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The Patentability of Human-Animal Chimeras

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In ancient Greek mythology, the chimera was a fire-breathing monster with a lion's head, a goat's body, and a serpent's tail. While most people no longer fear the ancient chimera, recent advances in biotechnology have created odd permutations of species that are no less disturbing. In the mid-1980s, scientists succeeded in producing chimeras of different mammal species, and now someone has filed a patent application for chimeras made from animals and humans.

On December 18, 1997, Dr. Stuart Newman, a cellular biologist at New York Medical College, and Jeremy Rifkin, a prominent opponent of biotechnology, filed a patent application with the United States Patent and Trademark Office (PTO) that covers the production of human-animal chimeras that could be up to 50% human. Newman and Rifkin hope that by obtaining this patent they can prevent other scientists from creating human-animal chimeras for at least two decades, presumably buying them sufficient time to convince the American populace to support a ban on such processes outright. In the event they do not receive the patent, they hope that the PTO will choose to reject their application on moral grounds and alter PTO procedures to prohibit the patenting of ethically questionable practices, as has been done in the European Community (EC). No matter what the PTO decides, Rifkin and Newman will have sparked a debate that should help clarify the rules regarding the patenting of life forms in the United States.

The chimera patent application is merely one of 13,000 biotechnology-related patent applications received by the PTO in the first half of 1998.


4. See Weiss, supra note 2, at A12.
5. See id.
6. See id.
7. See id.
8. See Langton, supra note 3, at 01.
That was one-third more than the PTO received in all of 1997. These applications add considerably to the litany of biotechnology inventions that have already been patented, including more than 1,800 genes and eighty-five genetically-engineered mice, three rats, three rabbits, a sheep, a bird, a fish, a pig, a guinea pig, an abalone, and a cow. Although these numbers suggest that advances in biotechnology are occurring at a rapid pace, there are surprisingly few guidelines governing their patentability.

Essentially, there are two legal grounds on which the PTO potentially could choose to reject the human-animal chimera patent application under current law. First, while the PTO now considers life forms in general to be patentable subject matter under 35 U.S.C. § 101, the PTO has interpreted the Thirteenth Amendment, which bans human slavery, as prohibiting the patenting of human beings. As such, the PTO could decide that human-animal chimeras qualify as human and, thus, are barred from patentability by the Thirteenth Amendment. Second, the PTO may apply a rarely invoked doctrine and decide that human-animal chimeras lack moral utility and are, therefore, not patentable.

This Note describes the legal basis for these two standards as they relate to biotechnology and explores how the human-animal chimera patent application might be evaluated under each standard. It determines that the Rifkin-Newman application probably passes muster under either test and suggests that the existing patent laws are not appropriately designed to deal with the moral issues being raised by the rapidly developing biotechnology industry. It concludes that biotechnology should be regulated, if at

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9. See id.
11. For the purposes of this Note, I am assuming that the Rifkin-Newman patent application is technically sound and will fulfill the traditional requirements of novelty, utility, nonobviousness, and enablement. Several commentators have speculated that the application likely will not fulfill at least one of these requirements. See, e.g., Renee Deger, Activist Puts PTO on Political Hot Seat, RECORDER, May 6, 1998, at News 1 (noting that without clinical data, Rifkin and Newman will not be able to prove enablement); Weiss, supra note 2, at A12 (arguing that the Rifkin-Newman application will be unable to meet the high standard of proof of feasibility traditionally imposed on unusual applications).
13. Indeed, the PTO has suggested it may take this approach. See Bruce Lehman, Facts on Patenting of Life Forms Having a Relationship to Humans (last modified Apr. 1, 1998) <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>.
all, by Congress directly, rather than through any manipulation of the patent laws by the PTO or the courts.

I. THE SCIENCE OF PRODUCING CHIMERAS

The exact nature of a chimera can be explained most readily by comparing it to a more familiar product of biotechnology—the hybrid. A hybrid represents a genetic cross between a male of one species and a female of another. As such, every cell in a hybrid animal contains one set of chromosomes from one species and one set from another. In a chimera, the genetic material of the two originating species does not mix. Rather, a given chimera is composed of some cells from one species and some cells from the other. Thus, the brain of a human-chimpanzee chimera would contain some human brain cells and some chimpanzee brains cells, but none of the brain cells would contain both human and chimpanzee genetic material.

No scientist has ever actually created a human-animal chimera, but molecular biologists have possessed the ability to create animal-animal chimeras for more than a decade. In the mid-1980s, scientists in the United Kingdom announced the creation of a “geep,” an animal that was part goat and part sheep. While the actual techniques have since been refined, the fundamental science remains the same. To create the “geep,” scientists allowed a pair of sheep and a pair of goats to mate naturally.

15. This holds true for all of an animal’s cells except its gametes, or sex cells, because these normally contain only one set of chromosomes. See, e.g., NORAH RUDIN, DICTIONARY OF MODERN BIOLOGY 153 (1997).
16. For example, a mule, which is a cross between a donkey and a horse, possesses one set of chromosomes from the donkey parent and one set from the horse parent in each of its body cells.
17. In this way, the cells always remain segregated by species. See Greene, supra note 14, at 14WC-3.
18. Because mammal-mammal chimeras have already been produced, it is questionable whether the creation of a human-animal chimera will be considered novel or nonobvious over the prior art. But as stated supra note 11, I have assumed for the purposes of this Note that the application will satisfy the traditional requirements. Indeed, because the Rifkin-Newman patent application describes techniques other than those used to produce mammal-mammal chimeras in the past, it may very well be considered novel and nonobvious.
20. See Meinecke-Tillman, supra note 19, at 637.
The resulting embryos were collected from the pregnant females several days later, at around the 8-cell stage of development. The scientists placed the two embryos together in a petri dish and manipulated them, such that the two embryos began to cooperate with each other, growing and dividing as one embryo. The scientists then surgically removed an embryo from another pregnant sheep and replaced it with the developing chimeric embryo. The sheep gave birth to the "geep" several months later.

The Rifkin-Newman patent application covers three procedures for producing human-animal chimeras, one of which is analogous to the procedure used to create the "geep." The second technique involves injecting only a small number of cells, called embryonic stem (ES) cells, from one embryo into a second embryo of a different species. The third procedure is the most complex. In this approach, ES cells at an early stage of development (known as 'early passage' ES cells) are introduced into an embryo that has been tampered with so that it cannot advance on its own beyond an early stage of development. Even though this embryo could not develop on its own, it acts somewhat like a 'host,' allowing the ES cells to develop into a viable embryo that also possesses some cells derived from the 'host' embryo.

Even though Rifkin and Newman have never created a human-animal chimera, scientists believe they could successfully produce such a creature if they combined a human embryo with that of an animal closely related to human beings. Monkeys, for example, are even more closely related to humans than goats are to sheep, so presumably scientists could create a human-monkey chimera with minimal difficulty. The Rifkin-Newman

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21. See id.
22. See id.
23. See id.
24. See id. The scientists were also successful in using female goats as the surrogate mothers. See id. at 635.
25. See David Dickson, Legal Fight Looms Over Patent Bid on Human/Animal Chimaeras, 392 NATURE 423, 424 (1998). Because the Rifkin-Newman patent application has not been published, all information about the application is derived from secondary sources.
26. See id.
27. See id.
28. See id.
29. See Weiss, supra note 2, at A12.
30. See id.
II. LEGAL BASIS FOR LIFE FORMS AS PATENTABLE SUBJECT MATTER

Currently, there are few restrictions on the patenting of life forms and human tissues in the United States. The first United States patent on a living organism was actually issued in 1873 to Louis Pasteur for a purified form of yeast. That patent notwithstanding, however, the PTO initially rejected patent applications for genetically-engineered organisms in the 1970s on the basis that such organisms were products of nature, and, therefore, not patentable subject matter.

The Supreme Court rejected this view, however, in its 1980 landmark decision, *Diamond v. Chakrabarty*. In *Chakrabarty*, a microbiologist had applied for a patent on a bacterium into which he had inserted several plasmids that enabled the bacterium to digest crude oil. Chakrabarty’s application consisted of three kinds of claims: on the actual method of producing the bacteria; on the process of using the bacteria to digest oil spills; and on the bacteria themselves. Initially, the PTO approved the first two sets of claims, but denied the claims for the bacteria on the grounds that living things were not patentable subject matter. The Supreme Court reversed, holding that Chakrabarty’s bacteria qualified as patentable subject matter, either as a “manufacture” or “composition of matter” within the meaning of § 101. The Court reasoned that Congress, in passing § 101, did not distinguish between inanimate objects and living things and, in fact, intended to allow the patenting of “anything under the sun made by man.”

31. See id.
33. See id.
34. 447 U.S. 303 (1980).
35. See id. at 305. As footnote one of the opinion explains, a plasmid is a strand of genetic material that exists physically separate from the chromosomes of a cell.
36. See id. at 305-06.
37. See id. at 306.
38. See id. at 309-10.
Five years later, in *Ex parte Hibberd*, the Board of Patent Appeals and Interferences extended the rule laid down in *Charkrabarty* by holding that nonnaturally occurring, manmade, multicellular plants were patentable subject matter under § 101. In 1987, the Board of Patent Appeals in *Ex parte Allen* held that multicellular animals could also be patented under the rule set out in *Charkrabarty*, though the particular patent application at issue in *Allen* was rejected on unrelated grounds. To dispel any doubt on the subject, the PTO issued a statement several days after the *Allen* decision, announcing that it now considered nonnaturally occurring, nonhuman, multicellular organisms, including animals, to be patentable subject matter. The PTO excluded humans from the new rule on the grounds that “the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.” The Commissioner did not specify the precise language in the Constitution that prohibits patenting human beings, but it has been assumed that he was referring to the Thirteenth Amendment’s ban on human slavery.

One year later, the PTO issued the first animal patent for the famous Harvard Onco-mouse, which contains a human gene that renders it susceptible to breast cancer. The PTO continues to issue animal patents on a regular basis today. In addition to allowing patents on animals, the PTO regularly allows patents on cell lines, including lines of human cells.

41. See id. at 447.
42. See 2 U.S.P.Q. 2d 1425 (Bd. Pat. App. & Interf. 1987), aff’d, 846 F.2d 77 (Fed. Cir. 1988). Despite holding that multicellular animals were patentable, the Board rejected the *Allen* application because a previous publication that explained how to induce polyploidy to increase growth in oysters had rendered the patent application obvious. See id. at 1427.
44. Id.
47. See Schmickle, supra note 10, at A7.
III. DOES THE THIRTEENTH AMENDMENT BAR THE PATENTING OF HUMAN-ANIMAL CHIMERAS?

The Thirteenth Amendment does not restrict the patenting of the process claims in the Rifkin-Newman patent application. Essentially, the PTO has interpreted the Thirteenth Amendment as a specific subject matter limitation, and the PTO does not generally employ this kind of limitation to deny a patent on a process that produces an unpatentable product.50 As such, even in *Diamond v. Charkrabarty*, the patent examiner originally allowed Charkrabarty’s claims on the method of producing the bacteria while rejecting his claims on the bacteria themselves.51 In the case of the Rifkin-Newman patent, then, the only question is whether the human-animal chimeras themselves are patentable under the Thirteenth Amendment.

The PTO’s policy of granting patents on human tissues and on genetically-engineered animals, some of which contain human genes, while abstaining from granting patents on humans outright, has left the question of the patentability of human-animal chimeras largely unanswered. The outcome depends on the type of rule adopted by the court to determine humanity under the Thirteenth Amendment.52 Currently, there is no case law discussing precisely how much human genetic material a creature must possess before it qualifies as human.53 Certainly, possessing just one or even a handful of human genes does not make an animal human. In fact, patents already exist on animals, like the Harvard Onco-mouse, that possess some human genes. At the high end of the spectrum, transplant patients who receive animal organs are surely still considered human. Indeed, it is probably safe to say that any organism composed of over 50% human genetic material would be considered human. From a common-

49. One now-infamous example of a patent on a human cell line is that obtained by Dr. David W. Golde and Dr. Shirley G. Quan of the University of California at Los Angeles for a cell line made from T-lymphocytes, which they isolated from John Moore while treating him for hairy-cell leukemia. See Moore v. Regents of the Univ. of Cal., 51 Cal.3d 120 (1990) (en banc), cert. denied, 499 U.S. 936 (1991).
50. See Morin, supra note 32, at 153.
52. Such a rule could have implications in other high-technology industries. For example, if cyborgs, the part-human, part-robotic entities so popular in science fiction, ever become a reality, they might be considered human under a broad interpretation of the Thirteenth Amendment.
53. See Weiss, supra note 2, at A12 (noting that Congress failed in its attempt to pass a law restricting patents on humans in 1989, in part because of the difficulty in defining “human”).
sense standpoint, this standard seems reasonable enough, but it is somewhat simplistic and artificial. Could an organism whose genes were 49% human in origin correctly be considered an animal for purposes of patentability? In any case, the Rifkin-Newman application was drafted to meet this standard — it covers only those human-animal chimeras composed of less than 50% human genetic material.

Even chimeras consisting of much less than 50% human genetic material might be considered human by many people. Because chimeras possess some cells that are entirely human in origin, it might be possible to create a chimera with the body and outward appearance of a chimpanzee, for example, but with the brain and nervous system of a human being. Because the total number of human cells in such a creature would be low, it would likely be patentable under a "less than 50% human" standard, yet many people would consider such a creature to be human.

Perhaps the appropriate question to ask is whether or not a chimera would consider itself to be human. If a creature possessed the ability to reason in this fashion (commonly known as self-awareness), the PTO likely would find it to be human under the Thirteenth Amendment. Still, such a standard only leaves open the question of how to determine if a chimera would, in fact, be self-aware before any chimeras have actually been created. In any case, Rifkin and Newman likely could amend their patent application to include in its scope only those chimeras that would not be self-aware.

At best, the Thirteenth Amendment is an unwieldy tool for regulating biotechnology inventions like the human-animal chimera. While it might be applied to biotechnology products, it does not restrict process claims at all. In addition, the Thirteenth Amendment cannot effectively and consistently be applied even to biotechnology product claims until the courts adopt a workable definition of "human being." Assuming arguendo that the courts develop a suitable definition of what it means to be human, there is little doubt that Rifkin and Newman could amend their patent application to conform to any such definition. Thus, while the Thirteenth Amendment may prohibit the patenting of a limited number of highly controversial technologies, it probably could not be used to reject the patent application for human-animal chimeras or applications for other products of biotechnology that are not strictly human in nature.

54. Indeed, this standard is analogous to the burden of proof in civil cases, under which a plaintiff must prove that, more likely than not, the defendant is liable. Similarly, if the government wanted to deny a particular patent, its burden would be to show that the invention in question is "more human than not."

55. See Langton, supra note 3, at 01.
IV. LEGAL BASIS FOR A MORAL UTILITY REQUIREMENT

Even if the Rifkin-Newman patent application is deemed not to violate the Thirteenth Amendment's limitation on patentable subject matter, the application may be denied for lack of moral utility. In fact, in an advisory opinion issued on April 2, 1998, PTO Commissioner Lehman stated that he will likely refuse to issue a patent to Rifkin and Newman for creating human-animal chimeras because producing such creatures would be immoral. In so doing, the Commissioner relied on Lowell v. Lewis, an 1817 case decided by Justice Joseph Story.

In Lowell, Justice Story found that an invention relating to the construction of water pumps satisfied the utility requirement. Story announced that "[a]ll 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." As examples of immoral inventions, Justice Story cited "a new invention to poison people, or to promote debauchery, or to facilitate private assassination."

The courts have applied Justice Story's approach to utility in two specific types of cases. The first involves inventions the only use of which is to deceive or commit fraud. Clearly, this line of cases is not relevant to biotechnology inventions like the chimera. The second line of cases involves gambling devices and other inventions historically frowned upon by society at large.

The earliest cases, dating around the late-1800s, held that an invention lacked moral utility if it could be used for at least one immoral purpose, regardless of the existence of other beneficial uses for the invention. It became apparent early on that this view excluded too many common in-

56. See Lehman, supra note 13.
57. 15 F. Cas. 1018 (D. Mass. 1817) (No. 8568).
58. See id.
59. Id. at 1019.
60. Id.
61. See, e.g., Rickard v. Du Bon, 103 F. 868 (2d Cir. 1900) (holding that a process for artificially producing spots on tobacco leaves used to wrap cigars, such that the leaves resembled those used to wrap high-quality cigars, was unpatentable for lack of utility).
63. See, e.g., Reliance Novelty v. Dworzek, 80 F. 902 (N.D. Cal. 1897) (invalidating a patent on a design for the cover of slot machines, despite the patent holder's contentions that his design could be used to cover other machines, like kinescopes).
ventions, like weapons, from patentability. As such, it quickly evolved into a broader test, such that an invention met the moral utility requirement if it had at least one beneficial purpose. For instance, in Fuller v. Berger, the Seventh Circuit considered the validity of a patent on a device that could detect bogus coins inserted into a vending machine. The court held that the device was patentable because it could be used in many different kinds of vending machines, even though its primary use was in gambling machines. Even under this somewhat relaxed standard, patents on inventions that could only be used for gambling were routinely invalidated on moral utility grounds well into the twentieth century.

In 1977, the PTO Board of Appeals put an end to the prohibition on patents for gambling devices. In Ex Parte Murphy, the court upheld a patent on a slot machine, noting 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 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.

The court’s opinion did not make clear, however, whether the court was rejecting the moral utility doctrine as a whole, or simply the doctrine’s application to gambling machines. Since 1977, at least one court appears to have rejected the moral utility doctrine outright. In Whistler Corp. v. Autotronics, Inc., a district court upheld a patent on a radar detector, rejecting claims that the device lacked

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64. See, e.g., Fuller v. Berger, 120 F. 274, 275-76 (7th Cir. 1903) (noting that if the courts were to reject patents for inventions that were “sometimes injurious to morals, or to health, or to good order…” then Colt’s revolver would not have been patentable).

65. 120 F. 274 (7th Cir. 1903).

66. See id.

67. See id. at 276-77. Interestingly enough, the bogus coin detector was originally invented to be used in coin-operated banjo-playing devices, but it was never ultimately put to this use. See id. One is left to wonder if coin-operated banjo-playing devices would be more commonplace today if they had, in fact, been outfitted with bogus coin detectors.

68. See, e.g., Meyer v. Buckley Mfg. Co., 15 F. Supp. 640 (N.D. Ill. 1936) (invalidating a patent on a coin-operated game in which a person manipulated a movable crane to grab prizes and drop them out through a chute).


71. Id. at 802.

72. See id.

moral utility because its sole purpose was to circumvent attempts to enforce the speed limit. In so doing, the court noted:

the matter is one for the legislatures of the states, or for the Congress, to decide. Stated another way, only two states have seen fit to prohibit such devices. Unless and until detectors are banned outright, or Congress acts to withdraw patent protection for them, radar detector patentees are entitled to the protection of the patent laws.

Given the attitude of the district courts towards the moral utility requirement, one might assume that the requirement is now defunct. There are at least two reasons to believe it may be making a comeback, however. First, in a recent decision, *Tol-o-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft*, the Federal Circuit declared that a patent on a rodless piston-cylinder was not invalid for lack of utility. In discussing the standard of utility under which the invention should be judged, the court noted that 35 U.S.C. § 101 "has been interpreted to exclude inventions deemed immoral." The court continued by quoting the Lowell opinion extensively. The willingness of the Federal Circuit to embrace such a controversial doctrine in a seemingly unnecessary situation (certainly the cylinder could not be thought of as immoral in any way) suggests that the court may be attempting to lay the groundwork for invoking the doctrine in the future.

Second, the moral utility requirement should not be dismissed out of hand because it has been widely utilized in other countries, particularly in Europe. In fact, Justice Story's approach to utility is nearly identical to that embodied in a new Directive of the European Parliament and the Council of the European Union. In July 1998, the Council issued a Directive allowing patents on genetically engineered plant and animal species in general, but forbidding the issuing of patents for any biotechnological applications that "would be contrary to ordre public or morality." The Directive improves upon prior similar Directives by citing several examples of inventions that would be considered immoral, including "processes

74. *See id.*
75. *Id.* at 1886.
76. 945 F.2d 1546 (Fed. Cir. 1991).
77. *See id.*
78. *Id.*
79. *See id.*
82. *Id.* at art. 6.1.
for cloning human beings,"83 "uses of human embryos for industrial or commercial purposes,"84 and "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes."85 It is currently too early to know if this Directive will have any impact on the United States, but it is at least conceivable that the United States may look to Europe for guidance in an area in which it has lagged behind in recent years.86

To summarize, it is no longer clear that the moral utility requirement is still valid law, though at least one recent Federal Circuit decision suggests the doctrine has not lost its effectiveness entirely. In addition, the moral utility requirement plays a significant role in European patent law, and its refinement in the new EC directive regarding biotechnology inventions could have some influence in the United States. Should the rule be invoked, the dominant test seems to require an invention to have at least one non-immoral use to be patentable, though some courts have tried to restrict the doctrine only to those instances where an invention has been outlawed.

V. DO HUMAN-ANIMAL CHIMERAS MEET THE TEST OF MORAL UTILITY?

As a preliminary matter, if the moral utility requirement is invoked, it could extend to the process as well as the product claims of the patent application.87 This contrasts with the outcome under the Thirteenth Amendment, which could restrict only the products themselves. As such, the moral utility requirement is potentially a much more flexible and powerful tool to regulate biotechnology.

Although the PTO Commissioner has strongly suggested that the PTO will reject the Rifkin-Newman patent for lack of moral utility,88 it is likely

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83. Id. at art. 6.2a.
84. Id. at art. 6.2c.
85. Id. at art. 6.2d.
86. Indeed, the United States has already begun to harmonize its patent laws with those of the rest of the world, as part of its obligations under the Trade Related Aspects of Intellectual Property (TRIPS) provision of the General Agreement on Tariffs and Trade (GATT). See, e.g., ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 192-93 (1997).
87. Although both kinds of claims could be rejected under a moral utility analysis, I will focus my discussion on the moral utility of the human-animal chimeras themselves, for the sake of consistency with the Thirteenth Amendment discussion. Any arguments relating to the chimeras themselves are likely to apply to the processes that produce them, as well.
88. See Lehman, supra note 13.
that, in light of the trend in the case law, such a rejection would be reversed on appeal.

Initially, it is not entirely clear that the moral utility requirement is still in full force and effect. A court could use this case as an opportunity to reject the doctrine as outdated and without a foundation in the patent laws, as the courts in Ex Parte Murphy and Whistler have suggested. Given the Federal Circuit's unambiguous and relatively recent statement in Tol-o-Matic, however, this outcome is unlikely.

Assuming the court accepts the moral utility requirement as valid, it is not clear what standard the court would adopt to evaluate whether or not a biotechnology invention met the requirement. Certainly, the court would not adopt the earliest formulation of the requirement, under which an invention lacked moral utility if it had at least one immoral use. On the other hand, the test requiring at least one non-immoral use seems ill-suited to biotechnology inventions like the chimera, since virtually every biotechnology invention has at least one use that is not categorically immoral. Even human cloning, which some people vehemently oppose, could be used to create children for otherwise infertile couples, a practice that many would consider at least morally neutral. Indeed, Rifkin and Newman identify several non-immoral uses for human-animal chimeras, including their use as models to study embryonic development.

Given that the current test for moral utility would be ineffectual if applied to biotechnology, it is conceivable that a court wishing to impose the moral utility requirement on biotechnology inventions might adopt a balancing test. Indeed, at least one U.S. court has suggested adopting such an approach, stating "'[g]eneral rules will not decide this question in particular cases, but the circumstances of each case must be carefully examined....'" Such a test would likely involve balancing the non-immoral (or beneficial) uses of an invention against the immoral elements of that invention. While balancing tests are often employed in complex situations, such a test would be difficult, if not impossible, to employ in the

91. 945 F.2d 1546 (Fed. Cir. 1991).
92. See Dickson, supra note 25, at 424.
93. In re Nelson, 280 F.2d 172, 178 (Cus. & Pat. App. 1960) (emphasis added) (quoting CURTIS ON PATENTS sect. 28 (1849)). See also Merges, supra note 69, at 1066 (suggesting some courts might apply a moral balancing test to biotechnology inventions).
94. This is precisely the test adopted by the Examining Division of the European Patent Office to decide the morality of biotechnology inventions, like the Harvard Oncomouse. See Darrell G. Dotson, Note, The European Controversy Over Genetic-Engineering Patents, 19 HOUS. J. INT'L L. 919, 933 (1997).
realm of morality. To demonstrate the shortcomings of a moral balancing test, the beneficial and immoral aspects of making human-animal chimeras must be explored.

The beneficial uses of human-animal chimeras are relatively discrete and well-defined. Their usefulness in studying development has already been noted. Additionally, human-animal chimeras would be of value to pharmaceutical companies in determining the medicinal benefits of new drugs. Currently, new drugs are tested on humans only after extensive testing on animals. Often, drugs that produce a beneficial effect in animals are ineffective in humans. Using human-animal chimeras would presumably take much of the guesswork out of this process, since the beneficial effects of new chemicals on human cells could be measured directly. Analogously, chemical companies could use human-animal chimeras to measure the toxic effects of new compounds. Finally, chimeras might be used as sources of organs, such as hearts or livers, for transplantation into desperate human patients whose organs are failing them. Human donors have always been in short supply, and transplantation of animal organs is generally unsuccessful because the human body quickly rejects them as foreign. Since chimeras would be partially human, their organs would more closely resemble human organs, making rejection less likely.

In contrast to the arguments in favor of human-animal chimeras, the major ethical objections to making chimeras are non-utilitarian in na-
First, some might object to human-animal chimeras simply because they are made from human embryos. Indeed, under the EC rules, human-animal chimeras would not be patentable for precisely this reason. Granting embryos a similar legal status in the United States would seem to contrast with the current protection of a woman's right to an abortion, however. Given the current legal position of embryos in the context of the abortion issue and the lack of consensus on the issue in society, a court would be unlikely to weigh this objection very heavily, if at all.

Another possible objection is that the production of human-animal chimeras would result in needless animal suffering. Again, this same objection can be found within the EC directive. This result is problematic, however, in that human-animal chimeras would be unlikely to suffer any more than animals currently used in research. One could argue that the suffering of a human-animal chimera should be weighed more heavily than that of an animal because the chimera is partially human. Presumably, though, any increase in suffering would be offset by the increased value of using chimeras, rather than animals, in research ultimately designed to benefit humanity.

Finally, Rifkin himself argues that inventions that cross species boundaries, like the human-animal chimera, fail to respect the right of the animal species in question not to be disturbed. Rifkin believes that each species possesses a "speciesness" that should be honored by humans. This concept of "speciesness" includes the right of each animal species to exist without human interference and the right of each individual member of a species to exist as a discrete and identifiable organism. There are several reasons a court might reject this theory as specious. First, the very concept of a species is nothing more than a human construct developed to facilitate the study of animal biology. Therefore, it seems untenable to argue that species have rights in and of themselves. Moreover, species are

104. See Council Directive 98/44, art. 6.2c, 1998 O.J. (L 213) 2. One could argue that human-animal chimeras meet this standard because they would be used primarily for research, and not industrial or commercial purposes. This argument is not convincing, however, given the commercial value of the research in question.
105. See id. at art. 6.2d.
106. See Merges, supra note 69, at 1056.
108. See id.
109. See Morin, supra note 32, at 170.
not static; they are constantly evolving in response to ecological pressures, some of which have long been caused by humans. Finally, humans have been interbreeding species and adapting them for their own use for millennia. It is difficult to see precisely how a biotechnology invention like the chimera would violate "speciesness" in a way that traditional breeding would not. It seems unlikely that a court would adopt a rule that would invalidate the traditional work of farmers and breeders, along with biotechnology inventions.

The problems a court would encounter in trying to apply a moral balancing test to biotechnology inventions like the chimera should now be apparent. While the benefits of biotechnology are generally instrumental, and, thus, readily measured, the objections are often deontological in nature. Such abstract moral arguments are incommensurate with the utilitarian benefits. How, for example, is a court to decide what weight to give animal suffering in light of the potentially hundreds of thousands of lives that could be saved with new cancer-fighting drugs? These objections are not entirely without merit; they are merely unquantifiable. Indeed, if a court were ever faced with such a situation, it would likely gravitate towards the discrete benefits of the invention and give little, if any, weight to the deontological arguments against the invention. As such, the balancing test would quickly devolve into the ineffectual "one non-immoral use" test.

In short, despite the PTO Commissioner's indication that he will probably reject the human-animal chimera patent application for lack of moral utility, an appeals court would likely reverse any rejection on moral grounds. Not only would the moral utility doctrine be exceedingly difficult to apply in practice, but even if a court subjected the Rifkin-Newman patent application to moral scrutiny, it would be unlikely to adopt a moral utility test that the application could not satisfy.

110. In one of the most famous examples of the effect of human activity on animal evolution, many white moth species have developed black-colored populations in industrial areas with significant air pollution; the darker coloration provides better camouflage on the blackened trees commonly found in such regions. See, e.g., THE NEW AMERICAN DESK ENCYCLOPEDIA 838-39 (3d ed. 1993).

111. The mule, mentioned earlier in this Note, is a classic example of the traditional human manipulation of "speciesness."
VI. BEYOND THE HUMAN-ANIMAL CHIMERA PATENT APPLICATION

Whatever the PTO and the courts ultimately decide about the human-animal chimera patent, Rifkin and Newman surely will have accomplished their goal of sparking social debate about the current lack of ethical restrictions on biotechnology. While their goal is unquestionably valid, their approach is somewhat flawed.

If Rifkin and Newman believe the patent laws should be altered to exclude controversial technologies, they should lobby Congress to amend the patent statute, not try to force the PTO into acting without authority. The spirit of Chakrabarty and its progeny is that because Congress intended the patent laws to be broad, the courts should not impose their own limitations on patentability without congressional approval. Because the PTO is largely unaccountable to the people, it should not exercise policy-making power over such significant matters.

Moreover, manipulating the patent laws at all confuses the essential issues raised by controversial technologies like the chimera. The ethical concerns shared by Rifkin, Newman, and others about biotechnology inventions do not actually relate to the patenting of such inventions, but to whether these inventions should be created at all. By focusing on the patentability question, Rifkin and Newman have drawn attention away from the real moral issues at stake.

Indeed, excluding controversial technologies from patentability would not prevent their development, as Rifkin and Newman hope. While the profit incentive would be significantly reduced, scientists at academic institutions, which operate ostensibly without a profit motive, would surely continue to conduct research on such technologies. Moreover, if a practical application for an otherwise controversial technology were found, someone would put it to use, even without a patent. This would be true particularly if use of the technology would lead to the development of patentable, and, therefore, profitable, inventions. In fact, eliminating patent protection for a class of inventions might actually produce the opposite result of the one Rifkin and Newman intend. Without the limited monopoly granted by the patent law, everyone would be free to make and use a new invention without permission from the original inventor. This might


113. For a more thorough discussion of these and other ethical issues raised by patenting life forms, see Reagan Anne Kulseth, Note, When Someone Builds a Better Mouse, 32 Ariz. L. Rev. 691 (1990).
make the use of controversial technologies even more widespread than under a patent regime.

Given these considerations, opponents of biotechnology should focus their efforts, not on altering the patent laws, but on convincing Congress to pass legislation that would regulate the kinds of experiments scientists may perform. While the merits of biotechnology regulation in general are beyond the scope of this Note, the preceding discussion suggests that congressional action would, at least, be superior to the route taken by Rifkin and Newman thus far.

VII. CONCLUSION

The Rifkin-Newman patent on the production of human-animal chimeras is unlikely to be rejected under the Thirteenth Amendment or the moral utility doctrine. While a prohibition on patents on human beings seems firmly grounded in the Constitution, it is unlikely that all human-animal chimeras as a class would be considered human within the meaning of the Thirteenth Amendment. The current legal status of the moral utility requirement is less certain. Even if a court were to apply the doctrine, it would likely find that human-animal chimeras satisfy the current formulation of the rule, in which an invention is acceptable if it has at least one beneficial use. Moreover, human-animal chimeras probably would pass a moral balancing test, given that the benefits are well-defined but the moral objections are abstract and problematic.

This assessment of the Rifkin-Newman patent demonstrates that the patent laws as currently written are simply not equipped to deal with the complex moral issues posed by biotechnology innovations. The two legal doctrines that most closely touch on moral concerns are vague and difficult to apply. At the same time, although biotechnology developments are occurring at what may be an uncomfortably rapid pace, the PTO should resist the urge to create its own guidelines to deal with the special questions posed by biotechnology. Any new restrictions on the patentability or development of controversial technologies like the human-animal chimera should originate from Congress, if at all.
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