 561 (describing the passed PatG and the amount of protection provided to human, animal, and plant sequences).

65. Ann, *supra* note 41, at 286.

files the patent application, he must name a definite function for which the patent will be exclusively granted.⁶⁶ This differs from the EPO, EU, and U.S. standards which only require identification of a definite function of the DNA sequence to grant absolute protection.⁶⁷

Germany chose to restrict protection for human DNA based on the belief that absolute protection of human DNA sequences should not be granted.⁶⁸ This was because of the importance of research involving DNA sequences and the fear that granting such broad protection might hamper research into additional uses of genes and DNA sequences.⁶⁹ By patenting DNA sequences based on the identification of one function, researchers will not be as inclined to continue research on that particular sequence to discover new applications of it.⁷⁰ Researchers, instead, will be more likely to investigate unpatented DNA sequences to obtain their own patent rights.⁷¹

The changes that Germany made to the PatG are changes that affect only national patents.⁷² They do not affect European patents, which are issued through the EPO and then nationalized in each country.⁷³ Therefore, changes to the PatG do not actually affect the granting of patents through the EPO.⁷⁴ Although Germany has stated its belief that human DNA sequences should not be granted such broad protections as those granted by the EPO and the EU, that belief is not actually enforceable in the way it has been enacted.⁷⁵ Currently, scientists can get around Germany's stricter patent function requirements by filing an application with the EPO and designating Germany as a country for nationalization.⁷⁶ After the EPO grants the patent, the patent holder can nationalize the patent in Germany and it will be enforceable based on the EPO standards of broad protection for DNA sequences, rather than the narrower

66. Ann, *supra* note 41, at 286. An application of the sequence must be listed on the patent application, and protection will only cover that application. *Id.*

67. Ann, *supra* note 41, at 285 (recognizing that DNA sequence patents will be granted under the EPC which does not limit protection for a specific function).

68. Zimmer, *supra* note 57, at 561.

69. See Kilger, *supra* note 45, at 572 (recognizing the issues being debated in Germany when the Biotech Directive was passed and why they were wary of implementing the Biotech Directive).

70. See Gitter, *supra* note 6, at 1668 (presenting the arguments over limited patent protection versus absolute patent protection).

71. See Gitter, *supra* note 6, at 1631 (describing the push by some companies to patent as many genes as possible).

72. See Zimmer, *supra* note 57, at 565 (specifying that the changes to patentability will only effect those seeking patents under the PatG).

73. Ann, *supra* note 41, at 284. Individualized national patent law is nonbinding on the EPO. *Id.*

74. See Ann, *supra* note 41, at 284 (indicating that national patent law only becomes an issue after a patent has been granted and the patent holder is seeking to nationalize a patent in an individual state).

75. See Ann, *supra* note 41, at 287 (describing the two separate bodies of law that are the PatG and the EPO and that one does not affect the other).

76. Ann, *supra* note 41, at 288. Had Germany implemented the changes in paragraph 9, the "effects" part of the PatG, rather than in paragraph 1a, patent applicants would not be able to sidestep the stricter patentability requirements for DNA sequences. See *id.* at 288-89.

German standards.⁷⁷

Although Germany cannot currently enforce its more restricted patent law against EPO patents, its actions have caused other countries to consider similar legislation.⁷⁸ Germany's limited protection legislation provides a model for Switzerland.⁷⁹ Although Switzerland is under no obligation to adopt the Biotech Directive due to their non-EU member status, they have agreed to voluntarily adopt it, because of their representation in the European Patent Organisation.⁸⁰ The legislation they are considering would limit the extent of patent protection on human DNA sequences, similar to Germany's plan, but it would exist in the nationalizing portion of the law.⁸¹ In this way, after a patent has been granted by the EPO and the applicant goes to Switzerland to nationalize it, it will be met with the restrictions of limited protection.⁸²

IV. General Patenting of DNA Sequences

The United States and the EPO take a broad approach to granting patent protection for biotechnological inventions, while Germany has taken a more limited position.⁸³ The broad amount of protection granted by the United States and the EPO is evidenced by the large number of patents granted for DNA sequences.⁸⁴ Even though patent offices have granted many DNA sequence patents, there are still many individuals who believe that DNA sequences do not satisfy the base requirements of patentable subject matter, utility, novelty, and nonobviousness for patentability.⁸⁵

A. Statutory Arguments

The first statutory argument presented is that DNA sequences are not patentable subject matter under 135 U.S.C. § 101 or EPC Articles 52 and 53 on

77. Ann, *supra* note 41, at 288. Nationalization occurs after a patent is granted by the EPO by filing translations and paying registration fees in the country designated. *Id.* at 289.

78. Ann, *supra* note 41, at 289; *see also* Schneider, *supra* note 5, at 3 (explaining that both Germany and France amended the Biotech Directive when it was adopted into national legislation).

79. Ann, *supra* note 41, at 289. Spain, Portugal, and Italy also all drafted weaker but similar legislation to that of Germany. *See* Schneider, *supra* note 5, at 3.

80. Ann, *supra* note 41, at 289.

81. Ann, *supra* note 41, at 289-90. Switzerland's planned amendments would include limited protection for all DNA sequences, not just human sequences like the United States, EU, and Germany. *Id.* at 289. By implementing the limitations in the nationalization portion of the patent granting process then patent applicants will be subject to national law rather than the EPO's regulations. *Id.* at 289-90.

82. *See* Ann, *supra* note 41, at 289-90 (explaining the reasoning behind Switzerland's proposed amendments).

83. *See* Gitter, *supra* note 6, at 1625.

84. Gitter, *supra* note 6, at 1624 (stating that thousands of patents have been granted for human DNA sequences since the 1980s); *see also* Murray, *supra* note 36, at 231.

85. Gitter, *supra* note 6, at 1624-25.

the basis that DNA sequences are chemical compounds found in nature.⁸⁶ The Supreme Court has consistently stated that products of nature are not patentable, but yet has held DNA sequences to be patentable.⁸⁷ The Federal Circuit, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*,⁸⁸ drew a distinction between DNA sequences that are taken from nature and specific DNA sequences that have been isolated from the naturally occurring sequence.⁸⁹ EU courts followed a similar reasoning as demonstrated by *Howard Florey/Relaxin*,⁹⁰ where the court held a gene patentable when the gene is isolated from its surroundings.⁹¹ Germany follows the same position as that of the United States and the EU, and accepts that DNA sequences are patentable subject matter.⁹²

A follow up argument is that DNA sequences do not satisfy the utility requirement under section 101 or Biotech Directive Article 5(3).⁹³ This argument is based on the large number of patent applications accepted for DNA sequences of unknown function.⁹⁴ Both the United States and the EU utility requirements may be met when a DNA sequence has a known application, or the gene it encodes is known, because the DNA sequence is being put to a specific use, beyond pure research. However, in many situations, it is only after the DNA sequences have been patented that multiple functions are associated with the sequence.⁹⁵ Germany differs from the United States and the EU regarding the utility requirement in that a known function for a DNA sequence will only provide protection for that function, not all functions of the

86. See 135 U.S.C. § 101 (2006) (describing patentable subject matter categories); EPC, *supra* note 37, at arts. 52, 53 (describing patentable inventions and nonpatentable inventions); Jameson, *supra* note 4, at 208-09 (describing the patentable subject matter requirement under EU and U.S. law).

87. *Diamond*, 447 U.S. 300, 309 (1980) (stating that “laws of nature, physical phenomena, and abstract ideas have been held not patentable”); see also Murray, *supra* note 36, at 231 (listing the number of patent applications filed and granted for DNA sequences for a specific period of time); Gitter, *supra* note 6, at 1625 (describing whether DNA sequences are patentable subject matter).

88. 927 F.2d 1200 (Fed. Cir. 1991).

89. See, e.g., Tyler, *supra* note 3, at 17-18 (examining the reasons behind DNA sequence patentability). DNA sequences are not considered products of nature because the patent is for the “purified and isolated” sequence, rather than the full sequence as it exists in nature. See *Amgen*, 927 F.2d at 1206.

90. Application no. 83 307 553.4, *Howard Florey/Relaxin*, (1995) E.P.O.R. 541, 547-48 (Opposition Div. 1994).

91. See Jameson, *supra* note 4, at 209 (describing patentable subject matter in the EU).

92. PatG, *supra* note 56, § 1(2) and § 1a(2). Patents will be granted for biological material, including elements or partial elements isolated from the human body. *Id.*

93. The statutory utility requirement in the United States requires that a patent application state the function of the claimed invention. 35 U.S.C. § 101 (2006). Biotech Directive, *supra* note 25, at art. 5(3) (describing the industrial application requirement added to the Biotech Directive). See, e.g., Gitter, *supra* note 6, at 1625-26 (presenting arguments against DNA sequence patentability); Jameson, *supra* note 4, at 212-13 (describing the utility requirement implemented under the Directive).

94. See Gitter, *supra* note 6, at 1625 (utilizing the CCR5 gene and its use in understanding the HIV virus as an example of a patent granted for unknown function).

95. See Gitter, *supra* note 6, at 1625-26 (recognizing that in certain situations an important function of a DNA sequence or gene may not be known until after a patent application is filed such as the function of the CCR5 gene being identified a year after the filing of the patent application).

sequence.⁹⁶

B. Ethical Arguments

An argument typically raised in Europe is that DNA sequences should not be granted patent protection because to do so violates *ordre public* or morality, relying on the language in the Directive and the EPC.⁹⁷ Commentators have raised this objection in the United States, but less frequently.⁹⁸ The ethical objection against the patenting of DNA sequences is that by granting a patent over a DNA sequence, an individual is gaining a patent over a piece of human life.⁹⁹ The patenting life argument, as well as the lack of acceptance of cloning, is the basis of the argument that patenting DNA sequences violates morality.¹⁰⁰ When enacting the PatG, Germany also questioned the extent of patent protection given for elements isolated from the human body.¹⁰¹

V. Limited Patenting of DNA Sequences

One of the policy reasons behind patent law is that it promotes innovation by providing a limited period of exclusive protection so as to encourage investment and promote disclosure.¹⁰² This is especially true in biotechnology, where large investments of both time and money are needed to develop new applications of genes and DNA sequences.¹⁰³ If absolute protection is granted by the United States or EPO for a human DNA sequence, then a scientist could

96. See PatG, *supra* note 56, § 1a(3) (stating that the industrial application of a sequence must be identified in a patent application). See also *supra* notes 63-65, 69-72 and accompanying text.

97. See Gitter, *supra* note 6, at 1625 (presenting arguments against DNA patentability). Due to the European view that an exception be provided for inventions that violate *ordre public* or morality the Agreement on Trade-Related Aspects of Intellectual Property Rights between the United States and the EU has left the issue open for each individual country to decide how to apply morality exceptions. Jameson, *supra* note 4, at 198.

98. See Murray, *supra* note 36, at 232 (presenting the arguments against patentability of DNA sequences, including arguments based on objections to the patenting of “life”); Gitter, *supra* note 6, at 1636 (identifying U.S. morality argument but acknowledging that argument has greater force in the EU).

99. See Jameson, *supra* note 4, at 202 (examining the *ordre public* and morality exceptions identified by the EPO). The EPO has a test for determining whether an invention will violate the ethical considerations of a state. The test is “whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.” *Id.*

100. See Biotech Directive, *supra* note 25, at art. 6 (specifically identifying certain areas that are not patentable, including: processes for cloning humans; processes for modifying the germ line genetic identity of human beings; and uses of human embryos for industrial or commercial purposes).

101. Kilger, *supra* note 45, at 572-73. The German government compromised between the belief that absolute protection should be given for DNA sequences and the belief that no protection should be given and reached an agreement that DNA sequences be given limited protection. See Zimmer, *supra* note 57, at 561 (portraying German government views on patenting DNA that led to passing the PatG).

102. See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1021-22 (1989) (presenting policy reasons behind granting of patents).

103. See Murray, *supra* note 36, at 256 (arguing that without patent protection private funding for the biotechnology industry would be greatly reduced).

recoup some of the funds spent on research by licensing the use of the DNA sequence to other scientists.¹⁰⁴ In addition, if other uses or functions are identified for the patented DNA sequences through other scientists' research, then those functions cannot be patented individually and the original patent holder will gain all of the rights.¹⁰⁵

If limited protection is granted, rather than absolute protection, by filing an application through the PatG, investors may be more likely to contribute to the study of DNA sequences.¹⁰⁶ This would be because the investors know that if another scientist identifies a function for a sequence, that scientist will only gain protection for that application, future identification of new functions will be protected, and profits will still be available.¹⁰⁷ In addition, if limited protection is provided, then it is more likely a scientist will continue research on a DNA sequence after another scientist patents a function on the basis that protection is still available.¹⁰⁸

The limited protection provided by the PatG not only encourages investment in DNA sequence research, but it also encourages scientists to continue their work, even if another discovers a possible application of a DNA sequence.¹⁰⁹ If there is an absolute protection patent on a DNA sequence, other scientists may not perform research on additional uses of that sequence due to licensing requirements; however, if there is limited protection then licensing fees would only be paid if researching the same function of the sequence.¹¹⁰ In addition, if limited protection is available then an inventor who discovers a new application for a DNA sequence will be able to gain protection for that application.¹¹¹

Germany's Parliament intensely debated whether to implement a more limited scope of protection than that required by the Biotech Directive.¹¹² To

104. See Gitter, *supra* note 6, at 1669 (presenting the situation that may arise if various gene patents are held by multiple entities requiring researchers to obtain a license from each individual entity).

105. See Gitter, *supra* note 6, at 1668 (identifying bioethicist Jon Merz's argument, which maintains that once a scientist obtains a patent on a gene, there is less incentive to continue the research because if another scientist further pursues uses of that gene the patent holder can claim the rights to those new developments).

106. See Gitter, *supra* note 6, at 1626 (describing the necessity of investors for DNA research).

107. See Gitter, *supra* note 6, at 1626 (presenting the argument that it costs a large amount of money to invest in the biotechnology industry and private funding is required to obtain new inventions).

108. See Gitter, *supra* note 6, at 1626 (presenting argument that relaxed application of the utility requirement may result in too broad of a protection for DNA sequences and will slow research). Many DNA sequences have multiple applications, so when one scientist discovers a function, other functions may still be available for discovery and patenting. Jameson, *supra* note 4, at 210-12.

109. See Kilger, *supra* note 45, at 572 (stating that part of the debate over the Biotech Directive was based on the fear of "deadlocking innovation").

110. Gitter, *supra* note 6, at 1667-70. By providing a patent for a DNA sequence based on a proposed function or one identified function, the research chain may be inhibited from the beginning due to researchers having to pay licensing fees to conduct research on the sequence or gene it encodes. *Id.*

111. Gitter, *supra* note 6, at 1667. If an inventor cannot gain protection for new functions of DNA sequences then there is little incentive to put the time and energy into that research area and it will also be more difficult to gain funding for an invention that will have no patent protection and may in fact be claimed by a separate inventor who first claimed the DNA sequence. *Id.* at 1668.

112. See Kilger, *supra* note 45, at 572 (describing the debate that occurred before Germany amended the

encourage inventors to conduct further research on DNA sequences, the German Parliament approved limited protection to a specified function or application of a DNA sequence.¹¹³ Germany's limited protection for DNA sequences, although it does not limit the protection granted under an EPC patent, makes the statement that over-broad protection should not be granted to inventors due to the risk of limiting important research into DNA sequences.

VI. Conclusion

The U.S. patent system is recognized as being the broadest patent protection system in existence, especially as it pertains to the biotechnology industry.¹¹⁴ To assist in the harmonization of biotech innovation and protection between Europe and the United States, the United States may want to consider interpreting patent laws regarding DNA sequences more rigidly.¹¹⁵ By following Germany's example of providing limited patent protection for DNA sequences, research could be better encouraged in this area of the biotechnology industry.¹¹⁶ As more DNA sequences are discovered and patented, research must be encouraged into the multiple uses of these sequences, to continue to solve the world's many health problems. To establish more restricted patent protection for human DNA sequences, the United States and the EU should look to the PatG and the proposed Swiss patent law as a model to follow for further amendments to their respective patent laws.

PatG).

113. See, e.g., Kilger, *supra* note 45, at 572; Gitter, *supra* note 6, at 1671. The German education and science minister specifically stated that the limited protection was in place to "make sure innovation is not obstructed and researchers have legal security." Gitter, *supra* note 6, at 1671.

114. See Jameson, *supra* note 4, at 196 (stating that the United States appears to have lower standards for patentability while the EU has more limitations).

115. See Jameson, *supra* note 5, at 196 (distinguishing the more liberal approach taken by the United States to patent protection as compared to the EU).

116. See *supra* notes 105-110 and accompanying text.