The human use of humanoid beings: chimeras and patent law

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As biotechnology advances, the day may soon come for the creation of a self-aware, human-nonhuman chimera. The USPTO has ruled on whether a patent may issue on such an organism, but Congress must still legislate a dividing line between human and non-human patentable subject matter.

In 1998, Stuart Newman and Jeremy Rifkin filed patent application 08/993,563 (Newman-Rifkin I), for combining human and nonhuman embryonic cells to develop a "humanoid" chimera. The claims were broadly written and encompassed embryos and developed organisms resulting from different human-animal combinations. The proportions of human to nonhuman cells were left open-ended in the claims. The objective of patent prosecution for the applicants was any outcome that would *prevent* the creation of human-nonhuman chimeras, either by their enforcement of an issued patent, or by triggering a United States Patent and Trademark Office (USPTO) policy banning the patentability of human-nonhuman chimeras.

After issuing a rejection, the USPTO issued a media advisory and cited a seldom-used morality interpretation of the utility requirement: "[I]nventions 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. …Congress has not specifically addressed the question of whether the terms machine, manufacture or composition of matter, as they are used in the patent statutes include a human being. Similarly, the court in *Chakrabarty* did not address whether human beings are patentable subject matter. …[W]hen there are paramount patent issues of first impression, in the absence of clear legislative intent and guidance from the courts, it is incumbent on the office to proceed cautiously"[1].

The USPTO's position was consistent with a 1987 statement that "a claim directed to or including within its scope a human being will not be considered to be patentable subject matter"[2]. This statement was codified in Section 2105 of the Manual of Patent Examining Procedure (MPEP): "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 USC §101 must be made indicating that the claimed invention is directed to nonstatutory subject matter."

In March 1999, Newman-Rifkin I received a final rejection[3] that avoided resorting to the morality aspects of the utility requirement. The application was rejected because of its failure to provide adequate enablement, disclose a best mode, overcome the nonobviousness requirement and claim statutory subject matter.

Since human materials are not mentioned in the Patent Act, rejection because of nonpatentable subject matter was based on an implied exclusion of human materials from statutory subject matter, the examiner stating, "the PTO believes that Congress did not intend 35 USC to include the patenting of human beings. Since applicant's claimed invention embraces a human being, it is not considered to be patentable subject matter."

Newman-Rifkin I also failed because of obviousness. The PTO determined that claimed techniques in the application were not sufficiently distinguished from the prior art to allow claims for the creation of human-nonhuman chimeras. Finally, the application did not include an enabling detailed description, including a best mode for practicing the invention.

In 2002, Newman and Rifkin refiled their application (Newman-Rifkin II). It was again rejected, with the USPTO pointing out

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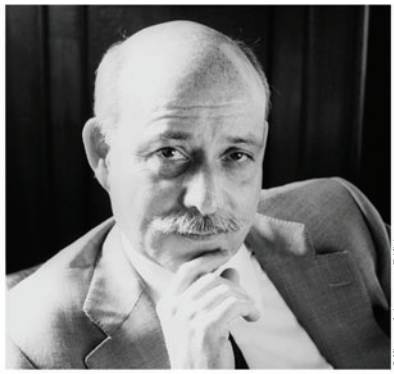

Office of Jeremy Rifkin

Professor Stuart A. Newman (left) of New York Medical College, who was denied a patent for human-animal chimeras, and the application's funder Jeremy Rifkin, president of the Washington, DC-based Foundation on Economic Trends and a noted critic of the biotechnology industry.

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that although 35 USC §101 did not explicitly restrict the patentability of humans, the agency's policy of denying such patents was implicitly supported by the statute. Newman and Rifkin let their six-month appeals period lapse in 2005, announcing that a bar to the patenting of human-nonhuman chimeras had been established. However, patentability is determined on a case-by-case basis, and no legal precedent was ever established. Moreover, to the extent that Newman-Rifkin I and II were rejected for technical shortcomings, these may be overcome in future applications that provide enabling disclosures, exemplary embodiments and a best mode.

A need for law

The issues raised by the Newman-Rifkin applications require legislation establishing the determinants of what is 'human' in a way that respects human rights and protects the financial incentives of the biotech industry in creating 'human' products of value. Such legislation should also maintain consistency and continuity with prior patent case law and statutory law, restrict patenting of those fundamental human characteristics that comprise sentience, be workable and predictable, and finally, be flexible enough to anticipate future developments in biotech.

Notwithstanding MPEP §2105, the USPTO has allowed patents for human cell lines, microorganisms and cell lines transfected with a limited number of human genes, and multicellular transgenic animals containing one or a few human genes. The challenge is to develop a policy that preserves these patentability decisions while preventing unethical exploitation of human material. The key lies in limiting the transfer of human characteristics to avoid endowing another species with human attributes or endowing members of *Homo sapiens* with super-human attributes, without restricting human benefits derived from the act of transference.

Chimeras and the prohibition of slavery

Diamond v. Chakrabarty removed the question of whether living organisms are legitimate subject matter. As long as the organism is not naturally occurring and results from the intervention of man, the *Chakrabarty* court ruled that it could be patented as either an article of manufacture or a composition of matter[4]. In rejecting the Newman-Rifkin applications, the USPTO circumvented *Chakrabarty* by concluding that Congress could not have intended humans to be included as subject matter under 35 USC. This conclusion was based on an interpretation of the 13th Amendment's prohibition of slavery as forbidding the patenting of human beings.

The practice in human systems of a chimera method already established in other species would not be protected as being nonobvious. This may be sufficient to bar all patent applications for the creation and ownership of human-nonhuman chimeras, where the creation process is known.

It is not apparent that the 13th Amendment would forbid patenting the process of producing a human being, although it would likely forbid patenting the human being as a product. The reach of the 13th Amendment into 35 USC §101, and whether statutory subject matter includes human-nonhuman chimeras, turns on the illusive definition of what is human, a subject the USPTO acknowledges is outside the scope of its jurisdiction. Currently, there is no statutory foundation for excluding partly human inventions on the basis of subject matter.

Utility

The USPTO's utility guidelines indicate that an application will be rejected on the basis of utility defects only if "it is not apparent why the applicant believes the invention to be useful" or "where an assertion of specific utility for the invention made by the applicant is not credible"[5]. If a case for utility is made, the USPTO has the burden of demonstrating that there is no reasonable basis for that conclusion.

Under the guidelines, the utility for most biotech inventions, including human materials, should not pose a serious challenge. Most are designed with a commercially marketable product in mind. Still, the USPTO may invoke an additional aspect of the utility requirement—the morality doctrine—to reject a patent application.

The morality doctrine originated as a part of the utility requirement in *Lowell v. Lowell*[6], which concluded that the word 'useful' was incorporated into the Patent Act "in contradistinction to mischievous or immoral," and that examples of immoral inventions included "a new invention to poison people…"[7].

The morality doctrine has been applied and interpreted erratically. It was used to prohibit the patenting of gaming machines[8], a position that has been overturned as societal concepts of morality changed[9]. Some courts have applied a balancing test between potential beneficial and immoral uses. As an example, whereas handguns may be injurious and place society at risk, they also have uses that override these risks[10].

Accordingly, the legal status of the morality doctrine is in limbo. Because 35 USC does not require a moral balancing, and because social concepts of morality are in a continuous flux, courts have been appropriately reluctant to use the morality doctrine as the sole basis for rejecting patent applications.

Obviousness

In rejecting the Newman-Rifkin applications, the USPTO relied upon the requirement that an invention must be nonobvious to be patentable, concluding that because the chimera creation processes had been carried out on other mammals, use of the same process in humans was an obvious extension of known technologies. The decision illustrates a dilemma in applying the nonobviousness requirement to biotech. Traditionally, courts have rejected a patent if the claim is "obvious to try with a reasonable expectation of success"[11]. However, transgenic and transfection methods are becoming increasingly commonplace and hence obvious. Once a gene and its product are identified, expression of that gene in alternative hosts is an obvious extension of that knowledge.

Recognizing this shortcoming of the traditional rule as applied to biotech, the Biotechnology Process Patent Act[12] amended the obviousness requirement by mandating that a biotechnological process should be considered nonobvious if it uses or results in a composition of matter that is new and unobvious. "Biotechnology" was defined to include only (i) genetic alterations of an organism, (ii) cell fusions resulting in cell lines or (iii) use of products created by processes defined by either (i) or (ii)[13].

Thus, Congress preserved novel uses of human genetic material through known means, but excluded the types of cellular combinations proposed in the Newman-Rifkin applications from its list of protected technologies. Therefore, practice in human systems of a chimera method already established in other species would not be protected by the statute as being nonobvious. This may be sufficient to bar all patent applications for the creation and ownership of human-nonhuman chimeras, where the creation process is known.

Novelty

Chakrabarty gave the novelty requirement meaning with respect to living organisms in requiring that a claim "is not to a hitherto unknown natural phenomenon, but to a

non-naturally occurring manufacture or composition of matter—a product of human ingenuity"[4]. Accordingly, the novelty requirement may only prevent approval of a patent if the disputed human composition has already been produced.

Detailed description

The disclosure requirement is also unlikely to prevent the patentability of human materials. 35 USC §112 requires that methods be sufficiently described such that one skilled in the art could make and use the invention, and that the best mode be identified if known. The failure of the Newman-Rifkin applications to make sufficient disclosure rested in part on the strict controls on human embryo research already in place. The same failure is less likely to arise in situations where experimentation using human cells or genetic material has been approved or experimental evidence is otherwise available. In summary, current patent law under 35 USC is ill equipped to deal with the patenting of human materials.

Legislative and administrative responses

In Congress, bills have been proposed to limit or suspend the patenting of any genetically engineered animals[14]. To date these have never passed, demonstrating a reluctance to establish a *per se* exclusion of all human materials as patentable subject matter. Several bills have also been introduced to ban human cloning or to ban federal funding of human cloning[15] that have yet to pass. One possible roadblock facing Congress in prohibiting human cloning and the use of human embryo tissue is an inability to find legislative authority and a Constitutional basis for prohibiting such work. Congressional power may be limited to legislative acts restricting federal research funding and the commercialization and patenting of biotech.

In 1995, President Bill Clinton established the National Bioethics Advisory Committee (NBAC) to examine the ethical implications of biotech[16]. The NBAC has since advised Presidents Clinton and George W. Bush on human cloning and research involving human embryonic cells and tissues. In response, a moratorium on federally funded research in these areas was established[17].

Recommendations

First, the USPTO should adopt a rebuttable presumption against patents on genes or cells known to endow sentience or to affect human intellect, emotion or behavior. The applicant should have the burden of disclosing the known effects of any human genes, cells or their products claimed in an application.

The traits that define humanity have been subject to philosophical debate for millennia. Some have argued that it is sentience, that is, self-awareness—a realization that man is unique as a species—that defines us as human[18]. Most theorists agree that humanity is defined not by physical characteristics but by intellectual, emotional and behavioral attributes[19].

Although many genes have now been identified that may affect intellect and behavior, our development into unique individuals involves a multitude of genetic and environmental influences. Because of poor understanding of how humanness develops, caution must be exercised in issuing human cell and gene transfer patents. Incorporation of human cells or genes known to influence traits of intellect, behavior or emotion should be excluded as patentable subject matter.

The presumption against using such material in a chimera or other transgenic system should be rebuttable. An applicant should be given the opportunity to either demonstrate no significant risk of imparting human intellect, emotion or behavior, or demonstrate that the societal benefits of the patent outweigh the potential risks of transferring human character.

Second, the USPTO should refuse to issue patents involving genes with unknown functions. The primary concern regarding the patenting of animals expressing human genes is that human 'character' or 'essence' will be incorporated into that animal. Although human character is an elusive concept, it cannot be controlled without first knowing the function of human genes transferred into animals. Until recently, this has been of little concern, because only individual genes with known functions have been introduced into animals. However, with recent developments in chromosome transfer techniques, thousands of genes may be introduced into a recipient with a single chromosome. Chromosome transfer may be an attractive method of introducing genes because in some instances related genes are expressed on the same chromosome, and important regulatory sequences may lie distant from the gene itself[20].

However, although the functions of certain genes may be known, the functions of other genes on a chromosome may be unknown. Until the functions of all of the genes on a given chromosome are identified, there is no way of knowing what attributes may be transferred along with the genes of known function. Therefore, patents involving transfer of genes with unknown function should also be considered illegitimate subject matter. The onus should be on the applicant to describe the function of all human materials transferred into a host organism.

These proposals provide guidelines to ban 'humanization' of animals without imposing undue burdens on the biotech industry. Congress and the executive branch retain discretion to limit federal funding for research in these areas, and decisions should be decided upon social policy, rather than patent ownership rights.

1. US Patent and Trademark Office. *Facts on patenting life forms having a relationship to humans.* Media Advisory No. 98-6 (April 1, 1998) <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>.
2. Commissioner of Patents and Trademarks. Policy statement on patentability of animals. 1077 *Off. Gaz. Pat. Office* 24 (1987).
3. PTO disallows bio-patent application as crossing line to 'embrace' humans. *Pat. Trademark & Copyright L. Daily* D2 (June 21, 1999).
4. 447 US at 309.
5. PTO Examination Guidelines on Utility. 50 *Pat. Trademark & Copyright J.* 295 (1995).
6. 15 F. Cas. 1018.
7. 15 F. Cas. 1018 at 1019.
8. See, e.g., *Meyer v. Buckley Mfg. Co.,* 15 F. Supp. 640 (Ill. 1936).
9. See *Ex parte Murphy,* 200 USPQ 801 (1977).
10. See *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903).
11. *In re Farrell*, 853 F.2d 894 (Fed. Cir. 1988).
12. Publ. L. 104-41, (1995), 109 Stat. 351, 1 (1995), 1996 U.S.C.C.A.N. 404-1 (1995) (statement of the President of the United States).
13. 35 USC 103(b).
14. Animal and gene patent moratorium bill is reintroduced. 45 *Pat. Trademark & Copyright J.* 347 (Feb. 25, 1993).
15. See, e.g., HR 922, 105th Cong. (1998); HR 923, 105th Cong. (1998); HR 2326, 106th Cong. (1999).
16. Exec. Order 12,975 3 CFR 409 (1996).
17. See, e.g., Wright. Cloning human beings: Report and recommendations of the National Bioethics Advisory Commission. 38 *Jurimetrics J.* 3 (1999).
18. Rivard, M.D. Toward a general theory of constitutional personhood: a theory of constitutional personhood for transgenic humanoid species. 39 *UCLA L. Rev.* 1425, 1487 (1992).
19. See, e.g., Fletcher, J. Humanness in humanhood: Essays in biomedical ethics, in *Bioethics: Health Care Law and Ethics,* edn. 3 (eds. Furrow, B.R. *et al.*). (West Group, Eagan, MN, 1997).
20. See, e.g., Hames, B.D. & Glover, D.M. *Molecular Immunology,* edn.2, 191 (Oxford University Press, New York, 1996).