IMMORAL PATENTS

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INTRODUCTION

If there were ever a controversial topic, it is abortion. Indeed, the constitutionality of laws restricting abortion[1] has been the topic of frequent, fervent debate in the United States. After *Roe v. Wade*[2] and later *Planned Parenthood v. Casey*,[3] much of the dispute over abortion has focused on the role of government in funding abortions,[4] related services,[5] and related organizations.[6] Another frequent topic is the constitutionality of government regulating abortion or abortion providers,[7] rather than the constitutionality of outright prohibiting abortion.[8] Moreover, public debate has considered government involvement in, and regulation of, research and development related to biotechnology, including reproduction

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[1] *See, e.g.*, Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, § 2(1), 117 Stat. 1201, 1201 (2003) ("A moral, medical, and ethical consensus exists that the practice of performing a partial-birth abortion . . . is a gruesome and inhumane procedure that is never medically necessary and should be prohibited.").

[2] *See* Roe v. Wade, 410 U.S. 113, 153 (1973) (finding a constitutional right "broad enough to encompass a woman's decision whether or not to terminate her pregnancy").

[3] *See* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 846 (1992) (retaining and reaffirming "the essential holding of *Roe v. Wade*").

[4] *See, e.g.*, Beal v. Doe, 432 U.S. 438, 447 (1977) (holding "that Pennsylvania's refusal to extend Medicaid coverage to nontherapeutic abortions is not inconsistent with Title XIX" of the Social Security Act); Maher v. Roe, 432 U.S. 464, 466 (1977) (holding that the Constitution does not require "a [Medicaid] participating State to pay for nontherapeutic abortions when it pays for childbirth").

[5] *See, e.g.*, Rust v. Sullivan, 500 U.S. 173, 196 (1991) (rejecting constitutional challenges to restrictions on federal funding of abortion counseling).

[6] *See, e.g.*, Planned Parenthood of Greater Ohio v. Hodges, 917 F.3d 908, 910 (6th Cir. 2019) (upholding restrictions on state funding to organizations performing nontherapeutic abortions).

[7] *See, e.g.*, Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292, 2310-11, 2314 (2016) (invalidating as unconstitutional requirements of admitting privileges and nearby surgical centers placed on abortion providers); EMW Women's Surgical Ctr., P.S.C. v. Beshear, 920 F.3d 421, 446 (6th Cir. 2019) (upholding Kentucky's Ultrasound Informed Consent Act against First Amendment challenge).

[8] That said, recent legislative proposals have sought to prohibit abortion in certain situations, including the very early weeks of pregnancy. *See, e.g.*, Sabrina Tavernise, *How Banning Abortion in the Early Weeks of Pregnancy Suddenly Became Mainstream*, N.Y. TIMES (Apr. 18, 2019), https://www.nytimes.com/2019/04/18/us/ohio-abortion-heartbeat-bill.html [https://perma.cc/X35T-WMVU].

technologies, and particularly the use and destruction of embryonic stem cells, embryos, and fetuses.[9]

But government funding, regulation, and involvement in research and development are not the only mechanisms the government uses to impact the development and use of controversial technologies, including abortion, biotechnology, and reproduction technologies. Another such mechanism is the patent system. The patent system provides an incentive for inventors and their supporters to invest in research and development of new technologies.[10] To the extent an invention is eligible for patenting, the inventor may obtain a patent on the invention so long as he or she satisfies the other patentability and disclosure requirements of the patent statute.[11] The invention, for example, must be new[12] and non-obvious to one of ordinary skill in the relevant field of technology.[13] And the patent application must disclose the details of the invention as well as how to make and use it.[14] If the invention

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[9] This debate played out publicly in national politics during the administration of George W. Bush. *See* O. Carter Snead, *Public Bioethics and the Bush Presidency*, 32 HARV. J. L. & PUB. POL'Y 867, 875 (2009) ("The moral, legal, and public policy dispute over embryonic stem cell research (and related matters, such as human cloning) is the most prominent issue in public bioethics of the past decade. Since the derivation of human embryonic stem cells in 1998 at the University of Wisconsin, the issue has been debated and discussed by scholars, politicians, members of the popular media, and the public at large. It has been a recurring issue in political campaigns and the activities of the political branches of government at the state and federal level. Without question, it is the defining issue for President Bush's contribution to public bioethics.").

[10] *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.").

[11] *See* 35 U.S.C. § 101 (2020) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

[12] 35 U.S.C. § 102 (2020) (describing the novelty requirement).

[13] 35 U.S.C. § 103 (2020) ("A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.").

[14] 35 U.S.C. § 112(a) (2020) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, 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, and shall set forth

and the patent application meet all these requirements, a patent issues to the inventor granting him or her a right to exclude others from using the patented invention[15] and a right to collect money damages from those who infringe the right to exclude.[16] These rights can be valuable. Thus, patents can provide monetary rewards to those who engage in research and develop inventions, and the possibility of obtaining these monetary rewards induces some inventors to engage in research and development.[17] The chance of obtaining these monetary rewards likewise induces investors to support inventors in these efforts.

While the patent system impacts the development and use of technologies, only to a limited extent have legislators recognized the moral and ethical implications of the patentability of controversial technologies like abortion, biotechnology, and reproduction technologies. Congress and the President have enacted legislation stating that, "[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[18] That's it. Other than this one example, the question of the patentability of technologies some deem immoral or unethical has not even been the subject of legislative debate. Indeed, the absence of debate related to the patentability of controversial technologies is not limited to abortion,

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the best mode contemplated by the inventor or joint inventor of carrying out the invention.").

[15] 35 U.S.C. § 154(a)(1) (2020) ("Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof."); 35 U.S.C. § 271(a) (2020) ("Except as otherwise provided in this title, 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 patent therefor, infringes the patent.").

[16] 35 U.S.C. § 284 (2020) ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.").

[17] Andrew Blair-Stanek, *Profits as Commercial Success*, 117 YALE L.J. 642, 650 (2008) ("The classical economic theory of patents sees them as a mechanism for inducing inventive activity and disclosure by providing the reward of monopoly protection.").

[18] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

biotechnology, and reproduction technologies. There also has not been debate regarding patentability with respect to other areas of concern, such as technologies that damage the environment.

I find this absence of legislative debate regarding the patentability of controversial technologies curious for at least four reasons. First, the judicial branch, as opposed to the political branches of the federal government that enact legislation, for nearly two centuries—until 1999—held that immoral or unethical technologies were not eligible for patenting.[19] Second, other nations' patent statutes and the European Patent Convention explicitly identify morality as a basis for denying an applicant a patent.[20] Third, as I have already described, for decades there has been an intense public debate in the United States over the government's involvement in, and regulation of, research and development related to abortion, biotechnology, and reproduction technologies, and particularly the use and destruction of embryonic stem cells, embryos, and fetuses—areas of considerable moral and ethical concern. And, fourth, Congress is currently considering proposals to amend the patent statute to change the law of patent eligibility[21]—and no one has recognized that these proposals would

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[19] *Compare, e.g.*, Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.) ("All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention.") *with* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999) ("Of course, Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness. . . . Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.").

[20] *See, e.g.*, Convention on the Grant of European Patents (European Patent Convention) art. 53(a), Oct. 5, 1973 (amended Nov. 29, 2000), https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ma1.html [https://perma.cc/NR92-A27P] ("European patents shall not be granted in respect of . . . inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.").

[21] Press Release, U.S. Senator Christopher Coons, Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), https://www.coons.senate.gov/news/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework [https://perma.cc/WKL5-YNA3] (announcing a "bipartisan, bicameral framework on Section 101

overturn the existing prohibition on obtaining a patent with "a claim directed to or encompassing a human organism."[22]

In this Article I explore the patentability of controversial technologies by identifying and analyzing the strengths and weaknesses of the argument that immoral or unethical technologies should not be patentable. Toward that end, I trace the history of the patent system's treatment of technologies deemed immoral or unethical, consider the arguments that moral and ethical considerations should cause the law to exclude technologies from the patent system, and identify the best approach should moral and ethical considerations be reintroduced into the patentability analysis. As part of this analysis, I explore several factors that might be relied upon to limit the patent eligibility of immoral or unethical inventions. I then analyze whether judicial, legislative, or agency control over moral and ethical concerns makes the most sense in this context. Surprisingly, despite clear parallels between the use of public policy arguments in contract law and patent law, my analysis presents the first attempt to conceptualize moral and ethical concerns in the patent field by considering the strengths and weaknesses of the traditional contract defense of unenforceability as against public policy.

In short, drawing upon critical analyses of contract law's public policy doctrine, I suggest that any moral or ethical concerns with patenting should be governed by express limitations on patent eligibility introduced through the political process, or, in other words, through legislation enacted by Congress and the President, rather than through judicial or agency processes. In this way, this Article contributes to the ongoing debate over patent eligibility, not only by reintroducing into the debate the important but overlooked possibility of ending the encouragement or rewarding of immoral or unethical activity, but also by presenting a novel analysis of the best approach to addressing these concerns.

Part I begins by addressing the legal landscape. Part I.A. considers the historical treatment of immoral and unethical inventions under patent law, while Part I.B. explains their modern

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patent reform" that would "[d]efine, in a closed list, exclusive categories of statutory subject matter which alone should not be eligible for patent protection").

[22] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

treatment. Part I.C. then highlights how current patent reform efforts would undermine the limited exception current law provides for patent claims encompassing human organisms. Part II, in turn, catalogs moral and ethical arguments relevant to the patentability of these technologies. Part II.A., for example, discusses whether personal autonomy ought to play a role in the determination of patentability. Part II.B. then analyzes the eligibility of immoral or unethical technologies from the countervailing standpoint of utilitarian and fairness concerns. Given this legal landscape and the consideration of prominent arguments for and against limiting patentability based on moral and ethical concerns, Part III evaluates the relevant mechanisms for reintroducing considerations of morality and ethics into the consideration of patent law. As mentioned, in a novel assessment drawing upon criticisms of contract law's public policy doctrine, I conclude that any moral or ethical concerns with patenting should be governed by limitations on patent eligibility expressed in the patent statute, rather than through ad hoc judicial or agency determination.

I. THE LEGAL LANDSCAPE

Here I set the stage for later discussion by considering patent law's historical treatment of immoral and unethical inventions before explaining patent law's modern treatment of these inventions.

A. Historical Treatment of Immoral and Unethical Inventions

Historically, patent examiners and judges had great discretion respectively to refuse to issue patents and to invalidate patents on inventions they deemed immoral or unethical. They did so by using patent law's usefulness requirement.

Patent law's usefulness requirement has constitutional and statutory underpinnings. The Constitution, for example, grants Congress the power to "[t]o promote the Progress of . . . *useful* Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[23] The patent statute, likewise, has—since the first Patent Act in 1790—stated that patents may be granted

[23] U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

for "any *useful*" invention.[24] Indeed, the Patent Act of 1790 stated that the original patent examiners (the Secretary of State, the Secretary of War, and the Attorney General) were required to determine whether the invention was "sufficiently useful" for a patent to issue.[25]

Judges, for their part, long understood this usefulness requirement as having moral and ethical elements. In 1817, for example, Supreme Court Justice Joseph Story, while "circuit riding"[26] instructed a jury regarding what a patentee must prove to obtain a verdict of patent infringement.[27] "He must, in the first place," Justice Story explained, "establish [his machine] to be a useful invention."[28] In this regard, he explained:

All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word "useful," therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention.[29]

In this short explanation, Justice Story set forth his understanding, complete with examples, that the "usefulness" requirement prohibited patents on inventions "injurious to the well-being . . . or sound morals of society" or, in other words, inventions "mischievous or immoral."[30] In another instance of circuit riding the very same year, Justice Story articulated a similar understanding of the usefulness requirement.[31] That said, the discussion in both

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[24] *See* Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 110 (1790) (emphasis added).

[25] *Id.*

[26] *See generally* Joshua Glick, *On the Road: The Supreme Court and the History of Circuit Riding*, 24 CARDOZO L. REV. 1753, 1753-55 (2003) (describing "circuit riding" as the "system of sending Supreme Court Justices around the country to serve as judges of the various federal circuit courts" and analyzing its history).

[27] Lowell v. Lewis, 15 F. Cas. 1018, 1019-21 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.).

[28] *Id.* at 1019.

[29] *Id.*

[30] *Id.*

[31] *See* Bedford v. Hunt, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) (No. 1,217) (Story, J.) ("By useful invention, in the statute, is meant such a one as may be applied to some beneficial use in society, in contradistinction to an invention, which is injurious to the morals, the health, or the good order of society. It is not necessary to establish, that the invention is of such general utility, as to supersede all other inventions now in practice to accomplish the same purpose. It is sufficient, that it has no obnoxious or mischievous

cases represented mere dicta, because in the first there was "no pretence" that the inventor's invention was "mischievous"[32] and in the second similarly "there [could not] be the slightest doubt, upon the evidence, that the patent is for a useful invention, in a very large sense."[33] Moreover, because Justice Story was circuit riding, his opinions did not have the precedential value of a Supreme Court opinion.

Judges over the next almost 175 years nevertheless applied Justice Story's understanding of the usefulness requirement, many to deny patents on inventions they deemed unethical or immoral. In 1820, just three years after Justice Story, another Supreme Court Justice circuit riding, Bushrod Washington, cited Justice Story's understanding of the usefulness requirement.[34] Justice Washington, however, like Justice Story, found the requirement met.[35] Later other judges would not.

In 1889, 1897, and 1922, for example, judges invalidated patents on gambling or lottery devices.[36] As one of these judges

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tendency, that it may be applied to practical uses, and that so far as it is applied, it is salutary. If its practical utility be very limited, it will follow, that it will be of little or no profit to the inventor; and if it be trifling, it will sink into utter neglect. The law, however, does not look to the degree of utility; it simply requires, that it shall be capable of use, and that the use is such as sound morals and policy do not discountenance or prohibit.").

[32] *Lowell*, 15 F. Cas. at 1019.

[33] *Bedford*, 3 F. Cas. at 37.

[34] Kneass v. Schuylkill Bank, 14 F. Cas. 746, 748 (C.C.D. Pa. 1820) (No. 7,875) (Washington, J.) ("[I]t is always difficult to prove the entire worthlessness of any discovery, or of any article susceptible of use. If the plaintiff's invention correspond substantially with the thing used by the defendants, how can the latter be permitted to say, that the thing so discovered and used is worthless? In the case of Lowell v. Lewis [Case No. 8,568], Mr. Justice Story, commenting upon this subject, lays it down, that the law only requires that the invention should not be frivolous or injurious to the well being, good policy, and sound morals of society.").

[35] *Id.* ("Now can it be urged that this definition is at all applicable to the plaintiff's invention? Let this question be answered by the witnesses in this cause. Those for the plaintiff agree that the invention is a security against the counterfeiting of the notes, and even Mr. Wilson, the witness most relied upon by the defendants, concurs in the same opinion, where the middle part of the plate is used, as it appears to have been by the defendants.").

[36] *See* Nat'l Automatic Device Co. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889) ("The law of the United States only authorizes the issue of a patent for a new and useful invention, and in an early case on that subject (*Bedford v. Hunt*, 1 Mason, 302) it was held that the word 'useful,' as used in this statute, means such an invention as may be applied to some beneficial use in society, in contradistinction to an invention which is injurious to the morals, health, or good order of society, and the principle thus enunciated has been

explained, "the only use to which the invention has been put being for gambling purposes, I must hold that it is not a useful device, within the meaning of the patent law, as its use so far has been only pernicious and hurtful."[37] Another of these judges invalidated a patent as lacking usefulness given that "the apparatus is used for gambling purposes, and that it cannot be used for any other purpose."[38] The third likewise invalidated a patent because "[n]o other utility than as a lottery device (in promoting sales or for similar uses) is suggested in the patent; and the claims themselves exclude any combination in which the element of the concealing means has no useful function."[39]

Other judges during the same time period took aim at other inventions focusing on deception. In 1900, for example, the Second Circuit affirmed the invalidation of a patent because the claimed invention "confer[red] no other benefit upon the public than the

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uniformly applied ever since. It is urged that this machine is susceptible of being utilized as a toy, or child's plaything; but it is a sufficient answer to this suggestion that no such use has been as yet made. The patent has been very recently issued, and it is possible that a useful application may yet be found for it; but as the case now stands, the only use to which the invention has been put being for gambling purposes, I must hold that it is not a useful device, within the meaning of the patent law, as its use so far has been only pernicious and hurtful."); Schultze v. Holtz, 82 F. 448, 449 (C.C.N.D. Cal. 1897) ("[T]he verified answer not only denies that the invention is new and useful, but alleges a specific fact, which, if true, disposes of the question of utility. It charges directly that the apparatus is used for gambling purposes, and that it cannot be used for any other purpose. Clearly, this is an allegation which, under the rule, should be treated as testimony in favor of the defendants, and, in view of the fact that the complainant has introduced no testimony to support the patent, it is, in my judgment, sufficient to entitle the defendants to a decree in their favor. The same conclusion would probably be reached in looking at the claims and specifications of the patent upon the allegations of the answer treated as merely raising the issue of utility."); Brewer v. Lichtenstein, 278 F. 512, 513-14 (7th Cir. 1922) ("In appellant's patent, as the specification and claims clearly disclose, the utility of the limitation of the covering element to a concealing means was to enable the gambling instinct of purchasers to be appealed to in promoting the sale of merchandise. No other utility than as a lottery device (in promoting sales or for similar uses) is suggested in the patent; and the claims themselves exclude any combination in which the element of the concealing means has no useful function. . . . At the oral argument appellant asserted, correctly enough, that not all drawings of lots are illegal, and suggested the case of two candidates who are directed by law to resolve a tie by drawing lots and also the case of the government's determining by lot the order in which eligible conscripts should go to war. But those instances seem to us to be beyond the range of any practical utility with which the patent law is concerned.").

[37] *Nat'l Automatic Device Co.*, 40 F. at 90.

[38] *Schultz*e, 82 F. at 449.

[39] *Brewer*, 278 F. at 513.

opportunity of profiting by deception and fraud."[40] The patent in question disclosed treating tobacco leaves to cause them to appear as if they were spotted by natural causes.[41] The court described this treatment as creating a "counterfeit" given that, unlike naturally-spotted leaves, the treated leaves did not "promote the burning quality of the leaf" or otherwise "improve its quality in any respect."[42] According to the court, this treatment was therefore not "beneficial" but instead "pernicious."[43]

Likewise in 1925 the Second Circuit similarly faulted another inventor for "decorat[ing] an old article of manufacture, or dress[ing] it to present an appearance to the eye that is not original as such," because "he does not change or improve the structure or the utility of the article."[44] This invention "relate[d] to a circular knit or seamless stocking" that imitated "some of the characteristic appearances of the straight or old-fashioned and seamed stockings."[45] The court admitted that through this imitation the invention "wins popularity and makes the [new] article more salable."[46] "But," concluded the court, "such accomplishment does not create a new useful discovery or invention."[47]

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[40] Rickard v. Du Bon, 103 F. 868, 869, 873 (2d Cir. 1900) ("We are of the opinion that neither the treatment applied by the defendant, nor that described or advised in the patent, has any tendency to promote the burning quality of the leaf, or to improve its quality in any respect, and that the only effect, if not the only object, of such treatment, is to spot the tobacco, and counterfeit the leaf spotted by natural causes. . . . In authorizing patents to the authors of new and useful discoveries and inventions, congress did not intend to extend protection to those which confer no other benefit upon the public than the opportunity of profiting by deception and fraud. To warrant a patent, the invention must be useful; that is, capable of some beneficial use as distinguished from a pernicious use.").

[41] *Id.* at 869.

[42] *Id.*

[43] *Id.* at 873.

[44] Scott & Williams, Inc. v. Aristo Hosiery Co., 7 F.2d 1003, 1004 (2d Cir. 1925) ("In this accomplishment, the inventor decorates an old article of manufacture, or dresses it to present an appearance to the eye that is not original as such; but he does not change or improve the structure or the utility of the article. The appearance is imitation, and thus, through it, wins popularity and makes the article more salable. . . . But such accomplishment does not create a new useful discovery or invention, and it was not the intention of Congress to grant protection to those who confer no other benefit to the public than an opportunity for making the article more salable.").

[45] *Id.* at 1003.

[46] *Id.* at 1004.

[47] *Id.*

Devices that lack operability have also been deemed deceptive or even fraudulent and therefore not patentable. In 1960, Judge Giles Rich described much of the history of the usefulness requirement.[48] As relevant here, he connected the idea of lack of operability with fraud. He did so by citing the 1940 decision of the Court of Customs and Patent Appeals in *In re Oberweger*.[49] In that case, the court affirmed the Patent Office's rejection of an application seeking a patent on an alleged invention for "treating the scalp for the purpose of producing hair growth."[50] The Patent Office had determined that affidavits "were not sufficient to show utility for a concoction which belongs to a class of compositions which from common knowledge has long been the subject matter of much humbuggery and fraud."[51] In affirming, the court explained that:

> It is a matter of common knowledge that numerous preparations, similar in many respects to the one at bar, have been advertised and sold for the purpose of producing hair on bald heads and which were totally lacking in utility, often harmful to the human body, and whose sale was generally understood to be a fraud upon the public.[52]

Other judges, however, during this same time period limited or rejected the approach of using patent law to address moral and ethical concerns. Some judges, for example, distinguished certain inventions from others found to be unpatentable based on the usefulness requirement. One case involved a patent on a

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[48] *In re* Nelson, 280 F.2d 172, 178-80 (C.C.P.A. 1960) (Rich, J.) (collecting treatises and cases addressing utility).

[49] *Id.* at 180 (citing *In re* Oberweger, 115 F.2d 826 (C.C.P.A. 1940)).

[50] *Oberweger*, 115 F.2d at 826.

[51] *Id.* at 828.

[52] *Id.* at 829. A more modern example is the current uproar over the Theranos patents, which are viewed as deceptive or fraudulent because they disclose ideas that do not work. Krista L. Cox, *Elizabeth Holmes and the Great Patent Scam*, ABOVE THE LAW (Mar. 7, 2019, 1:18 PM), https://abovethelaw.com/2019/03/elizabeth-holmes-and-the-great-patent-scam/ [https://perma.cc/2PLM-TQX5] ("Holmes was granted a patent for an idea, but not one that could actually be practiced. . . . Theranos is the clear example of what could and did go wrong, with fake patents—well, they were *granted* patents, so real from that perspective, but fake in the sense that the things they protected didn't actually exist—propping the company up, lending Holmes credibility that led to harm to who knows how many investors and hundreds of employees who were ultimately laid off in the wake of the scandal. With patents in hand, Holmes built a fraudulent company.").

shuffleboard game.[53] According to the Third Circuit, "[b]ecause of the cultural and prophylactic importance of games in our social structure, and the additional relevant factor of the huge annual expenditure for recreation we can properly conclude that the creation of a new game conforms to the patent requirement of being useful."[54] Thus, the court distinguished games from things "frivilous [sic] or injurious to the well-being, good policy, or sound morals of society," finding the former useful even if the latter were not.[55] The Seventh Circuit similarly distinguished pin-ball machines from gambling devices.[56]

Other judges sought to limit the invalidity theory of lack of usefulness to inventions incapable of any beneficial use. Thus, patents on inventions useful only in gambling or lottery devices would be invalid, but patents on inventions having any usefulness outside of gambling or lotteries would not be invalid. For example, the Seventh Circuit confronted a patent on "a bogus-coin detector for coin-operated vending machines."[57] While "the only practical use to which the detectors were put was to guard gambling machines, made and controlled by the company, from being operated by means of a bogus coins,"[58] the court nevertheless held that a patent covering the detectors met the usefulness requirement because "[t]he testimony of experts was not needed to show that the detector would perform its functions without regard to the character of the machine below its outlet."[59] According to the court, this invention

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[53] Cusano v. Kotler, 159 F.2d 159 (3d Cir. 1947).

[54] *Id.* at 162.

[55] *Id.* (quoting Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.)).

[56] Chicago Patent Corp. v. Genco, Inc., 124 F.2d 725, 727-28 (7th Cir. 1941) ("Defendant contends that the device of the patent is inherently a gambling machine without utility and, therefore, beyond protection by the patent laws. . . . Here the trial court made a specific finding that skill in operating the device is not wholly absent, that the machine may be operated 'without gain being a factor' and that the court could not conclude as a matter of law that it is incapable of legitimate use. . . . Bearing in mind that issuance of the patent creates a prima facie presumption of utility . . . the absence of any showing by defendant to overcome such presumption and the finding of the trial court, it is apparent that we can not say as a matter of law that the combination of the patent is inherently a gambling device.").

[57] Fuller v. Berger, 120 F. 274, 274 (7th Cir. 1903).

[58] *Id.*

[59] *Id.* at 277.

was, in relevant part, like the invention of Colt's revolver.[60] On the one hand it "was injurious to the morals, and injurious to the health, and injurious to the good order of society,"[61] but "[o]n the other hand, the revolver, by furnishing a ready means of self-defense, may sometimes have promoted morals and health and good order."[62] According to the court, "everything [is] useful within the meaning of the law, if it is used (or is designed and adapted to be used) to accomplish a good result, though in fact it is oftener used (or is as well or even better adapted to be used) to accomplish a bad one[.]"[63] This approach substantially limited the ability of the usefulness requirement to invalidate patent claims based on moral or ethical concerns.

Another similar approach that limited the ability of the usefulness requirement to invalidate patent claims based on moral or ethical concerns was to look for a minimal level of usefulness. The Court of Customs and Patent Appeals used this approach in the context of pharmaceutical inventions alleged to fail the usefulness requirement because of a lack of safety with regard to their use. Consider first *In re Anthony*.[64] In this case the Court of Customs and Patent Appeals recognized that "courts over the years have considered 'safety' as an aspect of the broader question of whether certain inventions—pharmaceuticals in particular—are 'useful' within the meaning of § 101 and its predecessors."[65] While "a composition unsafe for use by reason of extreme toxicity to the point of immediate death under *all* conditions of its sole contemplated use in treating disease of the human organism" would not meet the usefulness requirement, "'safety' is a relative matter, and . . . absolute proof of complete safety is realistically

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[60] *Id.* at 275.

[61] *Id.* (quoting WALKER ON PATENTS, 3d ed., § 82).

[62] *Id.* (quoting WALKER ON PATENTS, 3d ed., § 82).

[63] *Id.* (quoting WALKER ON PATENTS, 3d ed., § 82).

[64] *See generally In re* Anthony, 414 F.2d 1383 (C.C.P.A. 1969).

[65] *Id.* at 1394 ("Although the patent statutes do not establish 'safety' as a criterion for patentability of any of the statutory classes of patentable subject matter mentioned in § 101, yet it is undoubtedly true, as demonstrated by some of the cases cited by the examiner, that the Patent Office and the courts over the years have considered 'safety' as an aspect of the broader question of whether certain inventions—pharmaceuticals in particular—are 'useful' within the meaning of § 101 and its predecessors.")

impossible."[66] Given that the "evidence of record incontrovertibly [sic] establishe[d] that appellant's compositions [we]re effective in treating various types of mental depressions in humans,"[67] the court in this case reversed the Patent Office's rejection for lack of usefulness—even in the face of an admission that conditions of use disclosed in a New Drug Application to the Food and Drug Administration caused the patented drug to be "unsafe for use to a degree justifying its withdrawal from the market."[68] Likewise, in the later case of *In re Watson*,[69] the court concluded that another pharmaceutical invention met the usefulness requirement because "at least over a short period of use, [the claimed invention] meets

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[66] *Id.* ("No one, we suppose, would seriously maintain that, as a matter of policy, a composition unsafe for use by reason of extreme toxicity to the point of immediate death under *all* conditions of its sole contemplated use in treating disease of the human organism would nevertheless be useful within the meaning of the patent laws. But at the same time it must be recognized that 'safety' is a relative matter, and that absolute proof of complete safety is realistically impossible.")

[67] *Id.* at 1397 ("The evidence of record incontrovertably [sic] establishes that appellant's compositions are effective in treating various types of mental depressions in humans.").

[68] *Id.* at 1398-99 ("[I]t is no doubt true that an unequivocal finding by the FDA that a drug is totally unsafe in all circumstances of contemplated use should not be lightly regarded by the Patent Office as an aid in its determination of whether a drug is useful under 35 U.S.C. § 101. But what has the FDA found here? In concluding that the FDA has ruled 'Monase' to be 'unsafe,' without further qualification, we think the board has painted with too broad a brush, and has drawn inferences from the Suspension Order that are not justified by its specific language. The order does not contain any broad, pervasive finding, nor has Upjohn in any way 'admitted,' that 'Monase' is *completely* and *absolutely* unsafe under *all* conditions of use, i.e., that 'Monase' is medically 'useless.' What it does say, and what we understand appellant to concede here, is that *under the conditions of use upon the basis of which the application became 'effective,'* 'Monase' is unsafe for use to a degree justifying its withdrawal from the market and suspension of the effectiveness of the New Drug Application.").

[69] *In re* Watson, 517 F.2d 465, 476 (C.C.P.A. 1975) ("As this court stated in *Anthony*, 'safety' is a relative matter, absolute proof of safety is realistically impossible, and in the safety of pharmaceuticals Congress has given primary administrative jurisdiction to federal agencies other than the PTO. Assuming (as the solicitor contends) the Food and Drug Administration order determines that hexachlorophene is not suitable for use on mucous membrane, and assuming this is sufficient evidence to establish a prima facie case for lack of safety under § 101 (viz, that a mouthwash containing hexachlorophene is unsafe by reason of hexachlorophene being associated with toxic effects sufficient to require that continued marketing of hexachlorophene-containing products be carefully defined in order to protect consumers), nevertheless the Pader affidavit demonstrates, at least over a short period of use, that a mouthwash containing hexachlorophene, as in claim 5, meets the minimum level of safety needed to satisfy § 101.").

the minimum level of safety needed to satisfy § 101."[70] In both cases, the Court of Customs and Patent Appeals seemed comforted by the idea that "in the safety of pharmaceuticals Congress has given primary administrative jurisdiction to federal agencies other than the PTO."[71]

Eventually, in 1977, the Patent Office went even further than any of these judges in limiting the inquiry into morality and ethics. In a decision of the Board of Appeals, the Patent Office rejected wholesale any inquiry into morality or ethics, regardless of whether the invention in question was useful only, for example, for gambling: "while some may consider gambling to be injurious to the public morals and the good order of society, we cannot find any basis in 35 U.S.C. [§] 101 or related sections which justify a conclusion that inventions which are useful only for gambling ipso facto are void of patentable utility."[72] This decision set the stage for courts' modern treatment of morality and ethics in the consideration of the patentability of inventions.

B. Modern Treatment of Immoral and Unethical Inventions

In modern terms the "usefulness" requirement is called the "utility" requirement. This utility requirement differs, however, not just in name, but in substance from the traditional usefulness requirement applied by judges beginning in 1817. Indeed, it differs dramatically from the old usefulness requirement—morality and ethics now play no role in the utility requirement. Instead, modern patent law takes into account moral and ethical concerns through the doctrine of patent eligibility and through limitations on remedies. In this section I address all three of these modern doctrines: the utility requirement, the eligibility requirement, and limitations on remedies.

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[70] *Id.*

[71] *Id.*

[72] *Ex parte* Murphy, 200 U.S.P.Q. 801, 801-802 (P.T.O. Bd. App. 1977) ("We view the disclosed amusement device to be what is commonly referred to as a 'slot machine' or 'one-armed bandit.' . . . The sole basis of the rejection of all of the claims is under 35 USC 101 as lacking patentable utility. . . . We find ourselves in agreement with appellants and recognize that while some may consider gambling to be injurious to the public morals and the good order of society, we cannot find any basis in 35 USC 101 or related sections which justify a conclusion that inventions which are useful only for gambling ipso facto are void of patentable utility.").

1. Utility

The modern utility requirement, in contrast to the historic usefulness requirement, does not take into account morality or ethics. The story of how this came to be starts with two old Supreme Court cases.

The Supreme Court, while not addressing the usefulness requirement in particular, long ago laid the groundwork for later courts to distinguish between the rights granted by patents and general laws restricting use of technology based upon public policy, morality, or ethics. In short, in two cases decided in 1878 and 1880, the Court held that a patent provides no defense to the alleged violation of a generally-applicable law that limits use of the patented invention. [73] In other words, the Court recognized that the grant of a patent does not confer rights on the patent owner to violate generally-applicable laws related to the same subject matter. This recognition flows naturally from the basic principle that a patent grants a right to *exclude* use of technology, not a right to *use* technology.[74] But even if a patent granted a right to use technology, that right would not extend to any use otherwise deemed illegal. When the Patent Office grants a patent covering a new drug, it does not authorize the patent owner to sell the new drug to patients; the Food and Drug Administration is the government agency that must approve the new drug's sale after considering evidence of the drug's efficacy and safety.

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[73] Webber v. Virginia, 103 U.S. 344, 347-48 (1880) ("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. Whatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits."); *see also* Patterson v. Kentucky, 97 U.S. 501, 506-07 (1878) ("The right of property in the physical substance, which is the fruit of the discovery, is altogether distinct from the right in the discovery itself, just as the property in the instruments or plate by which copies of a map are multiplied is distinct from the copyright of the map itself. The right to sell the Aurora oil was not derived from the letters-patent, but it existed and could have been exercised before they were issued, unless it was prohibited by valid local legislation. . . . [T]he use of the tangible property which comes into existence by the application of the discovery is not beyond the control of State legislation, simply because the patentee acquires a monopoly in his discovery.") (citations omitted).

[74] Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 879 n.4 (Fed. Cir. 1991) ("It is elementary that a patent grants only the right *to exclude others* and confers no right on its holder to make, use, or sell.").

It took a long time for lower courts to use this distinction to hold that the utility requirement does not concern itself with public policy, morality, or ethics. While a lower court case, decided by the Federal Circuit in 1991, seemed to hold open the possibility that morality or ethics might render some inventions unpatentable,[75] the court later clarified its position in *Juicy Whip, Inc. v. Orange Bang, Inc.*,[76] a case decided in 1999. In this case the Federal Circuit confronted a district court's invalidation of a patent for lack of utility "on the ground that the patented invention was designed to deceive customers by imitating another product and thereby increasing sales of a particular good."[77] The Federal Circuit reversed.[78]

The Federal Circuit recognized Justice Story's formulation of the usefulness requirement as excluding inventions that are "injurious to the well-being, good policy, or sound morals of society," and noted the fact that "[c]ourts have continued to recite Justice Story's formulation."[79] But it also stated that "the principle that [patents] are invalid if [their inventions] are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years."[80] After reviewing the relevant historical precedent following Justice Story's approach, the court flatly declined to follow that precedent, holding instead that the precedent did not represent the correct view of the doctrine of utility.[81]

Under the correct view, according to the court, "[t]he fact that one product can be altered to make it look like another is in itself a specific benefit sufficient to satisfy the statutory requirement of

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[75] Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H., 945 F.2d 1546, 1552 (Fed. Cir. 1991) ("Section 101 has also been interpreted to exclude inventions deemed to be immoral, such as (until 1977) gambling machines . . . ."). The reference to "until 1977" likely refers to *Ex parte Murphy*, 200 U.S.P.Q. at 802 , where the Patent Office's Board of Appeals failed to find "any basis in 35 USC 101 or related sections which justify a conclusion that inventions which are useful only for gambling ipso facto are void of patentable utility."

[76] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999).

[77] *Id.* at 1365.

[78] *Id.*

[79] *Id.* at 1366 (citing Lowell v. Lewis, 15 F. Cas. 1018, 1018-19 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.)).

[80] *Id.* at 1366-67.

[81] *Id.* at 1367.

utility."[82] Moreover, the court pointed out, the accused infringer did not argue that using the patented invention violated the law.[83] "The requirement of 'utility' in patent law," explained the court, "is not a directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices."[84] At the same time, the court recognized, "Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness."[85] Because Congress had not declared unpatentable inventions with "the capacity to fool some members of the public," the court reversed the district court's judgment invalidating the patent in question.[86] This understanding of the utility requirement is still the governing law of the Federal Circuit today. And, given that the Federal Circuit holds exclusive jurisdiction over appeals from judgments in patent infringement cases and over appeals of rejections of patent applications by the Patent Office,[87] this understanding applies in all cases.

2. Eligibility

While modern patent law does not take into account moral or ethical concerns using its utility requirement, it does—in a minor way currently—take these concerns into account using its eligibility requirement. Patent eligibility refers to the requirement that, to be eligible for a patent, an invention or discovery must fall within the categories of subject matter identified in the patent statute. Specifically, according to the patent statute, the invention must be a "process, machine, manufacture, or composition of matter, or any . . . improvement thereof."[88] While this definition of eligible subject matter is broad, Congress and the President have at least twice

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[82] *Id.*

[83] *Id.* at 1367-68.

[84] *Id.* at 1368. The court went on to explain that "[o]ther agencies, such as the Federal Trade Commission and the Food and Drug Administration, are assigned the task of protecting consumers from fraud and deception in the sale of food products." *Id.*

[85] *Id.*

[86] *Id.*

[87] 28 U.S.C. § 1295(a)(1) & (a)(4)(A) (2020).

[88] 35 U.S.C. § 101 (2020). In addition, the Supreme Court has identified non-statutory exceptions to eligibility for abstract ideas, natural phenomena, and laws of nature. *See, e.g.*, Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 215 (2014).

specified exclusions. And one of these exclusions unquestionably has moral and ethical underpinnings.

Before considering these legislatively-defined exclusions to patent eligibility, however, it is important to recognize that the Supreme Court eschewed use of the eligibility doctrine to limit patentability based on its own understanding of relevant moral concerns. In *Diamond v. Chakrabarty*, the Court concluded that a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.[89] In the face of arguments that "grave risks . . . may be generated by research endeavors such as respondent's" including "a serious threat to the human race," the "spread [of] pollution and disease," the "loss of genetic diversity," and the "depreciate[ion of] the value of human life," the Court rejected the argument that it "should weigh . . . potential hazards in considering whether respondent's invention is patentable subject matter under § 101."[90] Institutional competency and political accountability formed the principal bases for rejecting this argument:

> [W]e are without competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[91]

In short, the Court deferred to Congress with respect to the question of what subject matter ought to be patent ineligible based upon moral, ethical, or any other concerns. Thus, it is important to recognize what limitations on eligibility have been enacted.

The first legislatively-defined exclusion relates to nuclear bombs. Within one year of the bombings of Hiroshima and

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[89] Diamond v. Chakrabarty, 447 U.S. 303, 305-10 (1980).

[90] *Id.* at 317.

[91] *Id.*

Nagasaki, President Truman signed into law the Atomic Energy Act.[92] Buried in that Act lay statutory exclusions of inventions related to nuclear bombs: "No patent shall hereafter be granted for any invention or discovery which is useful solely in the production of fissionable material or in the utilization of fissionable material or atomic energy for a military weapon."[93] The Act goes on to state: "No patent hereafter granted shall confer any rights with respect to any invention or discovery to the extent that such invention or discovery is used in the production of fissionable material or in the utilization of fissionable material or atomic energy for a military weapon."[94] Morality and ethics, however, did not provide the basis for excluding from patent eligibility inventions related to nuclear bombs. Instead, according to the Senate Report accompanying the Act, these exclusions sought to consolidate and control this type of research within federally controlled research facilities, and also to eliminate publication of information regarding nuclear technology through the patent system.[95] Indeed, the Act created a Patent Compensation Board that, according to the Senate Report, sought "to provide inventors with financial inducements in lieu of patent rights."[96]

The second legislatively-defined exclusion to patent eligibility, by contrast, unquestionably finds its roots in ethical and moral concerns. In 2011, the America Invents Act ("AIA") excluded from patent eligibility inventions related to human cloning.[97] The relevant part of the Act, which remains uncodified, states that, "[n]otwithstanding any other provision of law, no patent may issue

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[92] Atomic Energy Act of 1946, Pub. L. No. 79-585, 60 Stat. 755.

[93] *Id.* at § 11(a)(1).

[94] *Id.* at § 11(a)(2).

[95] S. REP. NO. 79-1211, at 26 ("In sections 4 and 6 the bill provides for a Government monopoly of the production of fissionable material and atomic weapons. In considering the patent implications of these provisions, the committee concluded that private patents can play no role in fields of activity reserved exclusively to the Government. For this reason, and to eliminate risks of disclosure of restricted information, risks which would be certain to arise under normal patent procedures, the bill provides that inventions and discoveries in these fields shall not be patentable matter.").

[96] *Id.* ("To assure the Commission of access to new inventions and to provide inventors with financial inducements in lieu of patent rights, the bill requires that such inventions be reported to the Commission and creates a Patent Compensation Board with authority to make awards to inventors.").

[97] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

on a claim directed to or encompassing a human organism."[98] The USPTO considers this provision to be a limitation on subject matter eligibility.[99]

The legislative history indicates the motivation of those who had a particular interest in this provision. Largely parroting the language of the legislation, Representative Lamar Smith stated that "this section operates to prohibit the use of appropriated funds to issue a patent containing claim that encompasses a human individual."[100] He, however, also explained that the provision is "directed as preventing the [Patent Office] from approving inventions related to human cloning."[101] Besides explaining his belief about inventions the provision would encompass and therefore bar from patent eligibility, he also identified various inventions he believed the provision would not encompass and therefore would remain patent eligible.[102]

Besides Representative Smith, the Patent Office's James Rogan presented a letter to Congress indicating that the Patent Office viewed the provision, known as the Weldon Amendment after Representative Dave Weldon, "as fully consistent with [the Patent

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[98] *Id.*

[99] *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 ("Congress has excluded claims directed to or encompassing a human organism from eligibility.").

[100] 157 CONG. REC. 91, E1183 (daily ed. June 23, 2011) (statement of Rep. Lamar Smith).

[101] 157 CONG. REC. 90, H4451 (daily ed. June 22, 2011) (statement of Rep. Lamar Smith).

[102] 157 CONG. REC. 91, E1183 (daily ed. June 23, 2011) (statement of Rep. Lamar Smith). ("1. [A]ny chemical compound or composition, whether obtained from animals or human beings or produced synthetically, and whether identical to or distinct from a chemical structure as found in an animal or human being, including but not limited to nucleic acids, polypeptides, proteins, antibodies and hormones; 2. [C]ells, tissue, organs or other bodily components produced through human intervention, whether obtained from animals, human beings, or other sources; including but not limited to stem cells, stem cell derived tissues, stem cell lines, and viable synthetic organs; 3. [M]ethods for creating, modifying, or treating human organisms, including but not limited to methods for creating embryos through in vitro fertilization, methods of somatic cell nuclear transfer, medical or genetic therapies, methods for enhancing fertility, and methods for implanting embryos; 4. [A] nonhuman organism incorporating one or more genes taken from a human organism, including but not limited to a transgenic plant or animal, or animal models used for scientific research.").

Office's] policy on the non-patentability of human life-forms."[103] He went on to explain:

The USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species Homo sapiens at any stage of development. It has long been USPTO practice to reject any claim in a patent application that encompasses a human life-form at any stage of development, including a human embryo or human fetus; hence claims directed to living "organisms" are to be rejected unless they include the adjective "nonhuman."[104]

The Patent Office thus understood the legislation as confirming its refusal to grant a patent covering a human being "at any stage of development, including a human embryo or human fetus."[105]

The Family Research Council likewise weighed in on the legislation, supporting passage of the Weldon Amendment. Among other things, the Family Research Council highlighted its understanding of what the provision would cover:

> The Weldon Amendment's use of the term "human organism" does include human embryos, human fetuses, human-animal chimeras, "she-male" human embryos, or human embryos created with genetic material from more than one embryo. The Weldon Amendment's use of "human organism" does not include the process of creating human embryos, such as human cloning, nor does it include non-human organisms, e.g., animals.[106]

Thus, it believed the provision would cover more than just human embryos and fetuses but clarified that under its understanding the provision would not cover the process of human cloning.

Notably, the Patent Office highlighted their belief the legislation would merely confirm the longstanding policy of the

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[103] *Id.* at E1184 (statement of James Rogan, U.S. Patent Office).

[104] *Id.*

[105] *Id.*

[106] *Id.*

Patent Office.[107] The Family Research Council provided more detail with respect to the Patent Office's historical practice.

The Family Research Council first cited what it referred to as the "Quigg memo," published in the Patent Office's Official Gazette on January 5, 1993.[108] Written by Donald Quigg, the Assistant Secretary and Commissioner of Patents and Trademarks, the memo announced in light of several recent cases that "[t]he Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. [§] 101."[109] The memo, however, went on to clarify that "[a] claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 U.S.C. [§] 101."[110] As for why, the memo explained that "[t]he grant of a limited, but exclusive property right in a human being is [unconstitutional]."[111]

The Family Research Council also cited "an official media advisory issued on April 2, 1998 in response to news about [a] patent application directed to a human/non-human chimera."[112] Significantly, the media advisory quoted and cited Justice Story's formulation of the usefulness requirement from 1817 by stating that "courts have interpreted the utility requirement to exclude inventions deemed to be 'injurious to the well being, good policy, or good morals of society."[113] This formulation provided the basis for the Patent Office to make it clear that it would not issue any patent on a human/non-human chimera:

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[107] *Id.* at E1184-85 ("The USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species Homo sapiens at any stage of development.").

[108] *Id.* at E1185. The Family Research Council mistakenly identified the date the Quigg memo was written as 1917, when in fact it was written in 1987. 1146 Off. Gaz. Pat. & Trademark Office 309 (Jan. 5, 1993) (including the date "Apr. 7, 1987").

[109] 157 CONG. REC. 91, E1185 (daily ed. June 23, 2011).

[110] *Id.*

[111] 1146 Off. Gaz. Pat. & Trademark Office 309.

[112] 157 CONG. REC. 91, E1185 (daily ed. June 23, 2011).

[113] Press Release, U.S. Patent and Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998) (quoting and citing Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.)). The media advisory also noted that Justice Story's statement had been quoted in Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H., 945 F.2d 1546, 1552 (Fed. Cir. 1991). *Id.*

[T]he existence of a patent application directed to human/non-human chimera has recently been discussed in the news media. It is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.[114]

Thus, the Patent Office indicated it would rely upon "the public policy and morality aspects of the utility requirement" to deny patentability.[115] The next year, however, the Federal Circuit would hold that the utility requirement did not concern itself with the moral or ethical nature of any particular invention.[116]

Beyond providing details with respect to the long practice of the Patent Office to deny patents covering human organisms, the Family Research Council also highlighted the fact that the Weldon Amendment for several years had been added to Patent Office appropriation legislation.[117] When he first introduced the amendment, Representative Dave Weldon similarly explained what he understood the provision would and would not do:

> [T]he U.S. Patent Office has already issued patents on genes, stems cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human

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[114] Press Release, U.S. Patent and Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998). For a detailed explanation of the circumstances causing the Patent Office to issue this media advisory, *see* Rick Weiss, *Patent Sought for Part-Human Creatures*, WASH. POST (April 2, 1998), http://www.washingtonpost.com/wp-srv/national/science/april98/patent.htm [https://perma.cc/M967-2A23].

[115] Press Release, U.S. Patent and Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998).

[116] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366-67 (Fed. Cir. 1999) ("To be sure, since Justice Story's opinion in Lowell v. Lewis, it has been stated that inventions that are 'injurious to the well-being, good policy, or sound morals of society' are unpatentable. . . . [B]ut the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years." (citations omitted)).

[117] 157 CONG. REC. 91, E1185 (daily ed. June 23, 2011) ("The Weldon Amendment is contained in the annual Commerce, Justice and Science Appropriations bills (CJS) and prevents the patenting of humans. Congress has passed it each year since 2004 . . . .").

> embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.[118]

Thus, Representative Weldon focused on excluding from patent eligibility human embryos and fetuses. One explanation for the need for Representative Weldon to introduce his amendment, however, may be the fact that the Federal Circuit eliminated the very legal basis for the Patent Office's longstanding policy of refusing to issue patents on human/non-human chimeras—the moral or ethical aspect of the usefulness requirement.[119]

When he spoke in favor of the Weldon Amendment in 2011, Representative Christopher Smith reintroduced Representative Weldon's prior testimony from 2003.[120] Characterizing the legislation as codifying a "pro-life policy," he also added his own comments in favor of the legislation:

> This amendment and USPTO policy reflect a commonsense understanding that no member of the human species is an "invention," or property to be licensed for financial gain. Patents on human organisms commodify life and allow profiteers to financially gain from the biology and life of another human person.[121]

These comments highlighted moral and ethical reasons for supporting the Weldon Amendment. Representative Christopher Smith further highlighted the moral underpinnings of the provision by explaining that "[c]odifying a ban on patenting of humans would not violate international obligations . . . in which member countries can exclude from patentability subject matter to prevent commercial exploitation which is 'necessary to protect ordre public or morality, [and] to protect human, animal or plant life.'"[122]

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[118] 157 CONG. REC. 91, E1179 (daily ed. June 23, 2011) (testimony of Representative Dave Weldon originally given in support of the Consolidated Appropriations Act of 2004, Public Law 108-199, 634, 118 Stat. 3, 101).

[119] Juicy Whip, Inc, 185 F.3d at 1366-67.

[120] 157 CONG. REC. 91, E1178-80 (daily ed. June 23, 2011).

[121] *Id.* at E1177.

[122] *Id.* (quoting and citing the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), Article 27, Section 5). He also highlighted that "the European Union prevents patents on human embryos on the basis of morality and public order without conflicting with the TRIPs agreement." *Id.* at E1178 (citing Guidelines for

3. Limitation on Remedies

In addition to using patent eligibility to address moral and ethical concerns, modern patent law also takes into account moral and ethical concerns by limiting remedies in appropriate circumstances. In particular, the patent statute limits remedies for "a medical practitioner's performance of a medical activity that constitutes an infringement" under either direct infringement or inducement of infringement.[123] The medical activity in question is "the performance of a medical or surgical procedure on a body" but does not include "(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent."[124] The patent owner in these situations does not have any remedy, whether injunctive relief, damages, or attorney fees.[125] One of the ideas underlying this limitation on remedies is the ethical obligation that doctors must be allowed to use their skills to aid their patients.[126]

C. Current Eligibility Reform Efforts

As shown, while modern patent law does not address moral or ethical concerns using the utility requirement, it does address them in targeted ways using limitations on patent eligibility and remedies. Significantly, however, current eligibility reform efforts,

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Substantive Examination, European Patent Office, Part C, Chapter IV, Section 4.5, iii (Rule 28c)).

[123] 35 U.S.C. § 287(c)(1) (2020).

[124] *Id.* § 287(c)(2)(A). The statute defines various other terms including "medical practitioner," "body," and "patented use of a composition of matter." *Id.* § 287(c)(2)(B)-(G). It also excludes from the limitation on remedies the activities anyone "who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services" in certain situations. *Id.* § 287(c)(3).

[125] *Id.* § 287(c)(1) ("With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.").

[126] *See* Leisa Talbert Peschel, *Revisiting the Compromise of 35 U.S.C. § 287(c)*, 16 TEX. INTELL. PROP. L.J. 299, 314 (2008) ("Opponents of the issuance of medical procedure patents highlight the ethical conflicts that granting these patents creates for physicians.").

and particularly certain reform proposals, would eliminate the limitation on patent eligibility. Remarkably, I am the only person who has recognized this potential change in the law.

A joint proposal by the American Intellectual Property Law Association and the Intellectual Property Owners Association provides one example. It would amend 35 U.S.C. § 101 and, in the process, overturn the prohibition on any patent issuing on a claim directed to or encompassing a human organism.[127] To see how this is so, consider the proposed text of the statute.

First, the proposal would create a new subsection, § 101(a), that would state that "[w]hoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title."[128] As discussed above, the relevant part of the AIA states that, "[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[129] Significantly, however, this language remains uncodified. In the AIA, Congress did not codify this law.[130] It is not part of Title 35. As a result, a statutory provision stating that the only basis to find a lack of patentability are the conditions and requirements set forth in Title 35 would overrule this uncodified law.[131]

Second, in place of any other standard of ineligibility, the proposal would put in place a statutory test in a new subsection, § 101(b), stating that "[a] claimed invention is ineligible . . . if and

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[127] *Joint AIPLA-IPO Proposal on Patent Eligibility*, AIPLA (May 2018), https://www.aipla.org/policy-advocacy/legislative/joint-aipla-ipo-proposal-on-patent-eligibility [https://perma.cc/9NEC-2SLD].

[128] *Id.*

[129] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

[130] *See id.*

[131] *See* Posadas v. National City Bank, 296 U.S. 497, 503 (1936) ("There are two well-settled categories of repeals by implication—(1) [W]here provisions in the two acts are in irreconcilable conflict, the later act to the extent of the conflict constitutes an implied repeal of the earlier one; and (2) if the later act covers the whole subject of the earlier one and is clearly intended as a substitute, it will operate similarly as a repeal of the earlier act. But, in either case, the intention of the legislature to repeal must be clear and manifest; otherwise, at least as a general thing, the later act is to be construed as a continuation of, and not a substitute for, the first act and will continue to speak, so far as the two acts are the same, from the time of the first enactment.").

only if the claimed invention as a whole (i) exists in nature independently of and prior to any human activity or (ii) is performed solely in the human mind."[132] This test would not necessarily exclude "a claim directed to or encompassing a human organism"[133] because any claimed human organism might be genetically modified or in some other way not "exist[] in nature independently of and prior to any human activity."[134] And it certainly would not exclude human/non-human chimeras.

Regardless, whatever the consequences of particular reform proposals, and whichever proposal may in the end be adopted by Congress and enacted into law or not, the current patent eligibility reform efforts provide a basis to pause and reconsider not only the AIA's prohibition on any patent issuing with a claim directed to or encompassing a human being, but also more generally the question of whether moral or ethical concerns ought to impact the patent system and, if so, how.

II. MORAL AND ETHICAL CONCERNS RELEVANT TO PATENTABILITY

There are many moral and ethical concerns with technology, concerns the patent system might take into account.[135] Different technologies, however, raise different moral and ethical concerns. While in the distant past moral and ethical concerns primarily related to gambling and deception, modern concerns primarily relate to biotechnology and human reproduction, including genes,

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[132] *Joint AIPLA-IPO Proposal on Patent Eligibility*, *supra* note 127.

[133] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

[134] *Joint AIPLA-IPO Proposal on Patent Eligibility*, *supra* note 127.

[135] Indeed, there are moral and ethical concerns with the patent system itself, regardless of the particular technology of particular patents. *See* E. RICHARD GOLD & BARTHA MARIA KNOPPERS, BIOTECHNOLOGY IP & ETHICS 16 (LexisNexis 2009) (noting that some skepticism "is linked to ethical concerns directly related to patent rights" including "distributional issues (*e.g.*, between developed and developing countries), management issues (*e.g.*, whether government health authorities have the ability to roll out new medical interventions in an efficient manner), [and] equity (*e.g.*, whether private enterprise should be able to profit from innovation funded largely through public support)"). Here, however, I focus attention on moral and ethical concerns with the technology that may be covered by patent rights. *Id.* ("Much of the controversy has little to do with patent law itself. For example, a rejection of biotechnology or a belief that only God can own life can suffice to vocalize opposition.").

gene editing, cloning, human-animal chimeras, embryos, embryonic stem cells, and abortion technologies. Indeed, the literature addressing moral and ethical concerns with biotechnology and human reproduction is vast and robust. Here I highlight two of the moral and ethical concerns with patenting these types of technologies: concerns with autonomy and the value of human life. I also describe what may be considered the countervailing concern with utilitarianism—the desire to encourage the development of technologies—before turning to the legal question of how the law ought to deal with moral and ethical objections to technologies.

A. Prominent Concerns

Modern moral and ethical concerns with patenting particular technologies primarily relate to the field of biotechnology and human reproduction and involve conceptions of autonomy and valuing human life.[136] I discuss both here. I also highlight other potential concerns with patented technology more generally before turning to the countervailing concern of utilitarianism.

1. Autonomy

One moral or ethical concern with patenting biotechnology and other technologies related to human reproduction is autonomy, or, in other words, control over one's human body.[137] Muireann Quigley, for example, describes concern with doctors filing patent applications covering a cell line—and methods for producing

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[136] *See, e.g.*, Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. Rev. 295, 297 (2007) (discussing how "[m]oral opponents of gene patents tend to be concerned with the implications of gene patents with respect to personal autonomy and human dignity").

[137] As a philosophical matter, concern over autonomy is not necessarily limited to human autonomy, but may be extended to other life forms. *See, e.g.*, VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 23 (North Atlantic Books 2016) ("Patenting living organisms encourages two forms of violence. First, life-forms are treated as if they are mere machines, thus denying their self-organizing capacity. Second, by allowing the patenting of future generations of plants and animals, the self-reproducing capacity of living organisms is denied."); *id.* at 123 ("The conservation of biodiversity, at the most fundamental level, is the ethical recognition that other species and cultures have rights, that they do not merely derive value from economic exploitation by a few privileged humans. The patenting and ownership of life-forms is ethically a statement of the opposite belief.").

products using the cell line—when the cell line and methods were derived from a patient without the patient's permission.[138] In her view, "the moral justification for, and analytical route to, ownership of (and property rights in) separated biomaterials is quite straightforward, *if* we start with self-ownership."[139] She explains that "[s]elf-ownership rights are those which persons ought to be accorded in virtue of their autonomy and which, when duly recognised (and enforced), can be seen as forming a perimeter of normative protection around their personal domain."[140]

This concern with autonomy extends beyond situations in which a patient has not given permission to doctors to obtain patent rights based on the patient's unique genetic characteristics. Indeed, this concern with autonomy may be used to explain opposition to patents covering human genes—any human's genes[141]—as well as human cloning and related technologies, including embryos and embryonic stem cells. This concern, moreover, may also be used to explain opposition to patents covering technology used to inhibit human reproduction.

On the one hand, some may use autonomy as a basis to argue that the patent system should not interfere with individuals' abilities to control their own reproductive system by granting someone the right to exclude use of technologies impacting that system.[142] On the other hand, others may use autonomy as a basis to argue that the patent system should not create incentives for the

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[138] MUIREANN QUIGLEY, SELF-OWNERSHIP, PROPERTY RIGHTS, AND THE HUMAN BODY 4-5 (Cambridge University Press 2018) (describing concern with UCLA doctors filing patent applications covering a cell line, and "a variety of methods for producing products from the cells," derived from a patient being treated for leukemia without his permission).

[139] *Id.* at 305.

[140] *Id.* at 305-06.

[141] *See, e.g.*, Holman, *supra* note 136, at 297 (describing how some "have questioned the equity of allowing a researcher who succeeds in chemically characterizing a genetic mutation to obtain exclusive patent rights relating to that mutation, and argue that patients suffering from a genetic disease should retain control over the mutations associated with their disease").

[142] *See, e.g.*, Timothy J. McCoy, *Biomedical Process Patents: Should They Be Restricted by Ethical Limitations?*, 13 J. LEGAL MED. 501, 515 (1992) ("To the extent that patenting biomedical processes interferes with physician autonomy or confidentiality, valid ethical problems may arise.").

development of technologies that abort pregnancies for nontherapeutic reasons, particularly for viable fetuses.[143]

2. Valuing Human Life

Another moral or ethical concern with patenting biotechnology and other technologies related to human reproduction is protecting the value of human life, or human dignity.[144] This concern with human dignity may be used to explain opposition to patents covering human genes, human-animal chimeras, human cloning, embryos, and embryonic stem cells.[145] But this concern may be used to oppose patents covering technology used to destroy or support the degradation of human life, including technologies that abort pregnancies for nontherapeutic reasons, particularly for viable fetuses.[146] This concern likewise explains opposition to patents restricting the ability to obtain medicine or other care to treat disease.[147]

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[143] *See* Trotter Hardy, *Introduction: Boundaries of Intellectual Property Symposium*, 51 WM. & MARY L. REV. 327, 334 (2009) ("Moral questions can most certainly be implicated by inventive activity; take research involving stem cells, or the patenting of animal (not to say, human) life generally, or my own hypothetical: a patent sought for an improved process to accomplish late-term abortions. Aside from the infrequently invoked requirement of 'utility' in this context, U.S. patent law does not typically specify moral constraints on the patentability of inventions. But, as Bagley shows, there is good reason to consider a different approach.").

[144] *See, e.g.*, Holman, *supra* note 136, at 297 ("For many, the genome possesses a singularly important, perhaps even sacred status as the blueprint of life. The notion that anyone can obtain private property rights in such a fundamental aspect of our common human heritage strikes some as an affront to human dignity.").

[145] *See id.* at 295.

[146] *See* Hardy, *supra* note 143 at 334 ("Moral questions can most certainly be implicated by inventive activity; take research involving stem cells, or the patenting of animal (not to say, human) life generally, or my own hypothetical: a patent sought for an improved process to accomplish late-term abortions. Aside from the infrequently invoked requirement of 'utility' in this context, U.S. patent law does not typically specify moral constraints on the patentability of inventions. But, as Bagley shows, there is good reason to consider a different approach.").

[147] *See, e.g.*, 35 U.S.C. § 287(c)(1) (2020) ("With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.").

3. Other Concerns

There are, of course, other moral and ethical concerns with technologies that might be the subject of patents. Some think the patent system should protect or at least not harm animals or the environment. Indeed, the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS") identifies "protect[ing] human, animal or plant life or health" and "avoid[ing] serious prejudice to the environment" as examples of moral reasons to exclude certain inventions from patentability.[148] The point is that, while I have highlighted autonomy and human dignity given their relevancy to biotechnology and human reproduction, areas of significant recent attention, there are numerous moral and ethical concerns that any individual might rely upon to suggest that the patent system not provide rights and incentives related to particular technologies.

B. Countervailing Concern of Utilitarianism

Set against the moral and ethical concerns addressed in the previous section stands the concern of utilitarianism, or, in other words, the desire to encourage the development of technologies. In this context, it reflects the idea that the patent system ought to be used to encourage the development of new inventions. Utilitarianism suggests that patents ought to incentivize the creation of new technology regardless of any countervailing moral or ethical concerns. A more moderate approach, however, simply suggests that moral and ethical concerns should be weighed against the value of encouraging inventive efforts.

Consider, for example, moral and ethical concerns with so-called bioprospecting, "the process of looking for potentially valuable genetic resources and biochemical compounds in nature."[149] One approach is to weigh or balance moral and ethical concerns with bioprospecting, on the one hand, with the goal of identifying useful inventions using bioprospecting, on the other

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

[149] PADMASHREE GEHL SAMPATH, REGULATING BIOPROSPECTING: INSTITUTIONS FOR DRUG RESEARCH, ACCESS AND BENEFIT-SHARING 1 (United Nations University Press 2005) ("Biodiversity prospecting or bioprospecting . . . refers to the process of looking for potentially valuable genetic resources and biochemical compounds in nature.").

hand.[150] Indeed, one conception of the right approach to addressing moral and ethical concerns with gene patenting is the idea that the patent system ought to balance relevant public interests.[151] These public interests include both preserving access to science (favoring limiting patent rights) and furthering inventive efforts that benefit society (favoring expanding patent rights).[152] And with respect to both, the value of the relevant technology may also be considered, for example, in terms of the possibility of improving human health.

What this discussion highlights is the determination of whether morality or ethics justifies excluding subject matter from the patent system (or putting in place other limits, such as limits on remedies) is ultimately a matter of policy.[153] It requires weighing the strength of the relevant moral or ethical concerns and the strength of the countervailing interest in encouraging inventive efforts.

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[150] *Id.* at 2 ("This book is an investigation into optimal property rights structures and institutional mechanisms that can facilitate the process of bioprospecting for drug research while balancing the goals of optimal drug R&D with the diverse demands placed by recognition of rights over traditional knowledge and access to genetic resources, benefit-sharing, and biodiversity conservation.").

[151] AURORA PLOMER, PATENTS, HUMAN RIGHTS AND ACCESS TO SCIENCE 162 (Edward Elger Publishing 2015) ("Intellectual property rights and patents were controversially extended to isolated genes and cells in the US since the 1980s and have become a global phenomenon since, raising profound moral and legal challenges for patent offices and constitutional courts around the world. At the heart of these challenges lies the question of the balance between public rights of access to science and the private rights of individuals over their scientific creations or 'inventions'.").

[152] *Id.* at 169 ("The underlying rationale is to avoid the private appropriation and enclosure of basic areas of science and knowledge which are the building blocks of scientific research and which are needed to advance research and develop downstream technological applications. Human rights principles and ideals may not be expressly articulated in these rationales. But they are arguably implicit in the idea that the aim of protecting the interests of inventors is not to support the self-serving interest of a few in market economies but to give due recognition to individual creative effort and in this way foster the advancement of science and knowledge as public goods.").

[153] *See* Amy L. Landers, *Patentable Subject Matter As a Policy Driver*, 53 HOUS. L. REV. 505, 528 (2015) ("[T]he European Directive is based on an expressed policy directed to facilitate research and development in biotechnology, including the social benefits of facilitating industrial development, research, and funding, fighting diseases, and developing the environment. During the course of formulating the Directive, the European system modified its proposal to include certain exceptions including uses that are 'unpatentable [because] their commercial exploitation would be contrary to *ordre public* or morality . . . .' This is one example of a patentability determination that was explicitly driven by considered policy choices." (citation omitted)).

Here I have introduced moral and ethical concerns related to particular technologies that have proven controversial in recent times, biotechnology and technologies related to human reproduction. I have also introduced the competing concern with encouraging the development of new technologies. I admittedly have not cataloged all of the relevant moral and ethical concerns with technology generally, but instead merely sought to introduce some of the most significant concerns in light of some the most controversial, modern technologies. Whatever the relevant moral or ethical concerns and whatever the particular technologies, however, the next question is how the patent system ought to resolve competing arguments over moral and ethical objections.

III. REINTRODUCING CONSIDERATIONS OF MORALITY AND ETHICS INTO PATENT LAW

If patent law ought to take into account one or more of the moral and ethical concerns I have described—or any others—the next question is how the patent system might do so. In this regard, drawing upon the last point—that the determination of whether morality or ethics justifies excluding subject matter from the patent system (or putting in place other limits, such as limits on remedies) is ultimately a matter of policy—I distinguish between judicial, legislative, and agency control over moral and ethical concerns. And to do so I draw from the contract law doctrine of voidness as against public policy and its criticisms.

A. Judicial Approach

As shown, the historical approach to dealing with moral and ethical concerns related to patenting technologies relied primarily upon judges making determinations using the usefulness requirement.[154] Significantly, this approach closely resembled the modern contract doctrine that renders some contracts and parts of contracts void as against public policy.[155] That is, historically judges

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[154] *See supra* Part I.A.

[155] *See generally* RESTATEMENT (SECOND) OF CONTRACTS § 178(1) (AM. LAW INST. 1981) ("A promise or other term of an agreement is unenforceable on grounds of public policy if legislation provides that it is unenforceable or the interest in its enforcement is

were effectively left to determine whether patents were void as against public policy. Like the contract doctrine, while judges might have derived the public policy from a relevant statute, they consistently derived the public policy from traditional judicial notions of right and wrong.[156]

Despite the persistence of the public policy doctrine in contract law, this is certainly not the modern approach in the patent law.[157] Nor is it the best approach. An English judge once famously described the contract doctrine of public policy as "a very unruly horse," because "once you get astride it you never know where it will carry you."[158] Indeed, "[i]t may lead you from the sound law."[159] That is, it is a doctrine that lacks significant constraints and therefore holds the potential to lead to unpredictable outcomes that seem to depend upon caprice rather than any rule or standard of decision. These and other common criticisms of contract's public policy doctrine would apply with particular salience were patent law to leave determinations of morality and ethics to judges.

For example, one criticism of the public policy doctrine in the context of contract law is that it balances interests *ex post* and therefore undermines the commercial goals of certainty and

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clearly outweighed in the circumstances by a public policy against the enforcement of such terms.").

[156] *Compare, e.g.*, Rickard v. Du Bon, 103 F. 868, 869-873 (2d Cir. 1900) (invalidating patent based upon policy derived from judicial sensibility that patents should not "extend protection to those which confer no other benefit upon the public than the opportunity of profiting by deception and fraud") *with* David Adam Friedman, *Bringing Order to Contracts Against Public Policy*, 39 FLA. ST. U. L. REV. 563, 581 (2012) ("Although categorizing cases can be a challenging and subtle exercise, a sizable number of these cases can be cast as attacks based on the underlying agreement's contravention or undermining of a statute or regulation. The remainder of the cases can be classified as an attack on the contract based on broader, more general public policy grounds and interests."). I say that in patent cases judges "might have derived the public policy from a relevant statute" because my study of the relevant patent cases reveals little such constraint—no real reference to statutes outlawing or even limiting use of the technology in question—even when invalidating patents based upon moral or ethical concerns. In short, the patent cases all fall within the second type enumerated by David Friedman, those in which judges identify "broader, more general public policy grounds and interests." *Id.* Notably, Friedman concedes that this second type of case "appears to present the most disorder and 'unruliness.'" *Id.* at 615.

[157] *See supra* Part I.B.

[158] Richardson v. Mellish, 130 Eng. Rep. 294, 303 (1824) (Burrough, J.).

[159] *Id.*

reliability.[160] Likewise, one problem with judicial resolution of moral and ethical concerns with patenting is the *ex post* aspect of the determination. Judges would necessarily determine whether to invalidate patents long after the investment in research and development has occurred, even long after the patents have issued. Such after-the-fact resolution of the validity of patents undermines the certainty and reliability of patents as tools to support investment decisions.

Indeed, a related criticism of contract law's public policy doctrine is the more general critique that it does not provide certainty and predictability.[161] It is difficult to predict how judges will resolve disputes over public policy, particularly policies derived not from statutes or regulations but instead from judges' own sense of policy.[162] Judicial resolution of moral and ethical concerns with the technology of patents similarly would not provide the certainty and predictability necessary for a property-rights regime such as patent law to spur investment in research and development.[163] And, unlike other patent law doctrines where an adversarial process would assist the relevant decisionmaker to make a decision based

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[160] *See* Jody S. Kraus & Robert E. Scott, *Contract Design and the Structure of Contractual Intent*, 84 N.Y.U. L. REV. 1023, 1103 (2009) ("New York uses formal doctrine to enforce bargains strictly and displays little tolerance of equitable principles that seek to balance interests ex post; California, by contrast, is far more willing to revise contracts ex post on the grounds of fairness, equity, or public policy. Miller concludes that '[t]he revealed preferences of sophisticated parties support arguments by Schwartz, Scott[,] and others that formalistic rules offer superior value for the interpretation and enforcement of commercial contracts.'") (quoting Geoffrey P. Miller, *Bargaining on the Red-Eye: New Light on Contract Theory* 1 (N.Y. Univ. Law & Econ., Working Paper No. 08-21, 2008), https://www.ssrn.com/abstract=1129805) [https://perma.cc/TC2F-YN5F].

[161] *See, e.g.*, Roger J. Johns & Mark S. Blodgett, *Fairness at the Expense of Commercial Certainty: The International Emergence of Unconscionability and Illegality as Exceptions to the Independence Principle of Letters of Credit and Bank Guarantees*, 31 N. ILL. U. L. REV. 297, 333 (2011) (noting that the contract public policy doctrine of illegality "damage[s] . . . commercial certainty, in general, by elevating fairness-based judgments about the risk-allocation choices of the parties to the underlying contract").

[162] *See* Geoffrey P. Miller, *Bargains Bicoastal: New Light on Contract Theory*, 31 CARDOZO L. REV. 1475, 1496 (2010) (noting that "the breadth of the public policy doctrine impairs the certainty and predictability of contractual enforcement").

[163] *See* David O. Taylor, *Formalism and Antiformalism in Patent Law Adjudication: Rules and Standards*, 46 CONN. L. REV. 415, 473 (2013) (discussing that "the encouragement of investment in research and development by prospective patent applicants is one of the very goals of patent law, and bright-line rules may encourage this investment by eliminating or at least reducing risk associated with this behavior").

on the best available information,[164] there is less reason to delay resolution of moral and ethical concerns with the underlying technology.

Other concerns with the public policy doctrine are that judges have no particular expertise to make policy decisions and, moreover, they are not politically accountable for their decisions. The concern with judges deciding matters of policy applies broadly to various areas of the law dependent upon expertise and information gathering.[165] Judges have no particular expertise to decide what is or is not a relevant moral or ethical concern justifying the denial of patentability. Nor are federal judges politically accountable for their decisions with respect to controversial subject matter. Patent law is a matter of federal law, and Congress has given exclusive jurisdiction over patent disputes to the federal courts.[166] Federal judges, of course, have the benefit of life tenure.[167] They purposefully are insulated from political accountability. While this insulation is a feature with respect to encouraging fidelity to the law rather than the views of the majority, insulation from political accountability is not a feature if the law merely directs the decisionmaker to make a decision based on his or her own view of the relevant moral and ethical concerns.[168]

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[164] The novelty and non-obviousness analyses represent patent law doctrines where an adversarial process generates significant informational benefits. In particular, as compared to patent examiners, accused infringers have much greater incentive to research prior art for potential use in a novelty or obviousness defense.

[165] *See, e.g.*, Norton v. S. Utah Wilderness All., 542 U.S. 55, 66 (2004) (arguing in the context of the Administrative Procedure Act that a principal purpose was "to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve").

[166] Gunn v. Minton, 568 U.S. 251, 261-62 (2013) (noting that "Congress . . . vest[ed] exclusive jurisdiction over actual patent cases in the federal district courts and exclusive appellate jurisdiction in the Federal Circuit") (citing 28 U.S.C. §§ 1338(a), 1295(a)(1)).

[167] U.S. CONST. art. III, § 1 (stating that federal judges "shall hold their Offices during good Behaviour").

[168] Justice Scalia made similar points repeatedly in various controversial contexts involving conflicting views of morality and ethics. *See, e.g.*, Ohio v. Akron Ctr. for Reprod. Health, 497 U.S. 502, 520-21 (1990) (Scalia, J., concurring) ("Leaving this matter [regarding abortion] to the political process is not only legally correct, it is pragmatically so. That alone—and not lawyerly dissection of federal judicial precedents—can produce compromises satisfying a sufficient mass of the electorate that this deeply felt issue will cease distorting the remainder of our democratic process."); Cruzan v. Dir., Missouri Dep't of Health, 497 U.S. 261, 293 (1990) (Scalia, J., concurring) (stating that "the point at which the means necessary to preserve [life] become 'extraordinary' or 'inappropriate,'

In sum, given the lack of certainty and predictability *ex post* decisions of morality and ethics engender, combined with the lack of expertise and accountability of judges, there is significant reason to think that judges should not be deciding which technologies should not be patentable based on moral and ethical concerns. While this lack of certainty and predictability is tolerated in the context of contract law, a recent study has shown that about two-thirds of invocations of public policy in contract disputes relate to policies derived from statutes and regulations, which tend to provide at least some order to the doctrine.[169] By contrast, my study of the relevant patent cases invoking moral or ethical concerns to invalidate patents reveals little such constraint—no real reference to statutes outlawing or even limiting use of the technology in question—and indeed the Federal Circuit has roundly rejected the idea of using statutes or regulation as a basis to invoke considerations of morality or ethics to invalidate patents.[170] Thus, next I turn to other possible approaches.

B. Legislative Approach

Given the same considerations studied in the last section, the best approach to dealing with the patentability of controversial technologies—technologies some may deem immoral or unethical—is to have the President and Congress determine eligible subject matter through legislation. This would not involve leaving patent eligibility decisions to an agency—here the U.S. Patent and

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are neither set forth in the Constitution nor known to the nine Justices of this Court any better than they are known to nine people picked at random from the Kansas City telephone directory . . . .").

[169] Friedman, *supra* note 156, at 615("The one-third of the cases where the defense appeals broadly to public policy (and typically fails) appears to present the most disorder and 'unruliness.'"). Friedman goes on to suggest that "[t]he first step in taming the [unruly] horse [that is the public policy defense in contract law] should be to declare that if there is no regulation or statute to invoke, the public policy defense is *completely* unavailable." *Id.* at 618. Applied to patent law, given that all of the relevant decisions appear to be based on judicial notions of morality and ethics not necessarily to regulation or statute, this proposal would suggest no public policy defense in patent law—at least one applied by judges.

[170] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999) ("The requirement of 'utility' in patent law," explained the court, "is not a directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices.").

Trademark Office. I discuss that alternative next. No, short of an override of a veto, Congress and the President would need to agree upon any exclusion from the patent system. The benefits of this legislative approach include *ex ante* determination, clarity leading to certainty and predictability, the ability to hold hearings and involve a wider swatch of interested parties, and also political accountability.

Consider, first, that there would be an *ex ante* determination of the patentability of controversial technologies. As a result, the expectations of those who invest in inventive efforts would not be thwarted. Instead, they would be able to rely upon the patent system (if patentability were allowed for a particular technology) or know that the patent system would not reward their efforts (if patentability were disallowed for a particular technology). This certainty and predictability, of course, would also depend upon the clarity of the expression of any exclusions based on moral and ethical concerns.

Another benefit of the legislative approach compared to the judicial approach is that Congress presumably would hold hearings to consider the views of a good number of interested parties rather than simply the particular parties involved in a lawsuit. In short, they would be able to weigh the interests of a wider array of people and groups. Congress and the President, moreover, are politically accountable to the electorate. Should voters disagree with their determinations over what moral and ethical concerns rise to the level of exclusion from the patent system, those voters could take their concerns to the ballot box.

C. Agency Approach

The remaining approach to consider is having an agency make decisions regarding moral and ethical concerns over patentability of technologies. The agency approach—where Congress and the President would enact a statute that merely delegates the subject to the U.S. Patent and Trademark Office—while better than the judicial approach, would still be subject to significant problems given the same considerations considered above with respect to the judicial and legislative approaches.

Determinations by an agency whether moral and ethical concerns rise to a level that justifies making patents unavailable

for certain technologies would be made *ex ante*—at least compared to determinations by judges. The U.S. Patent and Trademark Office presumably would be granted substantive rulemaking authority and then use notice and comment rulemaking to develop guidelines to identify what would cross the line of morality and ethics such that an applicant would not be eligible for a patent. In this way, those investing in research and development would know in advance whether the patent system would be available to support their investments in the form of rights to exclude users of any developed technology. In this way, an agency approach would provide more clarity, certainty, and predictability.

None of the other traditional justifications for delegation to an agency, however, exist in this context. In particular, agencies do not have expertise in determining whether the most relevant moral or ethical considerations (autonomy or valuing human life, for example) justify prohibiting or not prohibiting the patenting of certain technologies. These concerns would not present a subject where scientific or economic expertise would be necessary to make the best decisions—unlike what level of carbon dioxide emissions cause damage to the environment or to humans and what business practices cause harm to competition, where the Environmental Protection Agency and the Antitrust Division of the Department of Justice have important and necessary expertise to accurately administer regulatory regimes created through legislation.

Agencies, moreover, are politically unaccountable. No one elects patent examiners, of course, and the leader of the Patent Office, its Director, is only indirectly accountable to voters given that he or she is nominated by the President and confirmed by the Senate.[171] Agencies, too, are subject to capture. That is, they may make decisions consistent with the views of a small, motivated group of people rather than the views of the general public.[172] This

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[171] 35 U.S.C. § 3(a)(1) (2020) ("The powers and duties of the United States Patent and Trademark Office shall be vested in an Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (in this title referred to as the 'Director'), who shall be a citizen of the United States and who shall be appointed by the President, by and with the advice and consent of the Senate. The Director shall be a person who has a professional background and experience in patent or trademark law.").

[172] *See* Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1340 (2013) ("Capture describes situations where

political unaccountability theoretically could work either way in this context—the agency might ban patents on technology about which most would have no ethical or moral concern, or the agency might allow patents on technology most would deem morally or ethically improper. As a practical matter, however, in this context the more likely scenario is a U.S. Patent and Trademark Office responsive to patent applicants—those seeking patents. The dynamics of the operation of the U.S. Patent and Trademark Office and its relationship with the Federal Circuit as a reviewing court make it particularly vulnerable to over-patenting. [173] Therefore, in this context, it seems more likely that the Patent Office would ignore moral and ethical concerns with particular technologies and proceed to grant patents regardless of moral and ethical concerns.

In short, an agency approach—while better than a judicial approach—would not be the best approach to dealing with moral and ethical concerns related to patentability.

CONCLUSION

Reform proposals in the area of patent eligibility—in particular to the extent they would overrule the prohibition on patents encompassing human beings—should bring to the forefront of our collective consciousness the role of the patent system in encouraging use of technology some deem immoral or unethical. Patent law historically allowed judges to address moral and ethical concerns related to technology. Judges did so by determining on an ad hoc basis whether inventions were "injurious to the well-being . . . or sound morals of society" or, in other words, "mischievous or immoral."[174] While in some ways this historical approach resembles the modern contract doctrine of public policy, it is not the best approach. Indeed, given various considerations—certainty and predictability, clarity, expertise, and accountability chief among

organized interest groups successfully act to vindicate their goals through government policy at the expense of the public interest. For groups that are repeat players before specialized agencies, investments in long-term relationships can have substantial returns in terms of influence, raising capture concerns.").

[173] *See* Jonathan Masur, *Patent Inflation*, 121 YALE L.J. 470, 531 (2011) ("The PTO's interest in avoiding appeals and reversals, coupled with the Federal Circuit's asymmetric review of PTO decisions, are themselves enough to generate a surplus of invalid patents and an inflationary patent law.").

[174] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.).

them—judges and agencies should not be tasked with determining which technologies should not be patent eligible based on moral or ethical concerns. The best approach is to have Congress and the President address any moral or ethical concerns related to technology through legislation. And given that patent eligibility reform is currently a topic in Washington DC, the time to pass any relevant legislation is now. At a minimum, Congress should consider readopting as statutory text the Weldon Amendment, which would require amending 35 U.S.C. § 101 to state that "no patent may issue on a claim directed to or encompassing a human organism."