NOTHING UNDER THE SUN THAT IS MADE OF MAN

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ABSTRACT

Many have accused patent law of impermissibly treating human beings, and aspects thereof, as property by allowing human inventions to constitute patentable subject matter, thus contravening moral and ethic principles and violating laws such as the Thirteenth Amendment. Although patents have issued claiming human subject matter, patent law has consistently limited, or even eliminated, such patents, and reformed the patent law doctrines or practices that allowed such patenting mistakes. In addition to prohibiting the patenting of human beings per se, patent law has increasingly limited claims to human genes, human embryonic stem cells, human thought, and human in vivo conversion. Despite charges to the contrary, patent law provides little support for patent servitude. Rather, patent law has tended to be sensitive to the prohibitions of, and largely in compliance with, the Thirteenth Amendment.[**]

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** Portions of this article are adapted from previous articles written by Andrew W. Torrance. *See generally* Andrew W. Torrance, *Metaphysics and Patenting Life*, 76 UMKC L. REV. 363 (2007); Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629 (2010); Andrew W. Torrance, *Patenting Human Evolution*, 56 KAN. L. REV. 1075 (2008); Andrew W. Torrance, *An Extinction Bar to Patentability*, 20 GEO. INT'L ENV'T L. REV. 237 (2008); Andrew W. Torrance, *Patents to the Rescue – Disasters and Patent Law*, 10 DEPAUL J. HEALTH CARE L. 309 (2007). The author considers these adapted passages to be useful background to the broader argument made in the instant article: that is, that multiple lines of evidence suggest that human beings constitute unpatentable subject matter. As a guide to good practice in this regard, the author has relied on Pamela Samuelson, *Self-Plagiarism or Fair Use*, COMMUNICATIONS OF THE ACM, Aug. 1994, at 21, 21–25.

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INTRODUCTION

Upon first consideration, European Patent Number 0695351 would not appear to be a revolutionary document. Its technical-sounding title, "Isolation, Selection and Propagation of Animal Transgenic Stem Cells," and claims, which include "[a] method of isolating and/or enriching and/or selectively propagating desired animal stem cells" (Claim 1) and "[a] method of preparing a transgenic animal" (Claim 48), belie its controversial content.[1] Nevertheless, the patent's description, or "specification," contains fire to light an ethical fuse. It elucidates the real meaning of the

1. *See* Eur. Patent No. 0695351 claims 1, 48 (filed Apr. 12, 1994) (issued Dec. 8, 1999).

claims, clarifying that "[i]n the context of this invention, the term 'animal cell' is intended to embrace all animal cells, especially of mammalian species, *including human cells*."[2] In other words, as originally issued by the European Patent Office, European Patent Number 0695351 (hereinafter EP '351) claimed methods of propagating human stem cells, producing a human embryo, and preparing a human being.

Many worry that if patents can claim human beings, aspects of human beings, or processes involving human beings, they will indirectly turn human beings into property. Such patents can evoke "the visceral fear of corporate interests claiming ownership over our very bodies," and, in the United States, may implicate at least the spirit of the Thirteenth Amendment's prohibition on involuntary servitude.[3] In his final State of the Union address, President George W. Bush urged "Congress to pass legislation to ban unethical practices, such as the . . . patenting . . . of human life."[4] Nevertheless, the United States Patent and Trademark Office (USPTO) has granted patents that claim parts of human beings, processes requiring human beings, and sometimes even cells that could develop into human beings themselves.[5] EP '351 suggests a similar practice in Europe.

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2. *See id.* at description 11 (emphasis added).

3. Devanand J. Crease & George W. Schlich, *Is There a Future for 'Speculative' Gene Patents in Europe?*, 2 NATURE REVS. DRUG DISCOVERY 407, 407 (2003) (addressing specifically patents claiming the human genes, BRCA1 and BRCA2, owned by Myriad Genetics, and used to diagnose propensity for developing breast cancer). The Thirteenth Amendment ensures that "[n]either slavery nor involuntary servitude . . . shall exist within the United States, or any place subject to their jurisdiction." *See* U.S. CONST. amend. XIII, § 1. In 1987, the USPTO stated that "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." *See* Donald J. Quigg, *Animals – Patentability*, U.S. PAT. & TRADEMARK OFF. (Apr. 7, 1987), https://www.uspto.gov/web/offices/com/sol/og/2020/week52/TOCCN/item-176.htm [https://perma.cc/LK62-PFCG]. Although the PTO did not state its grounds for this conclusion, many commentators assume that the prohibition originates in the Thirteenth Amendment. *See, e.g.*, Janice A. Sharp, *The Patenting of Transgenic Animals*, *in* 1 EMERGING ISSUES IN BIOMEDICAL POLICY 199, 207 (Robert H. Blank & Andrea L. Bonnicksen eds., 1992).

4. *See* President George W. Bush, Address Before a Joint Session of the Congress on the State of the Union (Jan. 28, 2008), *in* 44 WEEKLY COMP. PRES. DOC. 117, 120 (Feb. 4, 2008).

5. *See, e.g.*, Primate Embryonic Stem Cells, U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001) (claiming more specific class of human embryonic stem cells); Primate Embryonic Stem Cells, U.S. Patent No. 7,029,913 (filed Oct. 18, 2001) (issued Apr. 18, 2006) (claiming more specific class of human

The failure of patent law consistently to exclude such "human inventions" from patentability may have unsettling implications not simply for human dignity in the abstract, but also for human liberties that laws such as the Thirteenth Amendment are meant to protect. This Article probes the claim that patent law may allow property-like rights—intellectual property rights—in human beings, and, by doing so, may contribute to a form of "patent servitude."[6]

Since the landmark United States Supreme Court (Supreme Court) decision of *Diamond v. Chakrabarty*, the range of patentable subject matter has extended almost to the limits of human imagination.[7] Nevertheless, much legal uncertainty surrounds the viability of patents that wholly or partially encompass a human being or that require the participation of a human being. "The laws of nature, physical phenomena, and abstract ideas have been held not patentable," but these exceptions have never been explicitly extended to patents claiming human beings.[8] Patents on "human inventions" (that is, inventions that include aspects of human beings' bodies or minds) are formally constrained only by a piecemeal collection of statutory safe harbors, congressional riders and a related, but obscure, statutory provision, judicial opinions, USPTO policies, and presidential statements regarding the patenting of human beings, human parts, or human processes. For example, the Mental Steps Doctrine traditionally barred patents on any process made up of "purely human thought."[9] Further restrictions have involved inventions related to human surgery and medicine, limiting liability for patent infringement by medical personnel and medical facilities, and the unpatentability of human–nonhuman genetic hybrids, or chimaeras.[10] The Weldon Amendment rider, which has been renewed several times since 2004, states that "[n]one of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human

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embryonic stem cells); Unique T-Lymphocyte Line and Products Derived Therefrom, U.S. Patent No. 4,438,032 (filed Jan. 6, 1983) (issued Mar. 20, 1984).

6. This Article recognizes that no property rights conferred by ownership of a patent can ever approach the tragedy of human slavery.

7. *See generally* 447 U.S. 303 (1980) (concluding that Congress intended patent law to include anything under the sun made by man).

8. *See id.* at 309.

9. *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

10. *See* 35 U.S.C. § 287(c); *Patent Application Is Disallowed as 'Embracing' Human Being*, 58 PAT. TRADEMARK & COPYRIGHT J. 203, 203 (1999).

organism."[11] The Weldon Amendment was eventually enshrined into the Patent Act by the Leahy-Smith America Invents Act Section 33, which provides, in Section 33 (a), that "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[12] Similarly, it has been the stated policy of the USPTO since 1987 that "[a] claim directed to or including within its scope a human being will not be considered to be patentable subject matter."[13] The USPTO Manual of Patent Examining Procedure (MPEP) specifically states at § 2105 that, "[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human organism, then a rejection under 35 U.S.C. 101 . . . must be made indicating that the claimed invention is directed to a human organism and is therefore nonstatutory subject matter."[14] President Bill Clinton even saw fit to announce publicly his opposition to human cloning, and with British Prime Minister Tony Blair, urged the biotechnology industry not to seek patents claiming human genes.[15] Finally, as mentioned above, President George W. Bush urged Congress to prohibit "the . . . patenting . . . of human life."[16]

Despite the absence of any clear statutory guidance, it has long been possible to infer the scope of patentability of human beings *per se* from the patentability of human inventions that implicate related interests. Limits on the patentability of human genes, human embryonic stem cells, human thought, and products of human *in vivo* conversion were imposed precisely in order to protect the autonomy and dignity interests that the Thirteenth Amendment seeks to protect. The rationales applied to judge the patentability of these categories of human inventions are applicable to human beings themselves. Even before the Supreme Court decided its landmark patentable

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11. Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101.

12. *See* Leahy-Smith America Invents Act, § 33(a). This provision is obscure because it is described in the Act as "35 USC 101 note" and has not been codified into the United States Code.

13. *See* Quigg, *supra* note 3.

14. *See* U.S. PAT. & TRADEMARK OFFICE, MPEP § 2105 (9th ed. Rev. 10.2019, June 2020).

15. *See* Eliot Marshall, *Clinton Urges Outlawing Human Cloning*, 276 SCI. 1640, 1640 (1997); Justin Gillis, *Clinton, Blair Urge Open Access to Gene Data - President, Briton Step into Controversy on Code*, WASH. POST, Mar. 15, 2000, at E01.

16. *See* Address Before a Joint Session of the Congress on the State of the Union, *supra* note 4.

subject matter cases, *Bilski*, *Prometheus*, *Myriad*, and *Alice*, it was clear that human beings are unpatentable. Thus, this Article argues that, despite widespread and vociferous protestations to the contrary, patent law largely avoids "patent servitude," comports with the prohibitions of the Thirteenth Amendment, and bars the patenting of humans.[17]

Part I provides an overview of patent law. Part II discusses the patenting of organisms, including human beings. Part III explores how patent law has reacted and adapted to inventions involving human genes, human embryonic stem cells, human thought, and the physiological processes and products of *in vivo* conversion. This Article concludes by suggesting that patent law itself has demonstrated a robust ability to limit property rights in human beings.

I. PATENTS

A. Patentable Subject Matter

Myriad biotechnological inventions have resulted from advances in biology, including new medicines, methods of treatment, methods of diagnosis, and medical devices. Patent law is generally permissive regarding what categories of technology are eligible for patent protection, and a diverse array of biotechnologies have long been considered patentable subject matter. In fact, when the Supreme Court famously defined as potentially patentable "anything under the sun that is made by man," the particular inventions at issue involved both genes and genetically engineered eubacteria.[18] Later judicial and administrative decisions further defined the broad borders of the patentable world of biotechnology to include such diverse inventions as multicellular organisms,[19] plants,[20] and mammals.[21] Currently,

17 *Cf.* Torrance, Andrew W., *The Unpatentable Human Being*, HASTINGS CTR. REP., Sept.–Oct. 2013, at 10, 10–11.

18. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309, 309 n.6 (1980) (quoting *Hearing on H.R. 3760 Before the H. Subcomm. No. 3 of the H. Comm. on the Judiciary*, 82d Cong. 37 (1951) (statement of P.J. Federico, Principal Draftsman, 1952 Recodification of Patent Laws)).

19. *See Ex parte* Allen, No. 86-1790, 1987 WL 123816, at *2 (B.P.A.I. Apr. 3, 1987).

20. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 124 (2001).

21. *See, e.g.*, Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988).

there are vanishingly few categories of inventive subject matter ineligible for patent protection in the United States.

B. The Patent Bargain

Society generally disfavors monopolies, and this disfavor is justified by economic theory and is implemented in antitrust law. A monopoly in a particular good or service tends to cause a deadweight loss to society due to inefficiently low output of that good or service.[22] The same logic can be applied to patents, which confer a monopoly right to exclude others from making, using, selling, offering to sell, or importing the claimed invention during the term of the patent, or from inducing or contributing to such infringement.[23] However, these patent monopoly rights are also widely assumed to produce beneficial incentives to invent and to disclose one's inventions. The legitimacy of the patent system is based, at least in part, on the premise that these benefits of invention and disclosure outweigh the deadweight loss incurred by the monopoly right to exclude others. However, this premise has long been controversial. A prodigious inventor himself, Benjamin Franklin wrote that "as we enjoy great advantages from the inventions of others, we should be glad of an opportunity to serve others by any invention of ours; and this we should do freely and generously."[24] More recently, it has been proposed that this premise may fail under certain circumstances,[25] and in certain technological arts,[26] notably biotechnology.[27]

Nevertheless, the supporters of the patent system have accepted this premise and it is woven into the law itself. The United States Constitution explicitly recognizes that the goal of the patent system

22. *See* N. GREGORY MANKIW, PRINCIPLES OF ECONOMICS 326–34 (3d ed. 2004).

23. The term of the patent generally extends twenty years from the filing date of the patent application. *See* 35 U.S.C. §§ 154(a)(2), 271(a)–(b).

24. *See* BENJAMIN FRANKLIN, THE AUTOBIOGRAPHY OF BENJAMIN FRANKLIN: THE UNMUTILATED AND CORRECT VERSION 238 (John Bigelow ed., 1909).

25. *See generally* Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 130 (2009).

26. In the terminology of patent law, "art" refers to field or area. For example, inventions directed to biochemicals, genes, polypeptides, carbohydrates, and lipids generally arise in the biotechnological arts.

27. *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 700 (1998).

is "[t]o promote the Progress of . . . useful Arts."[28] In theory, potential inventors should respond to the incentive created by the patent monopoly by allocating more of their valuable time, energy, and other resources into inventing "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" than they would have absent the patent system.[29] A particular advantage of this incentive system is that Congress need not offer inventors financial rewards for new inventions because, based on the right to exclude others, patent owners can directly extract monopoly rents from consumers wishing to make or use patented inventions. Furthermore, the disclosure of a patent application delivers informational benefits to society as soon as it is published (i.e., usually about eighteen months following the patent application's priority date).[30] An inventor must provide society with full disclosure of that invention which "adds a measure of worthwhile knowledge to the public storehouse."[31]

The high quality of information disclosed to the public by inventors seeking patent rights enhances the technological and scientific capacity of society. Society can use this information for any purpose other than to make, use, sell, offer to sell, or import an invention claimed in a valid and enforceable patent.[32] Information disclosed in patents enriches the existing body of technological and scientific knowledge, allowing scientists, engineers, and others to progress even further, creating even newer, and more advantageous, ideas and inventions. If scientists make progress by standing on the shoulders of giants, then the incentives provided by the patent system contribute additional shoulders on which to stand.

C. Patent Requirements

The success of the patent bargain is safeguarded by the various requirements that patent applications must meet before they can mature into valid patents. Some of these requirements are largely procedural, but several are substantive. The most significant of the

28. *See* U.S. CONST. art. I, § 8, cl. 8.

29. 35 U.S.C. § 101.

30. *See id.* § 122(b) (discussing how publication of a patent application generally occurs approximately eighteen months after the filing date of the patent application).

31. *In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring).

32. *See* 35 U.S.C. § 154(a)(1)–(2) (describing content and term of patents).

latter are legal requirements of utility,[33] novelty,[34] nonobviousness,[35] and disclosure.[36] A patent applicant must also provide a precise description in the patent "claims" of the metes and bounds of the invention for which patent protection is sought.[37]

1. *Utility*

An invention must be useful—that is, possess utility—to be patentable.[38] In most technological arts, the utility requirement represents only a modest hurdle. However, in biotechnology the utility requirement can be significant. One rationale for a heightened utility requirement is to ensure that inventions not receive patent protection before their uses are fully developed.[39] For example, the USPTO has set final "Utility Examination Guidelines" for gene-related inventions that require biotechnological inventions involving genes to meet relatively more rigorous utility showings to be patentable; under these Utility Guidelines, such inventions must be shown by the patent applicant to possess "specific," "substantial," "credible" utilities.[40]

2. *Novelty and Nonobviousness*

The common purpose of the novelty and nonobviousness requirements is to ensure that any invention on which a patent applicant receives a patent, which confers a powerful monopoly right to exclude others, is truly a new contribution to society. These two requirements prevent inventions already in the public domain from being secondarily clawed back into the realm of private property. Otherwise, the patent applicant could receive a doubly unjustified windfall: a patent monopoly to exclude society from practicing an

33. *See id.* § 101.
34. *See id.* § 102.
35. *See id.* § 103.
36. *See id.* § 112.
37. *See id.*
38. In Europe and many other jurisdictions, utility is referred to as "industrial applicability." *See* Christopher Wadlow, *Utility and Industrial Applicability*, *in* PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 355 (Toshiko Takenaka ed., 2009).
39. *See* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (stating that the benefit of a patent to the public is an invention with substantial utility).
40. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1092 (Jan. 5, 2001) (noting express support for the utility criteria).

"invention" already in practice in exchange for providing society with information already known.

3. *Disclosure*

In return for receiving the limited monopoly right to exclude, an inventor must provide the public with a full disclosure of how to make and use the claimed invention.[41] The purpose of this requirement is "to ensure that the scope of the right to exclude . . . does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification."[42] In other words, the disclosure requirement reflects the quid pro quo, or bargain, between inventor and society that is fundamental to the patent grant. In return for limited monopoly rights, the patentee contributes new information to the metaphorical public storehouse of knowledge. As the Supreme Court has stated, the disclosure requirement is "the *quid pro quo* of the right to exclude."[43] "The incentive to give this added measure of knowledge to the public . . . is the primary justification for the existence of the patent system."[44]

Disclosure has three statutory requirements: written description, enablement, and best mode.[45] Each serves an important function in protecting society from the patent monopoly. The requirement of "a written description of the invention" serves a notice function by providing the public with a specific indication of what the inventor considers the limits on his invention to be.[46] Additionally, it limits the inventor from pursuing *post hoc* claims by requiring her to establish precisely what inventions she possessed as of the date on which she filed the application. The best mode requirement forces disclosure of "the best mode contemplated by the

41. *See* 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it.").

42. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1371 (Fed. Cir. 2009) (quoting Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345–46 (Fed. Cir. 2000)).

43. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 142 (2001) (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974)).

44. *In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring).

45. *See* 35 U.S.C. § 112(a). This section also includes a definiteness requirement for claims. *See id.*

46. *See id.*

inventor . . . of carrying out his invention."[47] This subjective requirement, peculiar to the United States patent system, prevents an inventor from providing the bare minimum of information necessary to enable a person of skill in the art to practice the invention *in some manner* while preserving the best manner of practicing the invention as a trade secret. Failure to disclose the best mode in a patent application acts as a barrier to receiving a patent in the first instance and can later render claims in a granted patent invalid. The requirement of enablement calls for disclosure of "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same."[48] The courts have further explained that "to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation,'" and that undue experimentation is defined by "a standard of reasonableness, having due regard for the nature of the invention and the state of the art."[49]

Enablement represents the very core of the patent bargain and is "arguably the most important patent doctrine after obviousness."[50] By ensuring the full and complete disclosure of how to make and use the claimed invention, the enablement requirement ensures that the public storehouse receives a measure of worthwhile knowledge in return for tolerating monopoly rights to exclude others from claimed inventions.

4. *Claims*

The specification of a patent must also include "one or more claims particularly pointing out and distinctly claiming the subject matter which the [applicant] regards as [his] invention."[51] These claims serve several purposes. They provide the public with notice as to the metes and bounds of the patent monopoly right held by inventors, which allows the public to order its behavior so as not to infringe. The claims also allow the patent owner to police instances

47. *See id.*

48. *Id.*

49. *See In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

50. *See* Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 982 (Fed. Cir. 2002) (Radar, J., dissenting).

51. 35 U.S.C. § 112(b).

of infringement by asserting that the elements in a particular claim correspond to allegedly infringing devices or methods. Patents claiming human inventions include claims precisely specifying some aspect of, or method involving, human genes, human embryonic stem cells, human thought, or products of human physiology, and, in rare cases, even to human beings themselves.

D. Practical Aspects of the Patent System

Patents are expensive to obtain, on average costing an applicant for a patent pertaining to a complex technology more than $11,000 simply to file a patent application, and considerably more thereafter to obtain enforceable patent rights.[52] Patents take a long time to be granted. The examination system of the USPTO, where patent applications are examined, is staffed by technically or scientifically skilled patent examiners whose numbers are seldom commensurate with the volume of patent applications they must examine. Consequently, patent prosecution (the process through which a patent application must pass prior to issuance as a patent) generally takes from two and a half to five years, with the duration of prosecution rising for complex inventions, such as biotechnologies.[53]

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52. *See* Thomas C. Fiala & Jon E. Wright, *Preparing and Prosecuting a Patent That Holds Up in Litigation*, 875 PLI/PAT 515, 521–22 (2006) ("For example, based on the AIPLA Report of the Economic Survey 2005, the average expected charge in 2004 for preparing and filing a utility patent application was $11,218 for a relatively complex electrical or computer application and $12,373 for a relatively complex biotechnology/chemical application."); in person interview in Boston, Massachusetts, with Craig Smith, Partner, Fish & Richardson P.C. (Mar. 5, 2007) [hereinafter Interview with Craig Smith].

53. *See* Interview with Craig Smith, *supra* note 52. The USPTO Performance Report for fiscal year 2006 reports an average patent pendency time (defined as time from filing until patent issued or application abandoned by applicant) of 31.3 months and shows that this figure has been increasing over the past few years. *See* U.S. PAT. & TRADEMARK OFF., PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2006, at 22. However, the average pendency times estimated by the USPTO are likely underestimates.

> [T]he average prosecution (or pendency) time for an ultimately successful patent is 3.6 years, with a median of 2.7 years. Anecdotally, the time period from filing to issuance varies by technology and ranges from twenty-four to thirty-six months for chemical and mechanical arts and thirty-six to sixty months for electrical and software arts.

Kristen Osenga, *Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office*, 33 FLA. ST. L. REV. 119, 130 (2005).

In the biotechnological arts, the effective term of a patent is often much less than the theoretical twenty-year term because of time spent in patent prosecution and regulatory approval in the Food and Drug Administration (FDA). Although unreasonable delays caused by the USPTO or the FDA may be compensated by some extension of the patent term, the average enforceable lifetime of a patent lasts only about fifteen to seventeen and a half years. Enforcement of patent rights is also very expensive, with an average cost of patent litigation amounting to more than $5 million, depending on the amount of damages at issue.[54] Patent litigation is also fraught with considerable unpredictability, at least in part due to the proliferation of judicial barriers and available defenses to patent infringement.[55]

E. The Patent Exclusionary Right

The rights conferred by a patent are often misunderstood. While it is accurate that a patent confers a monopoly right to its owner, this monopoly right is not absolute. At its heart, a patent confers on its owner the legal right to exclude others. Other than the patent owner, "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the

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54. *See* Fiala & Wright, *supra* note 52, at 522.

> In comparison, the average estimated costs associated with litigating a patent in 2005 as reported by the same survey [AIPLA Report of the Economic Survey 2005] were: $769,562 for a patent infringement suit in which less than $1 million was at risk; $2,637,179 for a suit in which between $1 and $25 million was at risk; and $5,175,753 for a suit in which more than $25 million was at risk.

Id.

55. *See, e.g.*, Douglas R. Nemec, *Current Trends in Equitable Defenses to Patent Infringement: Prosecution Laches and Inequitable Conduct*, 804 PLI/PAT 1147, 1155 (2004) ("This article also compares several recent Federal Circuit decisions on inequitable conduct, and explores how these cases, together with Symbol Technologies, suggest an inclination by the Federal Circuit toward more vigorous policing and enforcement of the rules of conduct before the PTO.").

> This paper reviews the basic principles of claim construction and then discusses the current status of the doctrine of equivalents. As explained below, the Federal Circuit has erected several independent barriers to finding infringement under the doctrine of equivalents, but the most foreboding of such barriers may be the doctrine of claim vitiation.

David J.F. Gross et al., *Claim Construction, Patent Infringement, and the Growing Importance of the Claim Vitiation Defense*, 841 PLI/PAT 45 (2005).

patent therefor, infringes the patent."[56] However, a patent owner is granted no affirmative right to practice a patented invention. In fact, a patent owner may be precluded from practicing a patented invention due either to the risk of infringing patents owned by others or to other legal restrictions on activities necessary to practice the patented invention.

Finally, the right to exclude others lasts "for limited Times," and expires along with the patent.[57] Thus, because patent prosecution can stretch over a considerable period of years, a patent owner may have to wait a considerable period of time before a patent becomes enforceable, only then to face the expiration of the patent. Approximately eighteen months after its earliest priority date, a published patent application carries with it certain "provisional rights," including the possibility of a reasonable royalty to compensate for pre-grant infringement of a claimed invention.[58] However, the right to exclude others does not vest until the patent has actually been issued. Consequently, the term of a patent tends to be considerably less than its theoretical length of twenty years.

II. PATENTING LIFE

A. Patents and Nonhuman Organisms

1. *International Patent Law*

The United States, the countries of the European Union, Japan, Canada, and most other countries with patent systems are members of the World Trade Organization (WTO).[59] As members of the WTO, these countries must comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[60] The TRIPS agreement sets a baseline level of intellectual property protection that all member countries must offer. Although some countries, such as India, were allowed extended transition periods during which to

56. 35 U.S.C. § 271(a).

57. U.S. CONST. art. I, § 8, cl. 8.

58. 35 U.S.C. § 154(d).

59. *See Members and Observers*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm [https://perma.cc/8JGV-6XW6] (last visited Apr. 5, 2021).

60. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPs Agreement].

come into compliance with all TRIPS requirements, the agreement requires all countries to offer a baseline level of patent, and other intellectual property, protections.

TRIPS directly addresses the issue of patentable subject matter. Article 27 of TRIPS, entitled "Patentable Subject Matter," establishes broad guidelines regarding which categories of technology must be eligible for patent protection in a member country.[61] These categories are very broad. Article 27(1) mandates that "patents shall be available for any inventions, whether products or processes, in all fields of technology . . . [and] patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology."[62]

There are also some exceptions to patentable subject matter. Under Article 27(2), WTO member countries can

> exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[63]

In addition, Article 27(3) specifically allows member countries to exclude from patent eligibility certain categories of biotechnology subject matter. Exclusions can be made for "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."[64] While Article 27(2) generally allows countries to exclude any invention from patentability if such exclusion is necessary to protect the public from threats to public order, morality, health, and the environment, Article 27(3) specifically allows member countries to exclude animals or plants from patentable subject matter.[65] Nevertheless, the default rule under TRIPS is to allow animals, plants, and other biotechnologies to be patentable subject matter unless a country invokes Articles 27(2) or (3). Most WTO members, including the United States, members of the EU, Japan, Canada, and Australia, have tended to follow this

61. *See id.* art. 27(1), at 311.
62. *Id.*
63. *Id.* art. 27(2), at 311.
64. *Id.* art. 27(3), at 311–12.
65. *See id.* arts. 27(2), (3), at 311–12.

default rule, and have allowed patents claiming organisms great and small.

2. *United States Patent Law*

In 1980, the United States Supreme Court first decided the issue of whether or not a whole organism could constitute patentable subject matter. In *Diamond v. Chakrabarty*, the patent examiner had rejected a claim for a bacterium genetically engineered to metabolize hydrocarbons.[66] The Supreme Court portrayed the question to be decided as "whether respondent's micro-organism constitutes a 'manufacture' or 'composition of matter' within the meaning of the statute."[67] In interpreting the intended coverage of these two specific categories of patentable subject matter enumerated in 35 U.S.C. § 101 of the Patent Act, the Court decided that "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."[68]

Specifically, in light of Congress's intent, the Court decided that patentable subject matter should be considered to have an expansively broad scope as "[t]he Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[69]

The Court did exclude from patentability "[t]he laws of nature, physical phenomena, and abstract ideas."[70] However, the Court distinguished Chakrabarty's bacterium from these categories, holding that

> [Chakrabarty's] micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter . . . the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter.[71]

66. *See* 447 U.S. 303, 305 (1980).
67. *Id.* at 307.
68. *Id.* at 308.
69. *Id.* at 309 (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).
70. *Id.*
71. *Id.* at 309–10.

Rather than focus on any specific characteristic of the invention as an *indicium* of patentability, the Court considered whether the invention fell within the literal meaning of any of the statutorily enumerated categories or fell within any of the categories of prohibited subject matter. Finding that a genetically modified organism could be construed as a "composition of matter," and that Chakrabarty's specific bacterium did not fall within a prohibited category, the Court found Chakrabarty's whole organism invention patentable subject matter.[72] In the subsequent years, *Diamond* was interpreted broadly to qualify macroscopic plants,[73] animals,[74] and even mammals[75] as patentable subject matter. In 2001, the Supreme Court confirmed the patentability of whole living organisms in a case involving the patentability of sexually reproducing crop plants.[76]

The USPTO has issued further life-form patents on genetically altered nonhuman transgenic animals, such as mice, cows, goats, sheep, and rabbits, for purposes ranging from the production of low-lactose milk to the creation of animals suffering from corneal epithelial damage to test eye products.[77]

3. *Patentability in Other Countries*

As in the United States, the European law of patenting whole organisms tends to be permissive, including both micro-organisms and macro-organisms. The European Patent Office (EPO) has even granted patents covering nonhuman mammals. The "Harvard Mouse" patent provides a prominent example of patentability,[78]

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72. *See id.*

73. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145–46 (2001); *Ex parte* Hibberd, 1985 WL 71986, at *2 (B.P.A.I. Sept. 24, 1985).

74. *See Ex parte* Allen, No. 86-1790, 1987 WL 123816, at *2 (B.P.A.I. Apr. 3, 1987).

75. *See* Transgenic Non-Human Mammal, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1998).

76. *See J.E.M. Ag Supply, Inc.*, 534 U.S. at 132.

77. *See* Transgenic Animals Producing Low-Lactose Milk and Newly Identified Human Small Intestinal Extracellular Lactase-Phlorizin Hydrolase (ecLPH) Gene, U.S. Patent No. 7,501,554 (filed May 15, 2006) (issued Mar. 10, 2009); Experimental Animals for Evaluation of Therapeutic Effects on Corneal Epithelial Damages, U.S. Patent No. 6,924,413 (filed Jan. 10, 2002) (issued Aug. 2, 2005).

78. *See* Grant of European Patent No. 0169672 (Onco-Mouse/Harvard), 1992/10 Official Journal of the EPO 588, 588. Note that this is the European equivalent of U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988).

despite vigorous opposition to its patentability, including challenges under Article 53(a) of the European Patent Convention (EPC) on the grounds that patents on living organisms threaten *ordre public* and morality.[79]

However, not all countries have followed such a permissive pathway to the patentability of biological inventions. For example, the results in Canada have been strikingly different. In *Harvard College*, a five to four majority of Supreme Court justices held "higher life forms," such as plants and animals, to be unpatentable subject matter.[80] The Supreme Court majority decided that the mammal at issue, the "Harvard Mouse," did not constitute patentable subject matter because "[a] higher life form . . . is not a 'manufacture' or 'composition of matter' within the meaning of 'invention' in s. 2 of the *Patent Act*."[81]

The vigorous dissents faulted the majority for misinterpreting established Canadian patent law and considered the outcome of the case a serious jurisprudential mistake.[82] The agency primarily responsible for advising the Canadian government on biotechnology issues, the Canadian Biotechnology Advisory Committee (CBAC), having studied the scientific, economic, and legal concerns surrounding patentability of whole organisms, framed the dual international and domestic scopes of the issue:

> The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPs), in Article 27.3(b), allows member countries to exclude plants and animals from patentability. When the mandated review of this section takes place, some countries (mostly developing nations) can be expected to support maintaining or expanding this section, while other countries (most notably the United States) will likely want to either narrow or eliminate this exception. Canada will be better able to contribute to this debate by developing a domestic position on this matter prior to the commencement of these negotiations.[83]

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79. EPC Article 53(a) is similar to TRIPS Article 27(2). *See* Convention on the Grant of European Patents art. 53(a), Oct. 5, 1973, 1065 U.N.T.S. 199; *see also* Case T-315/03, President & Fellows of Harvard Coll. v. Brit. Union for the Abolition of Vivisection, 2004/05 Official Journal of the EPO 246 (July 6, 2004); Case T-19/90, Onco-Mouse/Harvard, 1990/12 Official Journal of the EPO 476 (Oct. 3, 1990).

80. *See* Harvard Coll. v. Canada, [2002] 4 S.C.R. 45, 105 (Can.).

81. *Id.* at 46.

82. *See id.* at 58–104 (McLachlin C.J., Major, Binnie and Arbour JJ., dissenting).

83. *See* CANADIAN BIOTECHNOLOGY ADVISORY COMM., PATENTING OF HIGHER LIFE FORMS AND RELATED ISSUES (2002).

Furthermore, the CBAC recommended that the Canadian government adopt as its "domestic position" affirmative recognition that animals and plants constitute patentable subject matter.[84] In a 2003 report, the CBAC made specific legislative recommendations "that higher life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable," as well as various recommendations for determining the scope of these patent rights.[85]

Two years after *Harvard College*, the Supreme Court of Canada made a second, though indirect, consideration of whether whole organisms could constitute patentable subject matter under Canadian patent law. *Monsanto Canada Inc. v. Schmeiser* involved a variety of rapeseed (*Brassica napus*) known as "canola" or "Canadian oil, low acid."[86] At issue was whether a Saskatchewan farmer, Percy Schmeiser, could be held liable for infringing patents by claiming, among other inventions, genes encoding beneficial traits, and cells containing those genes.[87] Although the majority opinion did discuss the implications of *Harvard College* on Monsanto's asserted patents, it found Schmeiser liable for having infringed those gene and cell patents, rather than any patents claiming whole canola plants *per se*.[88]

The Court found infringement because Monsanto's patent claims to genes and cells were not invalid and were infringed by virtue of the presence of the claimed genes and cells within the canola plants Schmeiser cultivated on his farm.[89] *Monsanto*, while not explicitly overturning the rule of *Harvard College* against the patentability of "higher life forms," did significantly vitiate its practical effect.[90] Most whole organism inventions are genetically modified, and thus include genes and cells that may themselves be independently patentable. Consequently, any whole organism whose body contains a patented gene or cell may still infringe a patent claim to such a gene or cell, whether or not the organism itself qualifies for patent protection. The *Monsanto* decision may have

84. *See id.*

85. *See* CANADIAN BIOTECHNOLOGY ADVISORY COMM., ADVISORY MEMORANDUM ON HIGHER LIFE FORMS AND THE PATENT ACT 7 (2003).

86. *See* Monsanto Can. Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 903 (Can.).

87. *See id.*

88. *See id.* at 916–17, 937.

89. *See id.* at 917, 937.

90. *See* Harvard Coll. v. Canada, [2002] 4 S.C.R. 45, 105 (Can.).

effectively established the *de facto* patenting of "higher life forms," such as plants and animals, in Canada.[91]

B. Patents and Humans

Many jurisdictions have grappled with the patentability of claims for human beings or methods of producing them. Since *Diamond v. Chakrabarty*, the patent law of the United States has limited such prospects largely through policymaking in the USPTO, judicial decisions, and Presidential statements, rather than through amendments to the Patent Act. By contrast, jurisdictions such as the EU and Australia have tended to employ a statutory or regulatory approach.

1. *The United States*

The USPTO long ago declared human beings *per se* to be unpatentable. In a policy statement issued in 1987, it accepted the patentability of "nonnaturally occurring non-human multicellular living organisms, including animals," but excluded any "claim directed to or including within its scope a human being" because "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution."[92] Although the USPTO did not state its grounds for concluding that the Constitution forbids granting such patents, many commentators assume that the prohibition originates in the Thirteenth Amendment.[93] This prohibition includes early developmental stages of human beings, such as human embryos.[94] The Court of Appeals for the Federal Circuit (Federal Circuit), dismissing a lawsuit to overturn this rule for lack of standing, noted that the rule did not change preexisting law, but only restated it.[95] It also noted that a plaintiff with an interest in blocking the "development and commercialization of genetically improved animals" would be ill-served to challenge the patentability

91. *See id.*

92. Quigg, *supra* note 3.

93. *See, e.g.*, Sharp, *supra* note 3, at 207.

94. *See generally* Stacy Kincaid, *Oh the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research*, 30 PEPP. L. REV. 553 (2003) (outlining the aspects of United States patent law that impact the research of embryonic stem cells).

95. *See generally* Animal Legal Def. Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) (pertaining to a Patent and Trademark Office notice that stated nonhuman living organisms, including animals, were patentable).

of animals, since "the issuance of a patent gives no right to make, use or sell a patented invention," while "the absence of a patent creates no legal prohibition against continued research or development."[96]

Congress also enacted a quasi-prohibition on patenting human beings when it approved, and President George W. Bush signed, the Consolidated Appropriation Act of 2004.[97] In the Weldon Amendment to the Act, Congress mandated that "[n]one of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism."[98] Various reenactments have kept these short-term prohibitions in force through 2010.[99] Although the purpose of the Weldon Amendment was to discourage patents claiming human beings, it does not ban research on human cloning and human embryonic stem cells by the private sector. The Weldon Amendment was eventually enshrined into the Patent Act by the Leahy-Smith America Invents Act Section 33, which provides, in Section 33(a), that "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[100]

2. *Other Countries*

A number of other countries have taken a more direct, statutory, approach to limiting patents claiming human beings. For example, § 18(2) of the Patents Act of Australia states that "[h]uman beings, and the biological processes for their generation, are not patentable inventions."[101] The EU approach deals with the

96. *Id.* at 935.

97. *See* Dana Wilkie, *Stealth Stipulation Shadows Stem Cell Research*, SCIENTIST (Mar. 1, 2004), https://www.the-scientist.com/profession/stealth-stipulation-shadows-stem-cell-research-50419 [https://perma.cc/9SC2-N3X9].

98. *Id.*

99. *See* Ryan Hagglund, *Patentability of Human-Animal Chimeras*, 25 SANTA CLARA COMPUT. & HIGH TECH. L.J. 51, 72–73 (2008).

100. Leahy-Smith America Invents Act, § 33(a). This provision is obscure because it is described in the Act as "35 USC 101 note" and has not been codified into the United States Code.

101. *See Patents Act 1990* (Cth) s 18(2) (Austl.). The 2003 "Submission to the Australian Law Reform Commission" on patenting and human life, in which the Australian Catholic Bishops Conference warned the Australian government that "[t]he commodification of human life is inimical to the recognition and protection of human dignity." MATTHEW RIMMER, INTELLECTUAL PROPERTY AND BIOTECHNOLOGY: BIOLOGICAL INVENTIONS 249 (2008) (quoting WARWICK NEVILLE, SUBMISSION TO THE AUSTRALIAN LAW REFORM COMMISSION ISSUES PAPER ON GENE PATENTING AND HUMAN HEALTH (2003)).

patentability of human beings separately from the patentability of methods of producing human beings, while adding additional prohibitions on the patenting of human substituents. Article 5(1) of European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions states that "[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."[102] Article 5(2) loosens this prohibition somewhat, allowing that "[a]n 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."[103] The European Patent Convention similarly states that human beings, and methods of producing or modifying them, generally constitute unpatentable subject matter. Rule 23d, which implements EPC Article 53(a), and corresponds to Article 6(2)(a)–(c) of the Directive, prohibits patentability of "processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; [and] uses of human embryos for industrial or commercial purposes."[104]

III. PATENTING HUMAN BEINGS

Despite legal efforts to restrict patenting of human beings, patents have continued to issue with claims that implicate aspects of humanness, or even human beings themselves. As an editorial in Natural Biotechnology concluded in 2003, "[n]o country's patent system has yet found a way of extricating itself from the philosophical and political morass associated with patent applications that encroach on definitions of humanness."[105] Four categories of human subject matter have emerged as particular challenges to prohibitions against patenting human beings and aspects thereof: human genes, human embryonic stem cells, human thought, and products of human *in vivo* conversion.

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102. Council Directive 98/44, art. 5(1), 1998 O.J. (L 213) 13, 18 (EC).

103. *See id.* art. 5(2), at 18.

104. Implementing Regulations to the Convention on the Grant of European Patents rule 28(1)(a)–(c), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Dec. 15, 2020) [hereinafter Implementing Regulations].

105. Editorial, *Patenting Pieces of People*, 21 NATURE BIOTECHNOLOGY 341, 341 (2003).

A. Human Genes[106]

The single greatest legal watershed thus far for the patenting of genes arrived in 1980. In approving the claim in a 1972 patent application for "[a] bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids," the Supreme Court in *Diamond v. Chakrabarty* seemed to place its *imprimatur* on the patenting of genes and of other DNA sequences.[107] A prerequisite technological watershed had occurred in the previous decade. Stanley Cohen and Herbert Boyer spent 1973 and 1974 developing a method for transferring DNA from one type of organism into the cells of a distinctly different type of organism.[108] Their patent, entitled "Process for Producing Biologically Functional Molecular Chimeras," claimed only recombinant DNA methods, not DNA molecules or recombinant organisms themselves.[109] However, their DNA transfer method, often called genetic engineering, and yielding recombinant DNA, launched a revolution in biology. Recombinant DNA technology offered "a simple method for isolating and amplifying any gene or DNA segment and moving it with controlled precision, allowing analysis of gene structure and function in simple and complex organisms."[110] By 1977, the gene for the human hormone somatostatin had been expressed within the eubacterium *Escherichia coli*.[111] When recombinant DNA technology was coupled with the relatively rapid DNA sequencing methods developed in the mid-1970s, modern biotechnology had been born.

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106. Portions of this section are adapted from Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. 157 (2010) and Andrew W. Torrance, *A Natural Experiment on Innovation Without Patents*, *in* REVOLUTIONIZING INNOVATION: USERS, COMMUNITIES, AND OPEN INNOVATION (Dietmar Harhoff & Karim R. Lakhani eds., MIT Press 2016).

107. U.S. Patent No. 4,259,444, claim 18 (filed June 7, 1972) (issued Mar. 31, 1981).

108. *See* Sally Smith Hughes, *Making Dollars Out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980*, 92 ISIS 541, 541–42 (2001).

109. *See* U.S. Patent No. 4,237,224 (filed Jan. 4, 1979) (issued Dec. 2, 1980). The original patent was filed November 4, 1974. *See* Smith Hughes, *supra* note 108, at 542.

110. Smith Hughes, *supra* note 108.

111. *See* Keiichi Itakura et al., *Expression in Escherischia Coli of a Chemically Synthesized Gene for the Hormone Somatostatin*, 198 SCI. 1056, 1056 (1977).

From the 1970s onward, biologists, and the institutions that employed them began securing significant numbers of patents claiming the complex organic molecules of life. In 1971, U.S. Patent Numbers 3,607,370 and 3,619,206 issued, claiming "polypeptide" and "protein" *per se*, respectively.[112] Earlier, patents had issued claiming methods involving polypeptides and proteins. In 1972, the first claim to a "peptide" *per se* appeared in U.S. Patent Number 3,645,689.[113] By 1973, "DNA" had been included as an element of a patented claim.[114] The term "gene" first appeared as a claim element in U.S. Patent Number 3,710,511.[115] By 1978, claims 10, 11, and 12 of U.S. Patent Number 4,116,770, which were directed to phenotypic traits expressed by specific genes, had issued.[116] Finally, in 1982, U.S. Patent Number 4,363,877 (the '877 patent) issued with independent claims 1 and 4, which were directed to recombinant DNA transfer vectors comprising specified nucleotide sequences of codons corresponding to "[h]uman chorionic somatomammotropin" and "growth hormones from other animal species," respectively.[117] This patent was the first "gene patent," claiming genes *per se*.[118] Although the claims of the '877 patent did not specifically recite the word "gene," the specification's "summary of invention" did identify "genes coding for RGH, the major portion of HCS and the major portion of HGH, respectively."[119]

Patents and patent applications claiming genes both increased rapidly in number subsequent to the *Diamond v. Chakrabarty*

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112. *See* Pressure-Sensitive Adhesive Tape Comprising Gluten Hydrolypate Derivatives, U.S. Patent No. 3,607,370 (filed May 29, 1969) (issued Sept. 21, 1971); Modified Protein, U.S. Patent No. 3,619,206 (filed May 21, 1969) (issued Nov. 9, 1971).

113. *See* Method and Apparatus for Analyzing Proteins, U.S. Patent No. 3,645,689 (filed Apr. 9, 1970) (issued Feb. 29, 1972).

114. *See* Diagnostic Method Utilizing Synthetic Deoxyrilionucleotide Oligomer Template, U.S. Patent No. 3,755,086 (filed Feb. 9, 1971) (issued Aug. 28, 1973).

115. *See* Procedures for Use of Genic Male Sterility in Production of Commercial Hybrid Maize, U.S. Patent No. 3,710,511 (filed Apr. 21, 1971) (issued Jan. 16, 1973).

116. *See* Waxy Barley Starch with Unique Self-Liquefying Properties, U.S. Patent No. 4,116,770 (filed Feb. 27, 1975) (issued Sep. 26, 1978).

117. Recombinant DNA Transfer Vectors, U.S. Patent No. 4,363,877 (filed Apr. 19, 1978) (issued Dec. 14, 1982).

118. *Gene Patents and Global Competition Issues*, GENETIC ENG'G & BIOTECHNOLOGY NEWS (Jan. 1, 2006), https://www.genengnews.com/magazine/41/gene-patents-and-global-competition-issues/ [https://perma.cc/P36A-QRWR].

119. '877 Patent, at col. 7–8.

decision in 1980. Annual patent application filings with "gene" in at least one claim during the period rose from just above zero in 1977 to more than 100 in 1984, more than 500 in 1993, almost 1,000 in 1994, to a peak of over 1,600 filed in 1995 alone.[120] After remaining at almost 1000 or above from 1994 until 2002, filings of such patent applications declined rapidly to well below 500.[121] By way of comparison, annual patent filings with "DNA" or "nucleotide sequence" in at least one claim followed the trajectory of filings with "gene," although there have been relatively fewer filings claiming "nucleotide sequence" and relatively more with "DNA."

Annual patent issuances with "gene" in at least one claim during the period rose from just above zero in 1981 to more than 100 in 1988, more than 500 in 1996, more than 1,300 in 1998, to a peak of almost 1,500 in 1999.[122] From 1998 to 2007, patent issuances remained above 1,000 per year in all but two years, and there was only a relatively gradual decline in issuances from the peak year of 1999.[123] By way of comparison, annual issuances of patents with "DNA" in at least one claim have followed the trajectory of filings with "gene," although with relatively more issuances.[124]

The products of the biotechnology industry consist substantially of inventions that change the degree to which a gene is expressed.[125] These inventions rely on technologies that can locate genes within the genome, sequence their deoxyribonucleotides, isolate these sequences out of their original genomic loci, and splice them into brand new loci. The biotechnology industry relies on the availability of patent protection to appropriate the economic value of these inventions, attract investments and other sources of funding, and protect their own immense investments in discovering, developing, securing regulatory approval, and successfully marketing their products. Consequently, the biotechnology industry also has strong incentives to maintain the patentability of gene inventions. As Sheila Jasanoff has described in her book, *Designs on Nature*,

> Especially in the United States, patents played a foundational role in the development of the biotechnology industry at several levels. First, the

120. Torrance, *supra* note 106, at 178.
121. *Id.*
122. *Id.*
123. *Id.*
124. *See id.*
125. Herein, the biotechnology industry is assumed also to include pharmaceutical companies significantly dependent on biotechnologies.

> extension of patents to the life sciences created new classes of property rights in things that were previously outside the realm of what could be owned, or even thought of as subject to ownership claims. As a result, these objects became commodities that could have value, be exchanged, circulate in markets, and foster productivity. Second, much of the early development of biotechnology occurred before there were any marketable products, and patents were the only evidence for eager venture capitalists that there might be something of future value to justify present investment. Third, patents provided some assurance to jittery investors that they would not be mired in endless legal wrangling if commercially useful products ever came on line. Fourth, patents proved to be a way of sorting out the competing claims to participants in an increasingly complex web of invention that linked together the disparate interests of patients, research subjects, farmers, academic researchers, universities, start-up firms, government, and industry.[126]

The patent system has long offered federal legal protection for gene inventions through patent grants, offering potentially powerful rights to exclude others from making, using, offering to sell, or selling patented genes within the United States, or importing patented genes into the United States.[127]

Biotechnology owes much of its rapid progress to the availability of patent protection for genes and their polypeptide products. Since 1980, when the United States Supreme Court held that genetically modified eubacteria constitute patentable subject matter, private enterprise, such as pharmaceutical and biotechnology firms, and public or nonprofit institutions, such as universities and government and independent research institutes, have identified, isolated, and patented myriad genes.[128] Patent protection is a keystone asset of pharmaceutical and biotechnology companies. In fact, some have argued that the main product of the biotechnology industry, which, as a whole, has yet to turn a profit, is not genes *per se*, or their uses or products, but patents claiming genes or the uses or products thereof.[129] Availability of patent protection for genes has generally been assumed to promote innovation in biotechnology, spurring the discovery and elucidation of relatively more new genes,

126. SHEILA JASANOFF, DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE UNITED STATES 203–04 (2007).

127. *See* 35 U.S.C. § 271(a).

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

129. *See, e.g.*, John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 163 (2001).

while simultaneously limiting others' access to those same new genes.[130]

From the beginning, the patenting of human genes has been highly controversial. Part of this controversy hinges upon the aggressiveness with which human genes have been patented. By 2005, almost 20% of human genes had been claimed in issued U.S. patents.[131] To some critics, allowing a large proportion of the human genome to be patented represents a "gold rush."[132] Others have worried that excess privatization of the human genome through patenting could result in a tragedy of the "anticommons" capable of hampering further genetic research and development.[133] However, perhaps the most persistent and widespread misgiving about allowing human gene patents has been the fear that patents claiming human genes could somehow confer upon patent owners control over human beings carrying corresponding genes. As Devanand Crease and George Schlich have portrayed the concern, "To the person in the street, the grant of a patent covering all potential uses of these genes raises the visceral fear of corporate interests claiming ownership over our very bodies!"[134] Even celebrity author Michael Crichton sounded the alarm, prominently writing in an op-ed in the New York Times in 2007 that "YOU, or someone you love, may die because of a gene patent. . . . Gene patents are now used to halt research, prevent medical testing and keep vital information from you and your doctor."[135]

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130. In their recent study of the role that the patent system plays in spurring innovation, James Bessen and Michael J. Meurer suggest the patent system may indeed promote innovation in the pharmaceutical/biotechnology industry. *See* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 85–88 (2008). As Bessen and Meurer have stated, "[t]he evidence certainly is consistent with the notion that patents encourage American pharmaceutical R&D." James Bessen & Michael J. Meurer, *Do Patents Stimulate R&D Investment and Promote Growth?*, PATENTLY-O (Mar. 13, 2008), http://www.patentlyo.com/patent/2008/03/do-patents-stim.html [https://perma.cc/CZ7V-LN5L]. *See* Heller & Eisenberg, *supra* note 27, at 701.

131. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005).

132. *See* Tom Hollon, *Gene Patent Revisions to Remove Some Controversies*, 6 NATURE MED. 362, 362 (2000).

133. *See* Heller & Eisenberg, *supra* note 27, at 701.

134. Crease & Schlich, *supra* note 3, at 407 (addressing patents claiming the human genes, BRCA1 and BRCA2, owned by Myriad Genetics, and used to diagnose propensity for developing breast cancer).

135. Michael Crichton, *Patenting Life*, N.Y. TIMES (Feb. 13, 2007), https://www.nytimes.com/2007/02/13/opinion/13crichton.html [https://perma.cc/

Patent law has responded in a number of ways to human gene patents, and the clear trend has been towards limitation. In 2005, the Federal Circuit decided *In re Fisher*, an appeal involving "expressed sequence tags" (ESTs).[136] These DNA sequences correspond with fragments of genes, rather than the complete nucleotide sequences of genes. Monsanto, the owner of the patent at issue in the appeal, argued that claimed ESTs were useful for locating complete genes within the maize genome.[137] The Federal Circuit held that the claims on ESTs were invalid for lack of enablement and utility.[138] As the Court stated,

> The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with *substantial utility*. Unless and until a process is refined and developed to this point—where *specific benefit exists in currently available form*—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.[139]

One consequence of *In re Fisher* has been to make the patenting of ESTs and other nongene sequences, including those derived from humans, much more difficult. This has placed a significant patentability barrier in the way of a human gene "gold rush."

Recent empirical evidence suggests that anxieties about a tragedy of the anticommons may be misplaced. After surveying all patent litigation involving human gene patents, Chris Holman found little evidence of any such tragedy. For example, with specific reference to the database of human gene patents compiled by Jensen and Murray,[140] Holman observes as follows:

> In view of the angst inspired by the Jensen and Murray article, it might surprise some to learn that my study identified only six litigations alleging infringement of a patent that appears in Jensen and Murray's dataset, involving a total of eighteen patents with claims reciting thirteen distinct human genes. Only one of the litigations, *Genzyme v. Transkaryotic Therapies, Inc.*, resulted in a substantive court decision, and in that case the court found the patent had not been infringed. Of the five remaining litigations, four settled at an early stage, prior to any substantive decision by the court, and one was recently dismissed based on the court's determination that the patent owner lacked standing to bring suit. As far as I can ascertain, not one of the 4,270 patents in the dataset has ever been

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136. *In re* Fisher, 421 F.3d 1365, 1367 (Fed. Cir. 2005).
137. *See id.*
138. *See id.* at 1379.
139. *Id.* at 1371 (quoting Brenner v. Manson, 383 U.S. 519, 534–35 (1966)).
140. *See* Jensen & Murray, *supra* note 131, at 239.

> found to have been infringed or been the basis of a preliminary injunction.[141]

Based on his empirical results, Holman goes on to address deeper fears about human gene patents and human liberty and dignity:

> [N]one of the fears regarding patent holders asserting ownership in other people's bodies have materialized, nor have people been sued for patent infringement based on the presence of patented genes in their bodies. While there are many who would maintain that the mere existence of patents relating to human genes is immoral and offensive, gene patents have not been asserted in a manner that would directly impact human dignity or personal autonomy.[142]

Despite the dearth of human gene patent litigation, suspicions of gene patents, both human and nonhuman, have grown so great that Congress has begun to consider statutory amendments to the Patent Act that would decrease or curtail the patentability of genes and their related chemical products. Most prominent among these initiatives has been Xavier Becerra's proposed Genomic Research and Diagnostic Accessibility Act. If passed, this Act would have added new § 106 to the Patent Act. Section 106 would end the patentability of human genes by providing that "[n]otwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."[143]

Opposition to human gene patents has also arisen in court. On May 12, 2009, the American Civil Liberties Union (ACLU) (on behalf of several medical associations, advocacy organizations, individual physicians, and female patients) filed a federal lawsuit in the Southern District of New York, naming the USPTO, Myriad Genetics, and Directors of the University of Utah Research Foundation as defendants in a patent case that directly challenged the patentability of human gene patents.[144] The ACLU, the self-proclaimed "guardian of liberty," has been a frequent litigant in American courts, its lawsuits often tending to focus on the protection of constitutional rights, such as freedom of speech, equal protection,

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141. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation & Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 353–54 (2007) (internal citations omitted).

142. *Id.* at 352 (internal citations omitted).

143. Geoff Watts, *The Locked Code*, 334 BMJ 1032, 1032 (2007).

144. *See* Ass'n for Molecular Pathology v. USPTO, 669 F. Supp. 2d 365, 369–70 (S.D.N.Y. 2009).

and rights to privacy.[145] However, this ACLU lawsuit sought nothing less than the elimination of human genes as patentable subject matter. In the words of its complaint,

> Every person's body contains human genes, passed down to each individual from his or her parents. These genes determine, in part, the structure and function of every human body. This case challenges the legality and constitutionality of granting patents over this most basic element of every person's individuality.[146]

In addition, the lawsuit condemned the patentability of methods of diagnosis reliant on human gene sequences, specifically "the concept of looking at or comparing human genes, and correlations found in nature between certain genes and an increased risk of breast and/or ovarian cancer."[147]

According to the National Cancer Institute, roughly 13% of American women will develop breast cancer at some point during their lifetimes.[148] These worrisome odds, roughly one in eight, translate into almost 200,000 new cases, and more than 40,000 deaths, per year.[149] Only lung and colonorectal cancers cause more deaths. The news is even grimmer for women who carry specific mutations in their BRCA (breast cancer) genes. Mutations in tumor suppressor genes BRCA1 (BRCA 1, early onset, located on Chromosome 17) and BRCA2 (BRCA 2, early onset, located on Chromosome 13) raise the lifetime risk of developing breast cancer substantially, to 36–85%.[150] In addition, these mutations raise the lifetime risk of ovarian cancer from about 1.7% to 16–60%.[151]

Learning that one is a carrier of undesirable BRCA1 or BRCA2 mutations can be devastating. However, the knowledge that one is a carrier of one of these mutations can serve as a warning to a woman or her children to attempt to minimize other risk factors, carefully monitor oneself for symptoms of cancer, or even to consider more

145. *See Guardians of Freedom*, ACLU, https://www.aclu.org/guardians-freedom [https://perma.cc/B3MP-JRSS] (last visited Apr. 5, 2021).

146. Complaint, Ass'n for Molecular Pathology v. USPTO, 669 F. Supp. 2d (S.D.N.Y. 2009) (No. 1:09-cv-04515-RWS), 2009 U.S. Dist. Ct. LEXIS 36030, at *1.

147. *Id.* at *3.

148. *Breast Cancer Risk in American Women*, NAT'L INST. OF HEALTH, https://www.cancer.gov/types/breast/risk-fact-sheet [https://perma.cc/LX5S-4FUT] (last visited Apr. 5, 2021).

149. *Id.*

150. Leslie A. Pray, *Questionable Prognostic Value of Genetic Testing*, 1 NATURE EDUC. 74, 74 (2008).

151. *Breast Cancer Risk in American Women*, *supra* note 148.

radical options, such as prophylactic removal of the breasts or ovaries. Obviously, knowledge that one does not carry BRCA1 or BRCA2 mutations is welcome, though even people without mutations can develop cancer. A strong desire among many women to know their BRCA status has proved to be a great economic boon to Myriad Genetics. This profitable Utah biotechnology company, formed in 1991, controls patents whose claims cover not only aspects of the BRCA1 and BRCA2 mutations themselves, but have also allowed Myriad to maintain a monopoly on the diagnostic tests used to detect these mutations—tests that are unaffordable to many lacking healthcare insurance.

In a decisive victory for the ACLU and its fellow litigants, on March 29, 2010, the court held both the claims to human genes and the methods of genetic diagnosis to be unpatentable subject matter. As the court explained,

> The claims-in-suit directed to "isolated DNA" containing human *BRCA1/2* gene sequences reflect the USPTO's practice of granting patents on DNA sequences so long as those sequences are claimed in the form of "isolated DNA." This practice is premised on the view that DNA should be treated no differently from any other chemical compound, and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character. Many, however, including scientists in the field of molecular biology and genomics, have considered this practice a "lawyer's trick" that circumvents the prohibitions on the direct patenting of DNA in our bodies but which, in practice, reaches the same result. . . . It is concluded that DNA's existence in an "isolated" form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to "isolated DNA" containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 USC 101.[152]

Myriad Genetics appealed this summary judgment decision to the Federal Circuit, with the support of the many pharmaceutical and biotechnology firms, universities, and others who own heretofore valuable human gene patents. Remarkably, on October 29, 2010, in a remarkable *volte face* of long-settled policy of the USPTO (one of the defendants), the United States Department of Justice filed an amicus curiae brief in this appeal arguing that "isolated but otherwise unmodified" human genes constitute unpatentable subject matter

152. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

because they are products of nature under 35 U.S.C. § 101.[153] Although the United States government had previously had many opportunities to express its misgivings about gene patents to the Federal Circuit, it was during litigation over human gene patents that it found its oppositional voice. In July 2011, a panel of three CAFC judges reversed much of Judge Sweet's decision, in *AMP v. Myriad Genetics*, and reaffirmed the patent-eligibility of human genes. However, the legal pendulum swung back on March 26, 2012, when the Supreme Court vacated *AMP v. Myriad Genetics*, and ordered the appeals court to reconsider the patentability of human genes in light of *Mayo v. Prometheus*, a case the Supreme Court had decided a week earlier. In *Mayo v. Prometheus*, the court unanimously held methods of using human metabolites in diagnosis and therapy to constitute unpatentable subject matter. By vacating *AMP v. Myriad Genetics* and demanding a new decision consistent with *Mayo v. Prometheus*, the Supreme Court cast considerable doubt on the patentability of human genes. On August 16, 2012, the CAFC again upheld the patentability of human genes. However, on June 13, 2013, the Supreme Court unanimously decided *AMP v. Myriad Genetics*, invalidating Myriad's patent claims covering isolated human genomic DNA, though it also suggested that at least some synthetic DNA remained patent-eligible subject matter.

In light of *In re Fisher*, which narrowed the patentability of DNA sequences, compelling empirical evidence suggesting that human gene patents are rarely, if ever, asserted or enforced, and Congressional proposals to abridge or curtail the patenting of human genes, the prospects for patentability of naturally occurring human genes increasingly dimmed. Then, Judge Sweet's district court decision in *Myriad*, declaring human gene patents unpatentable subject matter, the Department of Justice amicus curiae brief supporting the latter, and the Supreme Court's decision in *AMP v. Myriad Genetics* seemed to close the door on human gene patents proprietizing naturally occurring aspects of human beings.

B. Human Embryonic Stem Cells

On June 26, 1998, the University of Wisconsin Alumni Research Foundation (WARF), filed a patent application related to

153. *See* Brief for the United States as Amicus Curiae Supporting Neither Party, Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 2010-1406), 2010 U.S. Fed. Cir. LEXIS 832, at *7, *35–36.

embryonic stem cells. This patent application (and several subsequent patent applications) was based on a biological breakthrough achieved by a research group at the University of Wisconsin, led by Dr. James Thomsen, that produced the first successful isolation and cultivation of pluripotent human embryonic stem cells.[154] In all, this research yielded five isolated human embryonic stem cell lines. Patent applications, filed by WARF and others, that claimed embryonic stem cells or methods related to them, prompted clarification by the USPTO that isolated and purified stem cells would constitute patentable subject matter.[155] The USPTO issued United States Patent Number 6,200,806, entitled "Primate Embryonic Stem Cells," to WARF on March 13, 2001.[156] The "patent broadly covers both the method of isolating human embryonic stem cells and the five unmodified stem cell lines themselves."[157] Critics of WARF's patents, in general, and patents on embryonic stem cells, in particular, challenged the validity of the WARF patents in the USPTO by launching reexamination proceedings of the '806 and two related patents, U.S. Patent Nos. 5,843,780 (the '780 patent) and 7,029,913 (the '913 patent).[158] These reexamination proceedings resulted in initial findings by the USPTO that the claims of all three patents were invalid.[159] After the WARF amended the claims of all three patents to narrow their scopes, the USPTO agreed to allow new, narrowed claims.[160] Interestingly, some of the most important amendments required to achieve patentability emphasized the very early-stage origins of the claimed human embryonic stem cells (e.g., derived from a "pre-implantation embryos" or "human blastocysts") to distinguish them from cells

154. *See* RIMMER, *supra* note 101, at 259.

155. *See Stem Cell Research: Hearings Before a Subcomm. of the Comm. on Appropriations*, 105th Cong. 89–90 (1999) (statement of Q. Todd Dickinson, Commissioner, Patents and Trademarks).

156. *See* U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001).

157. RIMMER, *supra* note 101, at 259.

158. *See WARF Stem Cell Patents*, PUB. PAT. FOUND., http://www.pubpat.org/warfstemcell.htm [https://perma.cc/SS97-ATSZ] (last visited Apr. 5, 2021).

159. *See* Andrew Pollack, *3 Patents on Stem Cells Are Revoked in Initial Review*, N.Y. TIMES (Apr. 3, 2007), http://www.nytimes.com/2007/04/03/business/03cell.html [https://perma.cc/55G6-3GQS].

160. *See* Kevin E. Noonan, *Yes, It IS Time (Finally) to Stop the Hypocrisy Over Human Stem Cell Patents*, PAT. DOCS (Mar. 12, 2008), https://www.patentdocs.org/2008/03/yes-it-is-time.html [https://perma.cc/MPA4-9F9W].

derived from later stages of embryonic development (e.g., "post-implantation embryos") or limited claims to "in vitro culture" to distinguish them from cell cultures inside a human embryo.[161] Both of these illustrative amendments distance, or even remove, the claimed inventions from humans, human bodies, or more mature stages of human embryonic development.

The lengthy and expensive appeals WARF has endured appear to have convinced the organization to license its '780, '806, and '913 patents more widely, thus loosening the tight grip it had previously maintained over patent rights to make and use its human embryonic stem cells.[162] The appeals process within the USPTO involving the '780 and '806 patents concluded on June 17, 2008, with the issuance of reexamination certificates for both extensively amended patents.[163] However, on April 28, 2010, the Board of Patent Appeals and Interferences (BPAI) reversed the patent examiner's earlier (February 25, 2008) decision to allow the amended claims of the '913 patent.[164] This BPAI decision revoking the claims of the '913 patent may allow further legal challenges to the '780 and '806.[165] In the meantime, the claims of the surviving '780 and '806 patents probably no longer cover totipotent hESCs capable of producing a human. It is likely that these WARF patents, and other patents claiming human embryonic stem cells, will continue to face patentability challenges on various grounds, in large part because they implicate property rights in human beings.

By contrast with United States patent law, European patent law has been rather less inviting to the prospect of embryonic stem cell patents. In fact, Articles 5 and 6 of the 1998 European Union Directive on the Legal Protection of Biotechnological Inventions

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161. *See id.*

162. *See* Ubaka Ogbogu, *Latest WARF Patent Decision Further Underlines Legal Questions About Ownership of Life*, SIGNALS (May 25, 2010), https://www.signalsblog.ca/latest-warf-patent-decision-further-underlines-legal-questions-about-ownership-of-life/ [https://perma.cc/3ZCB-YYUQ].

163. *Ex Parte* Reexamination Order, U.S. Patent No. 5,843,780 (filed June 17, 2006) (issued Sept. 29, 2006); *Ex Parte* Reexamination Order, U.S. Patent No. 6,200,806 (issued Sept. 29, 2006)).

164. *See* Found. for Taxpayer & Consumer Rts. Requester v. Pat. of Wisc. Alumni Rsch. Found. Patent Owner, No. 2010-001854, 2010 WL 1734377, at *23 (B.P.A.I. Apr. 28, 2010).

165. *See Upholding of WARF Stem Cell Patent Reversed*, CONSUMER WATCHDOG (May 2, 2010, 5:00 PM), https://www.consumerwatchdog.org/upholding-warf-stem-cell-patent-reversed [https://perma.cc/4KS4-26CF].

offer a number of grounds for prohibiting patenting inventions such as human embryonic stem cells.[166] In addition, the European Commission's European Group on Ethics in Science and New Technologies (EGE) stated, in its 2002 Opinion on the *Ethical Aspects of Patenting Inventions Involving Human Embryonic Stem Cells*, that "such isolated cells are so close to the human body, to the foetus or to the embryo they have been isolated from that their patenting may be considered as a form of commercialization of the human body."[167]

On April 21, 1994, the University of Edinburgh filed a patent application with the European Patent Office (EPO), entitled "Isolation, Selection, and Propagation of Animal Transgenic Stem Cells."[168] On August 12, 1999, the EPO granted European Patent Number 0695351 (the Edinburgh Patent), whose claims included "methods of isolating and/or enriching and/or . . . propagating desired animal stem cells" and "a method of preparing a transgenic animal."[169] The specification of the Edinburgh Patent clarified that "[i]n the context of this invention, the term 'animal cell' is intended to embrace all animal cells, especially of mammalian species, including human cells."[170]

Upon grant, the Edinburgh Patent stirred immediate controversy because it appeared to claim a method of preparing a transgenic human being. Greenpeace Germany filed an opposition proceeding in the European Patent Office to invalidate any claims to human beings. On July 24, 2002, Greenpeace Germany prevailed, and the Opposition Division of the EPO forced the University of Edinburgh to narrow the scope of its claims to exclude human beings.[171] Although the University of Edinburgh appealed this decision of the Opposition Division, it failed to regain claims of the original scope.[172]

United States law offers no explicit prohibitions against the patentability of human embryonic stem cells. Existing prohibitions

166. *See* Council Directive 98/44, *supra* note 102, art. 5–6, at 18–19.

167. EUR. GRP. ON ETHICS IN SCI. & NEW TECHS. TO THE EUR. COMM'N, OPINION ON ETHICAL ASPECTS OF PATENTING INVENTIONS INVOLVING HUMAN STEM CELLS 16 (2002).

168. Eur. Patent No. 0695351 (filed Apr. 21, 1994) (issued Dec. 6, 1999).

169. *Id.* at claims 1, 34.

170. *Id.* at claim 11.

171. *See* RIMMER, *supra* note 101, at 265–69 (providing an overview of the Greenpeace decision).

172. *See Edinburgh Patent*, WP THOMPSON (May 12, 2007), https://www.wpt.co.uk/resources/news/60/ [https://perma.cc/PJV8-JHPG].

against the patenting of human beings, whether in statements made by Presidents or the USPTO, or in the Weldon Amendment rider, do not specifically address human embryonic stem cells. Neither did President George W. Bush's Executive Order forbidding federal spending for research on any but a strictly defined group of human embryonic stem cells lines in 2001 bear any direct relationship to patentability. Nevertheless, the results of litigations, reexaminations, and opposition proceedings concerning the WARF and Edinburgh patents suggest that, if any patent claims human embryonic stem cells in such a way as to encompass a human being, that patent will be found to be invalid.

C. Human Thought[173]

In 2004, Professor Henry T. Greely offered several predictions about how neuroscience might affect "Owning Thoughts."[174] There has indeed been a proliferation of patents claiming aspects of human neural processes and human neural networks.[175] However, there has been another unforeseen development that intersects patent law and neurobiology. A flowering of cases involving alleged infringement of patents claiming mental steps has revived interest the venerable Mental Steps Doctrine. This doctrine rendered unpatentable any patent claim to a process made up of purely mental steps.[176] In a famous statement of this rule, the court in *In re Abrams* declared that "[i]t is self-evident that thought is not patentable."[177]

Patent law itself strongly suggests at least two reasons why human thought itself should not be patentable subject matter. Natural phenomena, such as "laws of nature, physical phenomena, and

173. Portions of this section are adapted from Andrew W. Torrance, *Neurobiology and Patenting Thought*, 50 IDEA 27, 27–39 (2009) and Andrew W. Torrance, *A Natural Experiment on Innovation Without Patents*, *in* REVOLUTIONIZING INNOVATION: USERS, COMMUNITIES, AND OPEN INNOVATION, *supra* note 106.

174. *See* Henry T. Greely, *Prediction, Litigation, Privacy, and Property*, *in* NEUROSCIENCE AND THE LAW: BRAIN, MIND, AND THE SCALES OF JUSTICES 152–54 (Brent Garland ed., 2004).

175. *See, e.g.*, Associative Neuron in an Artificial Neural Network, U.S. Patent No. 6,625,588 (filed Mar. 23, 1998) (issued Sept. 23, 2003); Back-Propagation Neural Network with Enhanced Neuron Characteristics, U.S. Patent No. 6,876,989 (filed Feb. 13 2002) (Apr. 5, 2005); Neural Processing Element for Use in a Neural Network, U.S. Patent No. 7,082,419 (filed Feb. 1, 2000) (issued July 25, 2006).

176. *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

177. *In re* Abrams, 188 F.2d 165, 168 (C.C.P.A. 1951).

abstract ideas have been held not patentable."[178] Most obviously, thought might be construed as falling within, or overlapping, the category of "abstract ideas."[179] The extent of overlap depends on the precise meanings that are attributed to both concepts. If some thoughts belong to the set of nonabstract ideas, then the logical possibility exists that at least some thoughts constitute patentable subject matter. Second, the physiological processes involving neurons, neural networks, and electrical and neurochemical signals by which thoughts are generated within the brain are "physical phenomena."[180]

In 2006, the strange disposition of a case appealed to the Supreme Court appeared to clear the way to patents claiming methods that involve human mental processes. In *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, the Supreme Court first granted certiorari but later dismissed the writ of certiorari as improvidently granted, and thus never decided the case.[181] However, in a vigorous dissent to this dismissal, Justice Breyer, joined by Justices Stevens and Souter, offered an opinion for how the case should have been disposed of, had the writ of certiorari not been dismissed.[182]

Respondent, Metabolite Laboratories, was the licensee of a patent claiming "new methods for testing homocysteine levels using gas chromatography and mass spectrometry" developed by researchers in the 1980s.[183] Laboratory Corporation used these patented methods under a royalty-bearing license to Metabolite Laboratories until 1998, when the former started using a superior test created by Abbott Laboratories.[184] Laboratory Corporation decided to discontinue paying royalties after concluding that the Abbott test was not covered by the Metabolite Laboratories patent.[185] Metabolite Laboratories sued Laboratory Corporation for both patent infringement and breach of the patent license agreement.[186] At issue was claim 13, covering "[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps

178. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
179. *See id.*
180. *See id.*
181. 548 U.S. 124, 125 (2006).
182. *See id.* at 125–38.
183. *Id.* at 128.
184. *See id.*
185. *See id.* at 129.
186. *See id.*

of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate."[187]

The parties agreed that "assaying a body fluid" referred to any test that detects an elevated level of total homocysteine.[188] At trial, the inventors testified that "correlating" in this context simply refers to a doctor recognizing an elevated level of homocysteine, which "would occur automatically in the mind of any competent physician."[189] In the District Court, a jury found Laboratory Corporation liable, under 35 U.S.C. § 271(b), for actively inducing doctors to infringe the Metabolite Laboratories patent. On appeal, the Federal Circuit rejected Laboratory Corporation's argument that the claims were construed too broadly. It did not address its alternative argument that, "*if so construed*, claim 13 must be struck down as an improper effort to obtain patent protection for a law of nature."[190] The Supreme Court granted Laboratory Corporation's petition for certiorari, but limited the appeal to a single question: "[w]hether a method patent . . . directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."[191] It then declined to decide the case on the grounds that the writ of certiorari had been improvidently granted.

Justice Breyer's dissent recounted these facts, listed reasons why the Supreme Court should have proceeded to decide the case, and then turned to the merits of the dispute, characterizing the issue as follows:

> The researchers who obtained the present patent found that an elevated level of homocysteine in a warmblooded animal is correlated with folate and cobalamin deficiencies. As construed by the Federal Circuit, claim 13 provides those researchers with control over doctors' efforts to use that correlation to diagnose vitamin deficiencies in a patient. Does the law permit such protection or does claim 13, in the circumstances, amount to an invalid effort to patent a "phenomenon of nature"?[192]

Justice Breyer conceded "that the category of non-patentable '[p]henomena of nature,' like the categories of 'mental processes,'

187. *Id.*
188. *See id.*
189. *See id.* at 129–30.
190. *Id.* at 131.
191. *Id.* at 132.
192. *Id.* at 134 (Breyer, J., dissenting).

and 'abstract intellectual concepts,' is not easy to define."[193] For Justice Breyer, the issue on which the Supreme Court had granted certiorari was easy to decide because he considered the "correlation" between homocysteine and vitamin deficiency to be a "natural phenomenon."[194] Justice Breyer addressed Metabolite's arguments about whether the invention should constitute patentable subject matter (1) because it was "an *application* of a law of nature";[195] (2) because it entails a physical transformation of blood samples;[196] and (3) because it produces a "useful, concrete, and tangible result."[197] Justice Breyer then noted that, even if he were to assume that the invention met some requirements of process patentability, it would also have to meet the natural phenomenon requirement.[198]

However, despite Justice Breyer's dissent, the actual disposition of the case left the contested claim of the Metabolite Laboratories patent—a claim potentially infringed by human thought—intact, not invalid, and infringed by Laboratory Corporation. However, the Supreme Court's *nondecision* in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, presaged a string of actual Supreme Court decisions that would soon nail the coffin shut on human patents: *Bilski* (2010), *Mayo v. Prometheus* (2012), *Myriad Genetics* (2013), and *Alice* (2014).

After the Supreme Court declined to decide *Laboratory Corp.*, the Federal Circuit and the BPAI considered a flood of patent litigation involving patent claims encompassing human thought. These included *In re Nuijten*, *Ex parte Jakobsson*, *Ex parte Gutta*, *Ex parte Glenner*, and *Classen Immunotherapies, Inc. v. Biogen IDEC*.[199] Two cases were accorded special importance by the Federal

193. *Id.*

194. *Id.* at 135.

195. *Id.* (citing Diamond v. Diehr, 450 U.S. 175, 187 (1981)).

196. *See id.* at 135–36 (citing Cochrane v. Deener, 94 U.S. 780, 788 (1877); Gottschalk v. Benson, 409 U.S. 63, 70 (1972)).

197. *Id.* at 136 (citing State St. Bank & Tr. Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998)).

198. *See id.* at 137.

199. *See In re* Nuijten, 500 F.3d 1346 (Fed. Cir. 2007); *Ex parte* Jakobsson, No. 2006-2107, 2007 WL 1371371 (B.P.A.I. Apr. 16, 2007); *Ex parte* Gutta, No. 2007-1246, 2007 WL 1766997 (B.P.A.I. June 11, 2007); *Ex parte* Glenner, No. 2007-1089, 2007 WL 1874818 (B.P.A.I. June 28, 2007); Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2006 WL 6161856 (D. Md. Aug. 16, 2006).

Circuit, which ultimately considered them en banc: *In re Comiskey* and *In re Bilski*.[200]

In *In re Comiskey*, the invention at issue involved "a method and system for mandatory arbitration involving legal documents, such as wills or contracts."[201] The parties agreed that the claims did not require the use of a computer, but could be performed using human thought.[202] The USPTO Examiner had rejected this method on grounds of obviousness. Comiskey appealed to the BPAI, which sustained the Examiner's rejections.[203]

Upon appeal, the Federal Circuit affirmed the conclusion of the BPAI, but on statutory subject matter grounds, and without reaching the issue of obviousness.[204] First, the Federal Circuit evaluated whether it could address the statutory subject matter question. In the second part of the opinion, the court considered the substance of the statutory subject matter question. The Federal Circuit characterized the patent application at issue as a business method patent, and said that, while *State Street* allows the patentability of business methods, such inventions still must meet the other requirements of patentability, including the requirements of 35 U.S.C. § 101.[205]

The court then reviewed the history of the prohibition on the patenting of abstract ideas. The Federal Circuit found that abstract ideas are not patentable unless they have practical application (citing *AT&T* and *State Street*), and even if they do have a practical application, they must either (1) be tied to a particular apparatus, or (2) change materials to a different state or thing (citing *Flook* and *Diehr*, among other sources). Next, the court described the Mental Steps Doctrine:

> Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed. . . . It is thus clear that the present statute does not allow patents to be issued on particular business systems—such as a particular type of arbitration—that depend entirely on the use of mental processes. In other words, the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the

200. *See In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007); *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

201. 499 F.3d at 1368.

202. *See id.* at 1379.

203. *See id.* at 1368.

204. *See id.* at 1380–81.

205. *See id.* at 1374.

> framers and Congress intended to be beyond the reach of patentable subject matter. Thus, it is established that the application of human intelligence to the solution of practical problems is not in and of itself patentable.[206]

Applying this rule to the specific patent claims at issue, the Federal Circuit found that most of the claims violated the rule because they did not require the use of a machine but could have been carried out by the human mind.[207]

The Federal Circuit did find that some claims potentially constituted patentable subject matter, but only because, under a broad interpretation, they could have required the use of a computer. The Federal Circuit then remanded the case to the USPTO for a determination of whether those potentially patentable claims, with the addition of computer use, were obvious or not.[208] On January 13, 2009, acting en banc, the Federal Circuit vacated their previous panel decision of September 20, 2007, and withdrew the opinion of that panel.[209] Although the panel opinion was revised at the order of the en banc Federal Circuit, largely to remove confusing linkages the panel had made between nonobviousness (35 U.S.C. § 103) and patentable subject matter (35 U.S.C. § 101), the panel's original conclusions regarding the patentability of inventions involving mental processes remained unchanged in the en banc opinion.[210]

Almost simultaneously to *In re Comiskey*, in *In re Bilski*, the Federal Circuit reviewed a decision of the BPAI, *Ex parte Bilski*, regarding the patentability of methods encompassing human mental processes.[211] The Federal Circuit granted a hearing en banc in which it considered "[w]hether the claimed subject matter is not patent-eligible because it constitutes an abstract idea or mental process; when does a claim that contains both mental and physical steps create patent-eligible subject matter?"[212]

The claimed invention was "[i]n essence . . . a method of hedging risk in the field of commodities trading."[213] The Examiner had rejected claims 1–11 of the application, finding the invention to

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206. *Id.* at 1378–79.
207. *See id.* at 1381.
208. *See id.*
209. *See generally In re* Comiskey, No. 2006-1286, 2009 WL 68845 (Fed. Cir. Jan. 13, 2009) (en banc).
210. *See In re* Comiskey, 554 F.3d 967, 969–70 (Fed. Cir. 2009) (en banc).
211. *See In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc); *Ex parte* Bilski, No. 2002-2257, Pat. App. LEXIS 51 (B.P.A.I. Mar. 8, 2006).
212. *In re* Bilski, 264 F. App'x 896, 897 (Fed. Cir. 2008) (per curiam).
213. *In re* Bilski, 545 F.3d 943, 949 (Fed. Cir. 2008) (en banc).

be merely an "abstract idea" not within the "technological arts" under *In re Musgrave*.[214] The BPAI had characterized the patent as claiming "non-machine-implemented method[s]" and stated that "the claims do not recite how the steps are implemented and are broad enough to read on performing the steps without any machine or apparatus."[215] The Federal Circuit thus characterized the issue as whether the invention, involving human thought potentially unfettered from the use of a computer, constituted patentable subject matter.

The BPAI had begun its analysis by incorporating by reference the legal analysis of statutory subject matter in *Ex parte Lundgren* and presented a detailed summary of that analysis.[216] The BPAI then briefly discussed the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility 2005, giving several reasons why these guidelines are only of limited assistance.[217] The BPAI cited *Lundgren*, and rejected the proposition that there exists a separate "technological arts" test.[218] Instead, the BPAI applied three different tests:

(1) a transformation test (whereby an invention is a statutory process if it transforms something to a different physical state of that thing);[219]

(2) an "[a]bstract idea" test, (which relates to that judicially recognized category of unpatentable subject matter);[220] and

(3) a "practical application" or "concrete and tangible result" test (derived from *State Street*).[221]

Under all three tests, as well as under the INTERIM GUIDELINES, the BPAI decided that the invention did not constitute statutory subject matter and sustained the examiner's rejections.[222]

The Federal Circuit affirmed the decision of the BPAI. It agreed that the claimed invention of hedging commodities trading

214. *Id.* at 950.

215. *Ex parte* Bilski, No. 2002-2257, 2006 Pat. App. LEXIS 51, at *6 (B.P.A.I. Sept. 26, 2006).

216. *See Ex parte* Lundgren, 2004 WL 3561262 (B.P.A.I. Sept. 28, 2005).

217. *See id.* at *41–50.

218. *See id.* at *69–70.

219. *See id.* at *60 (summarizing *Lundgren*'s interpretation of Supreme Court precedent).

220. *Id.* at *56–60.

221. *Id.* at *60–61.

222. *See id.* at *80.

risks is unpatentable subject matter under 35 U.S.C. § 101. The Federal Circuit also articulated a new machine-or-transformation test for determining whether or not a claimed process constituted patentable subject matter. The Federal Circuit stated that,

> The Supreme Court . . . has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.[223]

Because the Federal Circuit determined that the invention neither was necessarily "tied to a particular machine or apparatus," but could be performed by human thought, nor "transforms a particular article into a different state or thing," the court held the claims to be unpatentable subject matter.[224] The Federal Circuit specifically prohibited the patentability of any invention capable of being performed entirely by thought. "Of course, a claimed process wherein all of the process steps may be performed entirely in the human mind is obviously not tied to any machine and does not transform any article into a different state or thing. As a result, it would not be patent-eligible under § 101."[225]

The Supreme Court then granted certioriari in *In re Bilski* in order to clarify the patentability of inventions involving human thought, especially in light of its failure to provide such guidance in *Laboratory Corp*.[226] On June 28, 2010, the Supreme Court issued its opinion in *Bilski v. Kappos*. It characterized the "machine-or-transformation test" as "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101," but "not the sole test for deciding whether an invention is a patent-eligible 'process.'"[227] With respect to the patent claiming methods of hedging commodities trading risks, the Court held the claims to be unpatentable subject matter. Specifically, it noted that "[t]he patent application here can be rejected under our precedents on the unpatentability of abstract ideas."[228]

Comiskey, *Bilski*, and several other recent cases involving patents claiming methods of medical diagnosis also signal the

223. *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc).
224. *Id.* at 954, 976.
225. *Id.* at 961 n.26.
226. *See* Bilski v. Doll, 556 U.S. 1268 (2009).
227. Bilski v. Kappos, 561 U.S. 593, 604 (2010).
228. *Id.* at 612.

vulnerability of patents involving human genes. In its December 2008 decision, *Classen Immunotherapies, Inc. v. Biogen IDEC*, the Federal Circuit affirmed the invalidity of patents with claims that involve "evaluating and improving [the] safety of immunization schedules."[229] Earlier, the district court had concluded that "the correlation between vaccination schedules and the incidence of immune mediated disorders that Dr. Classen claims to have discovered is a natural phenomenon."[230] Subsequently, in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, the Federal Circuit reversed a decision by the lower court that had held that methods of determining the best treatment of Crohn's disease constituted unpatentable subject matter.[231] In *Prometheus*, the claims involved three major steps: (1) administration of thiopurine to a patient, (2) measurement of the amount of thiopurine in the patient, and (3) use of the measured amount of thiopurine to calibrate drug dosages to be administered to the patient.[232] Although the final step was largely based upon human thought, the Federal Circuit asserted that "[a] subsequent mental step does not, by itself, negate the transformative nature of prior steps."[233] The Federal Circuit then concluded that, in accordance with their test in *Bilski*, this method "'transform[ed] an article into a different state or thing,' and this transformation is 'central to the purpose of the claimed process.'"[234] On June 29, 2010, the Supreme Court vacated and remanded the Federal Circuit's decision "for further consideration in light of *Bilski v. Kappos*," which the court had decided the day before.[235] Then, on December 17, 2010, the Federal Circuit again reversed the district court's grant of summary judgment of invalidity. The unanimous Federal Circuit panel, made up of Chief Judge Rader and Circuit Judges Lourie and Bryson, "again [held] that Prometheus's method claims recite patentable subject matter under § 101."[236]

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229. 304 F. App'x 866, 866–87 (Fed. Cir. 2008).

230. Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2006 WL 6161856, at *5 (D. Md. Aug. 16, 2006).

231. Prometheus Lab'ys, Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1339 (Fed. Cir. 2009).

232. *See id.*

233. *Id.* at 1348.

234. *Id.* at 1345 (quoting *In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008) (en banc)).

235. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 561 U.S. 1040, 1040 (2010).

236. Prometheus Lab'ys, Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1353 (Fed. Cir. 2010).

In 2011, the Supreme Court agreed to hear *Mayo v. Prometheus*, an appeal whose central issue concerned the patentability of methods of diagnosis and therapy. The claims at issue involved three principle steps: (1) administration of thiopurine to a patient, (2) measurement of thiopurine in the patient, and (3) calibration of drug dosage to be administered to the patient based on the measured amount of thiopurine. The district court had held these claims to be unpatentable, while the CAFC reversed in 2010, finding the claims patentable.

Just one day after deciding *Bilski v. Kappos*, the Supreme Court ordered the CAFC to reconsider its decision in light of the former court's decision in *Bilski v. Kappos*. Upon reconsideration, the CAFC came to the same decision it had before, this time justifying its result on the *Bilski v. Kappos* decision. Subsequently, the Supreme Court granted certiorari to hear an appeal of *Mayo v. Prometheus*.[237] On March 20, 2012, the Supreme Court unanimously reversed the CAFC, holding that methods of using human metabolites in diagnosis and therapy did not qualify as patentable subject matter.[238] This decision also effectively reversed the CAFC's decision in *Classen Immunotherapies v. Biogen IDEC*, a 2011 decision that upheld the validity of several claims to methods of evaluating and improving the safety of immunization schedules. Justice Breyer's dissent in *Laboratory Corporation of America Holdings v. Metabolite Laboratories* in 2006 turned out to be a harbinger that the Supreme Court was on the verge of establishing a new and unforgiving rule against the patentability of methods of human diagnosis and treatment – a rule that accords with the wider trend against the patentability of human-related inventions. More recently, on June 19, 2014, the Supreme Court's decision in *Alice v. CLS Bank International* further reinforced this trend.

This latest *Prometheus* decision may assist in illustrating the boundary between unpatentable "human inventions," on the one hand, and patentable inventions that involve treatment or diagnosis of humans, on the other. Step (1) requires the administration of a drug whose source is outside the human body. Step (2) consists of removing a sample from a human body, and then measuring the amount of thiopurine in the sample. Only step (3) involves a process carried out by a human body (in this case, human thought). Just as

237. *See generally* Mayo Collaborative Servs. v. Promethius Lab'ys, Inc., 566 U.S. 66 (2012).

238. *See id.*

the Supreme Court reasoned, in *Parker v. Flook*, that "a process is not unpatentable simply because it contains [an otherwise unpatentable] mathematical algorithm," a claimed invention involving (1) administration of a drug whose source is external to the human body and (2) extraction and measurement of a sample from a human body involving an otherwise unpatentable human process is not rendered unpatentable simply because an additional step involves a process carried out by a human body.[239]

Most recently, the district court decision in *Myriad* directly addressed the patentability of human gene diagnostic tests. In addition to determining that human gene patents constituted unpatentability subject matter, the court also rendered diagnostic tests based on comparisons of human gene sequences similarly unpatentable. As the court stated, "because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter under § 101."[240] It is highly likely that this decision will be appealed to the Federal Circuit, given the huge economic investments pharmaceutical and biotechnology firms have made in such diagnostic tests.

Many reasons have been offered to justify why thoughts should constitute unpatentable subject matter. For example, an article by Dan Burk, entitled *Patenting Speech*, suggests that "there would seem to be profound First Amendment implications to the concept of infringement by 'thinking patented thoughts.'"[241] Kevin Collins has offered a different rubric for denying patentability to thoughts, suggesting that the correlation step in *Laboratory Corp.* should be unpatentable because it is essentially involuntary, unavoidable, and unfairly susceptible to patent infringement due to "insufficient thought control."[242] And, as I have previously suggested, if thought is

239. *See* Parker v. Flook, 437 U.S. 584, 590 (1978).

240. Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

241. Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99, 140 (2000) (quoting Allen Newell, Response: *The Models Are Broken, The Models Are Broken!*, 47 U. PITT. L. REV. 1023, 1025 (1986)).

242. *See generally* Kevin Emerson Collins, *Construction Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 WISC. L. REV. 759 (suggesting that thoughts be unpatentable). Note that neurobiology might disagree with Collins' conclusions regarding voluntary and involuntary thoughts. Recent insights from neurobiology suggest that there exist at least two rather different categories of "thought." Cerebral cortex-like thoughts may possess a significant volitional character and may therefore be avoided with effort. Cerebellum-like thoughts cannot be controlled according to current evidence. These

to constitute patentable subject matter at all, thoughts subject to greater executive control should lie more to the patentable end of the spectrum than default thoughts less subject to executive control.[243] Regardless of rationale, unless the Supreme Court surprisingly reverses its long-standing Mental Steps Doctrine, and overturns the relatively clear prohibitions against patenting naked human mental processes expressed in *Bilski v. Kappos*, *Prometheus*, *Myriad*, and *Alice*, then human thought will continue to lie beyond the realm of patentability.

D. *In Vivo* Conversion[244]

Patent claims whose elements involve physiological processes that occur inside a human body fit uneasily into patent law. However, numerous U.S. patents have issued with claims covering chemical products of human *in vivo* conversion. "*In vivo* conversion is a process, often metabolic in nature, wherein one substance" (a "prodrug"), often "a chemical compound, is altered significantly by physiological pathways in the body into one or more different substances" (a "drug" or "drugs").[245] "For example, when a patient ingests a therapeutic drug, that drug is often converted by the natural physiolog[ical] [processes] of the [human] digestive system into one or more chemically different metabolites."[246] The products of *in vivo* conversion sometimes possess therapeutic efficacy.[247]

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two categories of thought may warrant different treatment under patent law. Although some might privilege cerebral cortex-like thoughts over cerebellum-like thoughts because the former often involve "higher" intellectual content than do the former, neurobiology might suggest the opposite result. Since cerebellum-like thoughts cannot be controlled, infringement of patent claim elements consisting of such thoughts could similarly not be controlled. Furthermore, even specific knowledge of the patent claim would not discourage infringement, because infringement could not be controlled. By contrast, cerebral cortex-like thoughts could be avoided with care and effort. Though the Supreme Court, in the *Laboratory Corp.* case, left patented a claim that involved a cerebral cortex-like thought, one might expect there to have been a different result if the thought in question had been cerebellum-like instead.

243. *See* Torrance, *supra* note 173, at 28.

244. Portions of this section are adapted from Andrew W. Torrance, *Physiological Steps Doctrine*, 23 BERKELEY TECH. L.J. 1472, 1500–05 (2008).

245. *Id.* at 1473. If the process of *in vivo* conversion transforms a precursor chemical into a second chemical that has therapeutic efficacy, the precursor is sometimes called a "prodrug," and the resulting therapeutic chemical a "drug."

246. *Id.*

247. *See* RICHARD B. SILVERMAN & MARK W. HOLLADAY, THE ORGANIC CHEMISTRY OF DRUG DESIGN AND DRUG ACTION 498 (3d ed. 2014).

Numerous patent applications have claimed such therapeutic metabolites, either as compositions *per se* or as parts of methods of treatment. Although the USPTO has granted patent claims to such products generated by *in vivo* conversion of ingested drugs, and courts have routinely noted the eligibility of such products as patentable subject matter, never has a United States court of final appeal upheld such a patent claim as valid, enforceable, and infringed.[248]

Courts in the United States have repeatedly considered whether transformation of a drug via *in vivo* conversion into a metabolite can trigger infringement of patent claims covering the metabolite or methods of using the metabolite. A growing number of such infringement disputes have yielded final judgments. However, none of the cases yielded a final judgment in which a claimed product of *in vivo* conversion triggered infringement.[249]

Courts have employed diverse rationales to avoid finding infringement in *in vivo* conversion cases. At least one court has pointed to difficulties of obtaining sufficient evidence of infringing products from within the human body.[250] Others have relied upon inherency (i.e., inherent anticipation) where there has been previous use, public knowledge, or sale of a precursor compound that is necessarily transformed by *in vivo* conversion into a claimed product.[251] Other courts have interpreted as meaningful difference between "synthetic" and "natural" biochemicals.[252] Still others have

248. *See* Torrance, *supra* note 244, at 1473.

249. *See, e.g.*, Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 936 (Fed. Cir. 1992). Two of norgestimate's *in vivo* products, norgestrel and norgestrel acetate, independently infringed claims to the '322 patent under the doctrine of equivalents. Thus, though it did involve a product of *in vivo* conversion, it did not base its finding on infringement triggered by *in vivo* conversion of a product claimed in a patent. *See generally* Ortho-McNeil Pharm., Inc. v. Mylan Lab'ys, Inc., 348 F. Supp. 2d 713 (N.D. W. Va. 2004). The Court found infringement of a claim covering the antimicrobial compound levofloxacin; however, levofloxacin is the levorotatory enantiomer of a racemic mixture, and, once it enters the human body, though it is possible that it undergoes a physical separation from the dextrorotatory enantiomer, it does not undergo any change in chemical form.

250. *See* Zenith Lab'ys, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1424 (Fed. Cir. 1994).

251. *See* Marion Merrell Dow, Inc. v. Geneva Pharms., Inc., 877 F. Supp. 531, 536 (D. Colo. 1994); *see also* Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003); *In re* Omeprazole Pat. Litig., No. 1291, 2001 WL 585534, at *4 (S.D.N.Y. May 31, 2001).

252. *See* Marion Merrell Dow Inc. v. Baker Norton Pharms., Inc., 948 F. Supp. 1050, 1053–56 (S.D. Fla. 1996); *see also* Mylan Pharms., Inc. v. Thompson,

attributed significance to whether claimed medicinal substances are located inside or outside the body.[253] The most parsimonious explanation for this diversity of rationales, but unanimity of findings of noninfringement, is a discomfort with the very idea that a product arising naturally within the body, or the activity of the body itself, can infringe, let alone be the subject matter of, a valid and enforceable patent claim. In an analogy to Mental Steps Doctrine, this principle has been named Physiological Steps Doctrine.[254]

United States law offers no existing theory that can explain why no court has ultimately found infringement of a patent claim by a product or process of *in vivo* conversion. It is highly improbable that such a one-sided outcome has occurred merely by chance. If the odds of a patent owner obtaining a finding of infringement in an *in vivo* conversion case were even (that is, 50%), the unanimous result of *in vivo* conversion cases in failing to find infringement would be equivalent to flipping a coin ten times in a row, and getting heads every single time, a result whose odds are less than 0.01%. Based on such stark math, it would appear that courts are reluctant to allow the involuntary activity of a human body to trigger patent infringement. This suggests an unrecognized explanation that underlies *in vivo* conversion court decisions.

The Mental Steps Doctrine suggests an answer. At least two reasons justify the unpatentability of thoughts: their overlap with abstract ideas, and their overlap with physical phenomena.[255] Just as thoughts result from natural human physiology, so are metabolites produced by the natural *in vivo* conversion of precursor chemicals. Thus, in humans, neither thoughts themselves nor products of *in vivo* conversion themselves should qualify as patentable subject matter. In fact, the Mental Steps Doctrine can be viewed as merely a subset of a broader Physiological Steps Doctrine that precludes patentability of claims covering products of human physiological processes.

There are particular intimations of this Physiological Steps Doctrine in the judicial decisions involving *in vivo* conversion. The court's opinion in *In re Omeprazole* included a statement that lends a more direct form of support for Physiological Steps Doctrine. In this

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139 F. Supp. 2d 1, 30 (D.D.C. 2001) (failing to address the claim construction by district court on the merits), *rev'd*, 268 F.3d 1323 (Fed. Cir. 2001).

253. *See In re* Buspirone Pat. Litig., 185 F. Supp. 2d 340, 353 (S.D.N.Y. 2002); *see also* Novartis Pharms. Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306, 1312 (Fed. Cir. 2004).

254. *See* Torrance, *supra* note 244, at 1501.

255. *See supra* Section III.C.

case, the '499 patent included claims purporting to cover sulphenamides, metabolites produced by *in vivo* conversion of the drug omeprazole.[256] In explaining why claims to sulphenamides themselves would be invalid, the court stated that "[b]y claiming patent protection for sulphenamides formed *in vivo* after the oral administration of omeprazole, Astra has merely attempted to patent the unpatentable—'a scientific explanation for the prior art's functioning.'"[257] Despite the formal use of inherency doctrine as the rationale for its decision, the court classified metabolites produced by *in vivo* conversion within the category of natural phenomena. Once a patient has ingested a drug, metabolites of that drug produced within the human body through the processes of human physiology may provide "a scientific explanation [of the drug's] functioning," but they are unpatentable subject matter.[258]

After finding claims 1 and 3 of the '233 patent invalid, the Federal Circuit in *Schering v. Geneva* stated that its conclusion on inherent anticipation "does not preclude patent protection for metabolites of known drugs."[259] However, the Federal Circuit then outlined a very strict standard governing how patent protection for products of *in vivo* conversion might be attained through "proper claiming."[260] "[Naturally occurring] metabolites may not receive [patent] protection via compound claims. . . . [because] [s]uch bare compound claims include within their scope the recited compounds as chemical species in any surroundings, including within the human body as metabolites of a drug."[261] Instead, "the metabolite may be claimed in its pure and isolated form . . . or as a pharmaceutical composition (e.g., with a pharmaceutically acceptable carrier)."[262] "The patent drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition."[263] However, according to this unanimous opinion of the Federal Circuit, one cannot obtain patent protection for a metabolite produced by *in vivo* conversion of a precursor drug, adding further

256. *See In re* Omeprazole Pat. Litig., 2001 WL 585534, at *1 (S.D.N.Y. May 31, 2001).

257. *Id.* at *12 (emphasis added) (quoting Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999)).

258. *Id.* at *9.

259. *See* Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003).

260. *See id.*

261. *See id.*

262. *Id.*

263. *Id.*

support for the existence of an unarticulated Physiological Steps Doctrine.

Thus, whether a court employs evidentiary rationales, inherency doctrine, or claim construction, the result is consistently and predictably the same: patent claims purporting to cover products of *in vivo* conversion are either invalid, unenforceable, or not infringing. Unlike explanations involving lack of evidence and inherency, the Physiological Steps Doctrine is consistent with the ultimate decisions in all conversion cases. The "natural occurring event" of *Feed Service v. Kent Feeds*,[264] the "synthetically produced TAM" of *Marion Merrell Dow, Inc. v. Baker Norton Pharmaceuticals, Inc.*,[265] the direct administration of 6-hydroxy-buspirone in *Mylan Pharmaceuticals, Inc. v. Thompson*,[266] the externally administered "dose" in *In re Buspirone*,[267] the unpatentability of metabolites produced within the human body by *in vivo* conversion of *In re Omeprazole*,[268] *Schering Corp. v. Geneva Pharmaceuticals, Inc.*'s rule that "[naturally occurring] metabolites may not receive [patent] protection via compound claims[,]"[269] and *Novartis Pharmaceuticals Corp. v. Eon Labs Manufacturing, Inc.*'s "limit[] to a medicinal preparation . . . outside the body"[270] all suggest the existence of an implicit Physiological Steps Doctrine in United States patent law. Unlike explanations involving lack of evidence and inherency, the Physiological Steps Doctrine is consistent with the ultimate decisions in all *in vivo* conversion cases.[271]

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264. *See* Feed Serv. Corp. v. Kent Feeds, Inc., 528 F.2d 756, 764 (7th Cir. 1976).

265. Marion Merrell Dow Inc. v. Baker Norton Pharms., Inc., 948 F. Supp. 1050, 1057 (S.D. Fla. 1996).

266. *See* Mylan Pharms., Inc. v. Thompson, 139 F. Supp. 2d 1, 23 (D.D.C. 2001).

267. *See In re* Buspirone Pat. Litig., 185 F. Supp. 2d 340, 353 (S.D.N.Y. 2002).

268. *See In re* Omeprazole Pat. Litig., No. 1291, 2001 WL 585534, at *12 (S.D.N.Y. May 31, 2001).

269. Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003).

270. Novartis Pharms. Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306, 1309–10 (Fed. Cir. 2004) (defining medicinal preparation as "a preexisting product that is administered to treat disease and therefore must necessarily be prepared outside the body").

271. Furthermore, an article by Professor Dan Burk, entitled *Patenting Speech*, may even suggest a Constitutional justification for a Physiological Steps Doctrine. Burk writes that "there would seem to be profound First Amendment

Europe endorses explicitly what American courts appear to endorse implicitly. European patent law expressly limits the patentability of inventions relating to the human body, including methods of medical surgery, therapy, and diagnosis. The European Patent Convention (EPC) Article 53(c) places limits on patentable subject matter related to biological entities, stating that "European patents shall not be granted in respect of: . . . methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body," though it does add that "this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."[272] EPC Article 52(4), which was replaced by Article 53(c), declares that such subject matter "shall not be regarded as inventions which are susceptible of industrial application."[273] More specifically, Section (1) of Rule 29 ("The human body and its elements") of the Implementing Regulations to the Convention on the Grant of European Patents declares that "[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements . . . cannot constitute patentable inventions."[274]

On the other hand, Section (2) of Rule 29 allows that "[a]n element isolated from the human body or otherwise produced by means of a technical process . . . may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."[275] The Guidelines for Examination in the European Patent Office clarifies that,

> Such an element is not a *priori* excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to produce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself.[276]

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implications to the concept of infringement by 'thinking patented thoughts.'" Burk, *supra* note 241, at 140 (quoting Newell, *supra* note 241, at 1025). If thinking patented thoughts implicates the First Amendment, then surely involuntarily engaging in physiological processes, such as *in vivo* conversion, that trigger infringement would have equally profound Thirteenth Amendment implications.

272. Convention on the Grant of European Patents, *supra* note 79, at art. 53(c) (as amended Nov. 29, 2000).

273. Convention on the Grant of European Patents art. 52(4), Oct. 5, 1973, 1065 U.N.T.S. 255, 272.

274. Implementing Regulations, *supra* note 104, at rule 29(1).

275. *Id.* at rule 29(2).

276. EUR. PAT. OFF., GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE pt. G, ch. II, § 5.2, at 32–33 (2021).

Thus, the EPC recognizes a distinction between the patentability of chemical inventions practiced outside and inside the human body. An "element isolated from the human body" or "produce[d] . . . outside the human body" may constitute patentable subject matter, but, by implication, an element not isolated from, or produced inside, the human body is unpatentable.[277] Similarly, the World Trade Organization Agreement on Trade-Related Aspect of Intellectual Property offers very comparable provisions in Articles 27(2) and (3).[278]

This patentability criterion is consistent with the Physiological Steps Doctrine, and with the *in vivo* conversion cases discussed above. It would thus appear that European patent law definitively encompasses a Physiological Steps Doctrine, in contrast with the implicit Physiological Steps Doctrine of United States patent law.

The unanimity of results in cases involving patent infringement triggered by *in vivo* conversion is striking. In fact, its very improbability suggests a common underlying explanation for why *in vivo* conversion does not ever seem to trigger patent infringement. Explanations based on inherency or a lack of evidence provide a satisfactory explanation for only a minority of *in vivo* conversion cases. The Physiological Steps Doctrine, which suggests that products and processes of *in vivo* conversion are unpatentable subject matter under United States patent law, offers an explanation that spans all *in vivo* conversion cases.

Though the rationales offered to explain the results in a number of *in vivo* conversion cases are suggestive, there are several advantages for a more explicit recognition of the Physiological Steps Doctrine. Consistent with much international, European, and United States patent law, the Physiological Steps Doctrine provides a theoretical underpinning to explain the results in cases involving products and processes of *in vivo* conversion. This theoretical underpinning not only has explanatory power for interpreting previous case law, but is also useful in predicting the outcome of future *in vivo* conversion cases. In addition, the Physiological Steps Doctrine increases the understanding of where inventions involving human beings, and the biological products and processes thereof, whether human genes, human embryonic stem cells, human

277. Implementing Regulations, *supra* note 104, at rule 29(2); EUR. PAT. OFF., *supra* note 276, at pt. G, ch. II, § 5.2, at 33.

278. *See* TRIPs Agreement, *supra* note 60, art. 27(2)–(3), at 331.

thoughts, or human *in vivo* conversion fit within the spectrum of patentable subject matter.

CONCLUSION

Almost 200 years ago, Justice Story suggested that inventions "injurious to the morals, the health, or the good order of society" should not be patentable.[279] This doctrine of "moral utility" was long applied by courts to prohibit the patenting of such "immoral" inventions as a "card-playing slot machine."[280] However, judgments of ethics and morality have since waned in their relevance to patentability. Albert Einstein, a patent examiner in the Swiss Patent Office, expressed his fondness for the isolation from nontechnical issues his position afforded him by referring to the Office as a "secular cloister."[281] Isolated within this cloister, Einstein and other patent examiners avoid many ethical controversies not directly relevant to judging the utility, novelty, nonobviousness, and sufficiency of disclosure of inventions claimed in patent applications. Courts have also noted the separation of issues of ethics and morality from issues of patentability. For example, in *Juicy Whip, Inc. v. Orange Bang, Inc.*, the Federal Circuit questioned the continued vitality of moral utility, observing that it "has not been applied broadly in recent years."[282] As Matthew Rimmer has observed, "The dominant sentiment within the courts and the patent offices is that ethical considerations are necessarily extrinsic to patent law."[283]

Nevertheless, the body of patent law surrounding human inventions may suggest an exception to this principle of ethical indifference. As the Supreme Court emphasized in *Webber v. Virginia*, patent law exists within the wider context of the legal system, and must conform to other laws: "Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted."[284] To

279. Bedford v. Hunt, 3 F.Cas. 37, 37 (C.C.D. Mass. 1817).

280. *E.g.*, Reliance Novelty Co. v. Dworzek, 80 F. 902, 902–04 (C.C.N.D. Cal. 1897).

281. Letter from Albert Einstein to Michelle Besso (Dec. 12, 1919), *in* MICHELE BESSO, CORRESPONDENCE 1903–1955, at 147–49 (Pierre Spezioli ed., 1972).

282. 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

283. RIMMER, *supra* note 101, at 263.

284. 103 U.S. 344, 347–48 (1880).

allow the patenting of human inventions would likely violate the norms and laws, both explicit and implicit, that such powers are intended to protect.

Although the Supreme Court referred specifically to the "States," there is a more general principle to its statement: patent law may not countermand other laws, especially those that promote "the health, good order, peace, and general welfare of the community."[285] The Thirteenth Amendment of the U.S. Constitution is an exemplar of such a law, arising, as it did, out of a tragic conflict that threatened all of these values. Just as it must be consistent with many other laws, patent law must be consistent with the Thirteenth Amendment.

Many have accused patent law of treating human beings, and aspects thereof, as property by allowing human inventions to constitute patentable subject matter. Although patents have issued claiming human subject matter, patent law has consistently limited, or even eliminated, such patents, and reformed the patent law doctrines or practices that allowed such patenting mistakes. In addition to prohibiting the patenting of human beings *per se*, patent law has increasingly limited, and sometimes prohibited, claims to human genes, human embryonic stem cells, human thought, and human *in vivo* conversion. The recent quartet of Supreme Court decisions reinforces the ineligibility of human-based inventions for patentability. These trends in the patentability of human inventions suggest the evolution of a "human bar to patentability." Despite charges to the contrary, patent law provides little support for patent servitude. Rather, patent law has tended to be sensitive to the prohibitions of, and largely in compliance with, the Thirteenth Amendment and the many other laws that prohibit the patenting of human beings.

285. *See id.*

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