A Short History of the United States Patent and Trademark Office Position On Not Patenting People

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Patents Generally

Congress created the patent system in the United States under the Constitutional clause authorizing it to promote the progress of useful arts. The clause provides that Congress may grant an inventor a time limited “exclusive” right to the discovery. U.S. Const. Art. I, sec. 8, cl. 8. The implementing statutes establishing patents, in Title 35 of the United States Code, require that an inventor file an application for a patent and that the application be examined for compliance with various conditions. A statement of the kind of subject matter that can be patented is written into Section 101, which reads:

Inventions Patentable.

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.\(^1\) (Emphasis added).

Patent Eligible Subject Matter

The subject matter categories listed in Sec. 101 have been essentially the same since 1790, as the word “process” replaced the word “art” in the Patent Act of 1952. Most courts construing the categories, or statutory classes of subject matter, explain their breadth as accommodating unanticipated technologies, and say they are to be given a liberal interpretation. In its Chakrabarty decision, for example, the Supreme Court wrote that the categories are “expansive,” and the word “any” indicates they should be given a wide scope.\(^2\)

The Court itself, however, has long held that although the statutory classes of subject matter are broad, some things are not eligible for patenting. Laws of nature, natural phenomena


and abstract ideas have long been excluded from coverage. In practice, the United States Patent and Trademark Office (PTO) occasionally refused to issue patents on what it viewed as natural phenomena, but has been reversed in some cases by its reviewing court. Two relatively recent examples are of interest.

In the first example, when presented with claims to prostaglandin compounds isolated from human prostate glands, the PTO refused to issue a patent on the ground that the claimed compounds were products of nature and therefore not eligible for patenting. The court reversed, explaining that a purified composition of matter, such as a chemical compound isolated from nature, is a human-made invention eligible for patenting, not an ineligible “product of nature.” That is, the purified prostaglandin isolated from human prostate glands is not naturally occurring because the pure form does not exist in nature. Thus, a compound such as aspirin that occurs in nature can be eligible for patenting if it is claimed in a non-naturally occurring form, e.g., purified aspirin. Whether subject matter that meets the eligibility test is otherwise patentable depends on the further conditions and requirements in Title 35.

The second example is more pertinent to today’s subject. Dr. Ananda Chakrabarty developed a new kind of bacterium that could digest oil, and claimed the bacterium in a patent application. The PTO rejected the claims on the ground that living things were not eligible for patenting, but the PTO’s reviewing court reversed, and the government petitioned for certiorari. The Supreme Court granted the government’s petition for certiorari and affirmed the lower court. The Court explained that “the relevant distinction [for purposes of patent eligibility] was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.” While holding that microorganisms were patent eligible subject matter, the Court was undoubtedly aware of the lower court’s view that “we are not dealing with [patent eligibility of] all living things, including man…”

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3 Id.; see also, Diamond v. Diehr, 450 U.S. 175, 185 (1981); Le Roy v. Tatham, 55 U.S. 156 (1852); Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498 (1874); O’Reilly v. Morse, 56 U.S. 62 (1853).


5 Diehr, 450 U.S. at 188.

6 Chakrabarty, 447 U.S. at 312.

7 In re Bergy, 596 F.2d 952, 976 (CCPA 1979), aff’d sub nom., Diamond v. Chakrabarty, 447 U.S. 303 (1980).
The PTO Holds That A Patent Cannot Claim A Human Being

Following the Court’s *Chakrabarty* guidance, the PTO determined that living materials are eligible for patenting when the living material is a “human-made invention.”8 Thus, isolated cell lines, isolated tissues, animals and plants, may be eligible for patenting under Sec. 101, and such claims would usually be examined for compliance with Title 35. However, the PTO concluded that human beings were not within the scope of Sec. 101, and published a Notice in the PTO’s Official Gazette advising the public of its conclusion.9 The Notice advised that “A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101.”10

Shortly after the PTO published its notice of intent not to patent human beings in April, 1987, it informed Congress of the decision by direct testimony. A subcommittee of the Committee on the Judiciary, House of Representatives, held hearings11 on “Patents and the Constitution: Transgenic Animals” during 1987. On June 11, 1987, the PTO’s Assistant Commissioner testified before the subcommittee that a claim including a human being within its scope “will not be considered to be patentable subject matter.”12

The PTO provides guidance to its patent examiners in the Manual of Patent Examining Procedure (MPEP) (8th Ed., Rev. 5, Aug. 2006). The section on patent eligible subject matter, Sec. 2105, “Patentable Subject Matter–Living Subject Matter,” includes this instruction:

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12 Id. at 5, 19-20 and 22.
During examination, the PTO examiner must construe the inventor’s claims as broadly as reasonable in view of the specification. In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Inventors claiming an animal invention in broad terms construed to cover a human being can avoid that kind of rejection by writing the term “non-human” into the claim to exclude a human from the coverage.13

Beginning in 2004, appropriation bills for the Department of Commerce (the PTO is an agency in the Department of Commerce) have included the provision:

None of the funds appropriated or otherwise made available under this act may be used to issue patents on claims directed to or encompassing a human organism.

According to remarks by the funding provision’s original author, Hon. Representative Dave Weldon of Florida, the provision reflects the same scope as the PTO’s MPEP instruction.14 In his remarks, Mr. Weldon read excerpts from the PTO’s 1987 Official Gazette Notice and the above sentence from the MPEP Sec. 2105 into the record, and commented that “the USPTO clearly distinguishes between organisms that are nonhuman and therefore patentable and those organisms that are human and therefore not patentable subject matter.” In the same remarks, Rep. Weldon explained that the funding limitation had no effect on issuing patents with claims to stem cell lines, procedures for creating human embryos, prosthetic devices, or drugs or products that might be used in or for human beings. In his view, claims to a chimera, for example, or other new claims, would be addressed by the PTO on a case-by-case basis. In earlier remarks, the Congressman indicated that the amendment has no bearing on stem cell research or patenting genes.15

To date, no court has reviewed the PTO’s understanding that a claim encompassing a human being at any stage of development is not patent-eligible. Several legal arguments may be used to exclude the patentability of claims directed to human beings.

As noted earlier, Sec. 101 of the Patent Act contains the requirements that a patentable invention be “new and useful” and fall within one of the statutory categories: process, machine, manufacture, or composition of matter. Canons of statutory construction favor the ordinary meaning of terms, and the ordinary meanings of the terms “machine,” “manufacture,” or “composition of matter” do not include a human being. Conferring exclusive rights over a

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human being would also raise Constitutional questions, and canons of statutory construction counsel the interpretation that avoids Constitutional issues. In addition, some courts have interpreted the utility requirement to exclude inventions deemed to be “injurious to the well being, good public policy, or good morals of society.”

PTO actions on patent applications must have basis under the statutes, as interpreted by the federal courts. The PTO does not have substantive rulemaking authority. Legal challenges to the PTO’s interpretations of patent eligible statutory subject matter under Sec. 101 are typically via review of a decision by the PTO’s Board of Patent Appeals and Interferences. A challenge to the non-patentability of human beings would be a case of first impression.

Conclusion

The availability of patent protection for newly arising technologies has been vital to the development and commercialization of innovations in biotechnology. The U.S. biotechnology industry has more than doubled in size since 1993, with revenues increasing from $8 billion in 1993 to $22.3 billion in 2000. Experience in the biotechnology industry has been that its patents are widely licensed and they are considered to be some of the most profitable patents. The profitability is largely due to their widespread use in the advancement of biological research. These advances would not have been possible without broad patent eligibility and the balance the patent system strikes between generating intellectual property and distributing those ideas.

Despite the benefits afforded by technological advancements, some technologies are raising profound legal and ethical issues. However, restrictions that would limit the patent eligibility of biotechnological inventions must be carefully crafted to avoid unintended consequences, such as a general negative effect on biotechnology advances.

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17 In Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), the court held that 35 USC § 6(a) [see current 35 USC 2(a)(2)] authorized the Director to promulgate procedural rules for conducting PTO proceedings, but not substantive patenting regulations.