

Second, I have tried to exhibit the peculiarly illogical character of basing an objection to a secular policy on religious revelation. The objectors should concede that nothing they have to say in criticism of the policy ought to persuade a disinterested person. That being so, we had best pass over their objection in silence, for there is nothing that could be said in criticism of it that the objector has not already conceded.

Once again, let me emphasize that none of these considerations applies to those portions of religiously based morality — most of religiously based morality, I think, for all of the world's great religions — that can also be justified by publicly accessible reasons. St. Thomas Aquinas, for example, insisted that the precepts of natural law could be derived from a reasoned examination of the nature of the common good, without the assistance of divine revelation, and thus he had no need to enter into the paradoxes surrounding the leap of faith. On most moral issues, men and women of faith can participate fully in political debate, knowing that the public reasons they are offering are also in

accord with their professions of faith. When they have no public reasons to offer, however, they should retire from the public arena.

— David Luban

Sources: Kent Greenawalt, *Private Consciences and Public Reasons* (Oxford University Press, 1995); Robert Audi, "The Separation of Church and State and the Obligations of Citizenship," *Philosophy and Public Affairs*, vol. 18 (1989); Stephen L. Carter, *The Culture of Disbelief: How American Law and Politics Trivialize Religious Devotion* (Basic Books, 1993); Immanuel Kant, *Kant's Political Writings*, edited by Hans Reiss (Cambridge University Press, 1970); John Rawls, *Political Liberalism* (Columbia University Press, 1993); Søren Kierkegaard, *Philosophical Fragments, or, A Fragment of Philosophy* (Princeton University Press, 1967), *Fear and Trembling, and the Sickness unto Death* (Princeton, 1968), and *Concluding Unscientific Postscript to Philosophical Fragments* (Princeton, 1992); David Hume, *An Enquiry Concerning Human Understanding*, section 10 ("Of Miracles").

Animals as Inventions: Biotechnology and Intellectual Property Rights

Since 1988, the U.S. government has granted nine patents for genetically engineered animals. A coalition of religious leaders called last summer for a moratorium on such patents. They declared, in a joint statement issued in the nation's capital, that "the gift of life from God, in all its forms and species, should not be regarded solely as if it were a chemical product subject to genetic alteration and patentable for economic benefit. Moral, social, and spiritual issues deserve far more consideration before binding decisions are made in this area."

For its part, the biotech industry argues that without patents, companies would be unwilling to invest in, or unable to attract capital for, research that benefits humankind. For example, the development of the "Oncomouse" patented by Harvard University may lead to more rapid progress in the management and prevention of breast cancer.

This essay invokes the distinction between "inventions," which are rightfully patented, and mere "products," which are not, in order to cast doubt on current Patent Office policy. However, I also propose reason-

able ways of granting protection to biotechnological innovations — ways that might be acceptable to those who object specifically to the patenting of life and not necessarily to biotechnology itself. I begin with an account of the meaning of creation and ownership, courtesy of John Locke.

The Occasions of their Being

Locke's *First Treatise of Government* (1698), which languishes in the shadow of his more famous *Second Treatise*, refutes Sir Robert Filmer, who had upheld the divine right of kings. Filmer argued that just as God, having made Adam, owned him absolutely, so Adam owned his children, and so princes, who inherit this right from Adam, hold authority over their subjects.

Locke replied that while ownership is, indeed, a consequence of authorship, God alone is able "to frame and make a living Creature, fashion the parts, and mould and suit them to their uses." Humans, starting with Adam, produce offspring but do not frame and fashion and, therefore, do not own them. Even those who desire and intend to beget children are "but the

occasions of their being," says Locke, and "do little more towards their making, than *Ducalion* and his Wife in the Fable did towards the making of Mankind, by throwing Pebbles over their Heads."

Of course, no one thinks that genetic engineers proceed in quite the accidental way that *Ducalion* and his wife do in the fable to which Locke alludes. Still, Locke's discussion offers guidance on the question of whether genetic engineers can claim an intellectual property right or patent in the organisms they produce. Whether the organisms should be patentable turns, in part, on how we construe the activity of their producers: do biotechnologists create these organisms, or do they serve merely as "the occasions of their being"? It seems to me that many reservations concerning the patentability of these products stem from an uncertainty about how much their producers, as it were, author or design them, and thus have contributed to the world's store not just of useful things but also of useful knowledge.

Technologists may claim intellectual property rights in organisms, I believe, insofar as they design them, using ideas that are not found in nature but are their own. This is the principle that underlies the patenting of inventions generally. Thomas Edison received a patent to the light bulb because he contributed the novel idea — the use of the glowing carbon filament — that made it work. What made the light bulb Edison's intellectual property is that he not only produced but also designed it. To put this distinction in Aristotelian language, the inventor can claim intellec-

tual property rights if he or she provides not just the efficient but also the formal cause of the mechanisms he or she creates.

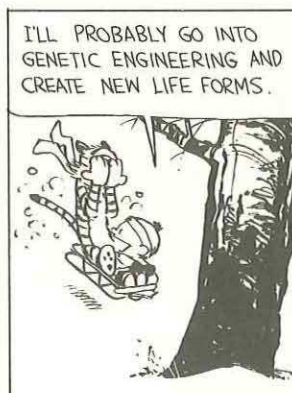
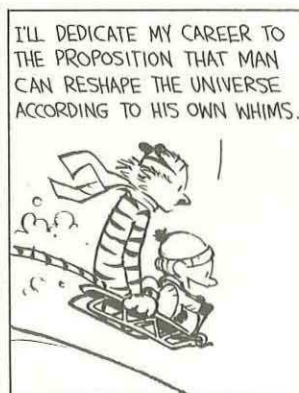
Consider another example. Samuel Morse could patent telegraphic instruments he invented but not — as he wanted — the use of electromagnetic waves to send and receive signals. Morse claimed as intellectual property "the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for making or printing intelligible characters . . . at any distance." But the Supreme Court held that Morse had invented only a particular instrument to take advantage of electromagnetism, and that he could not prohibit others from harnessing by other means the same natural forces or materials.

Similarly, in *Funk Brothers Seed Company v. Kalo Inoculant* (1948), the Supreme Court held that a scientist's combination of bacterial strains found separately in nature did not constitute "an invention or discovery within the meaning of the patent statutes." According to the Court, "a product must be more than new and useful to be patented; it must also satisfy the requirements of invention." The Court regarded the repackaging of genetic information taken from nature as a commercial not a scientific advance: "Even though it may have been the product of skill, it certainly was not the product of invention."

These and other cases illustrate a fundamental logical limitation on the scope of intellectual property rights. These rights can extend only to what someone designs — what he or she devises and constructs, as it

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were, from simpler materials, by reason of a plan or principle which that person invents. Intellectual property does not include objects, such as natural forces and materials, which the individual does not design but simply uses or manipulates by applying a novel instrument or process. The instrument (the telegraph) or the process (for combining bacteria) is patentable, but the product is not.

Patenting Organisms

Thus far I have described the traditional conception governing the awarding of intellectual property rights. However, the practice of the U.S. Patent Office changed dramatically after a 1980 decision, *Diamond v. Chakrabarty*, in which the Supreme Court held by a 5-4 majority that Chakrabarty, a microbiologist, could patent a novel organism because "his discovery is not nature's handiwork, but his own." The "discovery" in question was a bacterium which Chakrabarty had hybridized by inserting plasmids from other bacteria. The Court determined that the hybridized microorganism could be patented because it was not found in nature but was "the result of human ingenuity and research."

The Supreme Court in *Chakrabarty* emphasized that the bacteria it had to consider differed from those in *Funk Brothers* in that they had been genetically changed and were not naturally occurring strains. Yet one might argue that there is no more creation in the second instance than in the first. In both cases, the inventors manipulate design already found in nature; they do not introduce a new design of their own. The organism — although altered slightly from its naturally occurring state and therefore more useful — may result from the application of a novel process to natural materials, but the element of design resides in nature.

On the strength of the *Chakrabarty* decision, however, the Patent Office began routinely to award patents on hybridized and recombinant organisms — and very broad patents at that. The current high-water mark in this flood of patents came with an application from Agracetus of Middletown, Wisc., which in 1992 received a patent covering "all cotton seeds and plants which contain a recombinant gene construction (i.e., are genetically engineered)." By using a well-known process to introduce foreign genes into a cotton plant, Agracetus gained the right to exclude other companies from introducing any other genes into that plant without its consent. "All transgenic cotton products . . . will have to be commercially licensed through us before they can enter the marketplace," a vice president of Agracetus said.

The Patent Office apparently reasoned that anything that is not a product of nature must therefore result from invention or design. This is perhaps not an unwarranted inference from *Chakrabarty*, but it does

confuse *invention* with the *production* of anything novel and useful. The Patent Office went on to establish as intellectual property the genome of any organism — Agracetus also received a patent for soy — that a company manages to alter using novel technical means. In several instances when a company seeking to patent an organism had used fairly well-known, if laborious, methods for manipulating its genome, the Patent Office still allowed a patent on that genome as the material for further genetic manipulation. The Patent Office, in other words, failed to distinguish manipulating or changing a genome from designing or inventing it.

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Competitors were slow to challenge the Agracetus patent, perhaps believing that their interest would be better served by acquiring similar intellectual property rights to broccoli, bananas, and a host of other organisms whose genomes they could alter using the same technique Agracetus applied. Eventually challenges mounted up, including a major and successful suit by the U.S. Department of Agriculture. The Patent Office is now reviewing the Agracetus patent, which is unlikely to be sustained.

Breeders' Rights

The manipulation of genetic material in nature to produce novel and useful forms of life is not new. Breeders have worked for centuries — and over the past hundred years, in the light of Mendelian genetic theory — to give us the crops we eat, the flowers we enjoy, the livestock we raise, and the pets we keep in our homes. The history of patent law with respect to their work casts further light on issues surrounding the patenting of life.

Under the standard or utility patent act, breeders have not traditionally been able to protect their products. Luther Burbank, the man responsible for the Shasta daisy, the Burbank potato, and scores of other important varieties, decried this situation: "A man can patent a mousetrap or copyright a nasty song, but if he gives the world a new fruit that will add millions to the value of the earth's annual harvests, he will be fortunate if he is rewarded by so much as having his name connected with the result." Though Burbank himself did fairly well, he never received the riches he deserved because he could not patent the varieties he created. Thomas Edison is reputed to have told him,

"The things you have created for the American people are worth far more than what I have created for them. The law protects my creations but gives no protection to yours."

We can explain this situation. Edison could claim an intellectual property right in his inventions — and therefore a "utility" patent in them — since they arose from new knowledge he discovered and disclosed, thus enabling others intellectually to reproduce his own inventions and to make many more besides. Burbank, a superb breeder for whose work we cannot be too grateful, did not provide new ideas or knowledge that would enable others to build further varieties. Rather, he depended entirely on his skill in conventional techniques of breeding. Thus, the daisy for which Burbank is justly famous can be reproduced biologically but not intellectually. Burbank gave us many wonderful plants, but he left the science of plant breeding essentially unchanged.

The genetic information contained in seeds and tubers is the work not of the breeder (who could hardly specify what it is) but of nature.

Confronted with the inapplicability of intellectual property law to new varieties of plants and animals, Congress enacted the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, which protect new varieties respectively against unauthorized asexual and sexual reproduction. In enacting these statutes, Congress sought to "afford agriculture, so far as practicable, the same opportunities to participate in the benefits of the patent system as have been given industry." Congress recognized that plant breeders could not claim to design the new varieties they created; indeed, they could hardly claim that the methods they used were anything but obvious, nor could they describe the genome of the plants they produced. (Under the "specification" requirement of patent law, inventors are required to describe their invention so that others can understand precisely how it works.) Nevertheless, Congress wished to give an adequate economic incentive to breeders and reward their efforts, even if those efforts did not produce new knowledge and therefore did not result in the creation of intellectual property.

The laws written for plant breeders greatly weakened the traditional standards for the awarding of patents. The 1970 statute, for example, replaces the specification requirement with a mandate that seeds be deposited in a public repository. This may represent good social policy, insofar as it encourages plant

breeders to continue their useful endeavors. It may also be fair, since Congress, by giving breeders rights over the use of their plants for reproduction, may have recognized the rights of creators to control their personal property, including the seeds and tubers of the plants they produce. But the genetic information contained in these seeds and tubers is the work not of the breeder (who could hardly specify what it is), but of nature. For this reason, the Plant Protection Act does *not* give a breeder intellectual property rights to this information. Rather, the statute provides that anyone who develops the same variety independently does not infringe the patent.

This legislative framework was shaken, in turn, in April 1987, when the Patent Office announced that it "now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter." The trade paper *Genetic Engineering News* immediately inferred that the ruling "will lead to protection of animals developed not only through genetic alteration but also through animal husbandry and breeding." The intellectual contribution of breeders, after all, may be as great as or greater than that of genetic engineers with respect to the organisms they create. Breeders have to keep dozens of traits in mind and navigate among them, while engineers make a far more surgical strike on the genome of the organism. Plant breeding and artificial selection generally, moreover, typically change the genome of target animals far more broadly than the more surgical techniques employed by genetic engineers.

It is unsurprising, therefore, that conventional plant breeders immediately saw an opening to claim their products as intellectual property — even though these "inventions" may exhibit no more new knowledge than those of Luther Burbank. At first, the Patent Office was unwilling to draw this inference. But a 1985 decision established a precedent whereby, as one law journal noted, "a plant breeder may obtain a utility patent on a newly developed plant variety." Organisms produced by conventional breeding techniques now routinely receive utility patents, as do products of genetic engineering. It seems no longer to matter to the Patent Office whether new knowledge is involved; all that seems to matter is useful innovation.

A Compromise Solution

The religious critique of biotechnology and the patenting of life focuses on our ability to override or obliterate the distinctions between life and matter, nature and technology, humanity and God on which our spiritual estate seemed to depend — distinctions that helped us think that man belongs to nature, not the other way around. The religious leaders who signed the declaration last summer made this point

when they asked for a moratorium on the patenting of life forms. These leaders deny that genetic engineers, any more than conventional plant breeders, design organisms, as it were, from scratch, and accordingly that these organisms should be considered intellectual property of anyone but God. As Dr. Richard D. Land of the Southern Baptist Convention testified: "Humans and animals are pre-owned beings. We belong to the creator God. The . . . decision to grant patents on animal or human genetic information represents a usurpation of the ownership rights of the Sovereign of the Universe."

Insofar as these religious leaders are concerned to dispel the idea that human beings create life forms just as God created Adam, however, there appears to be a way to reconcile their objection with the needs of the biotech industry. This is true because the industry is also concerned to dispel the idea that it is "playing God." It cares less about its pretensions to having designed life than about its access to a particular set of rights to certain products. Whether or not these rights carry with them a pretension to intellectual property in the moral sense is of no concern to the biotech companies; from their perspective, what matters is only the legal effect, not the ethical meaning or basis, of the law.

There seems to be room for compromise between the concerns of the industry and those of religious leaders. Indeed, each group has sought to accommodate the other. Activist Jeremy Rifkin, characterizing the position of the religious leaders he led to Washington, emphasized that they had "no problem" with process patents nor even with protecting biotech products with the sort of marketing exclusivity conferred on "orphan" drugs. Rabbi David Saperstein, who heads the Religious Action Center of Reform Judaism, decried the idea that scientists would "arrogate to themselves the ownership of the life they are creating," but went on to observe that there are "ways through contract laws and licensing procedures to protect the economic investment that people make." Like Rifkin, Saperstein objected to the hubris of claims that organisms are intellectual property, not to legal regimes per se intended to reward and encourage effort and investment in biotechnology.

On the industry side, spokespersons have been eager to assure their clerical critics that what they want is not to upstage the Creator but to enjoy a legal regime that protects and encourages investment. Biotechnology Industry Organization President Carl Feldbaum emphasizes this point:

A patent on a gene does not confer ownership of that gene to the patent holder. It only provides temporary legal protections against attempts by other parties to commercialize the patent holder's discovery or invention. This is a critical distinction because no one, in our view, can or should own life itself.

It is not hard to see the outlines of a solution that can embrace both the view of religious leaders and the needs of the biotech industry. Novel organisms might be covered by a new patent statute which, like the old Plant Protection Acts, recognizes that those who produce these organisms may alter or recombine but do not design and therefore cannot claim to own them as intellectual property. Such a statute might not differ further from utility patents in the terms, conditions, and rights for the patenting of organisms.

A compromise along these lines would bring patent law into harmony with the important distinction between production and invention which we borrowed from Locke at the beginning of this essay. To claim novel organisms as intellectual property is to confuse, as did Sir Robert Filmer, the way God and humans create life. The difference is that God knew what He was doing in a way that plant breeders and even genetic engineers do not. To cross strains of plants or microinject genes into embryos is not to invent, design, or create living things.

— Mark Sagoff

Sources: Edmund L. Andrews, "Religious Leaders Prepare to Fight Patents on Genes," *New York Times* (May 13, 1995); Claudia Mills, "Patenting Life," *Report from the Institute for Philosophy and Public Policy*, vol. 5, no. 1 (Winter 1985); John Locke, *Two Treatises of Government*, Book I, chap. 5, section 53; Fred Powledge, "Who Owns Rice and Beans? Patents on Plant Germplasm," *BioScience*, vol. 45, no. 7 (July 1995); *Pittsburgh Post-Gazette* (Sept. 3, 1995); H.R. Rep. No. 1129, 71st Cong., 2d Sess. 2 (1930) (Rep. Purcell quoting from a telegram received from the widow of Luther Burbank); Dienger, "Patents for Biological Specimens and Products," *Journal of the Patent Office Society*, vol. 35 (1953); U.S.C. Section 112, first paragraph; *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); Hearings on H.R. 11372 before the House Committee on Patents, 71st Cong., 2d Sess. 4, 7 (1930) (memorandum of Patent Commissioner Robertson); Hearing before the Subcommittee on Departmental Operations of the Committee on Agriculture, 91st Cong., 2d Sess. (1970); Unsigned note, "Altering Nature's Blueprints for Profit: Patenting Multicellular Animals," *Virginia Law Review*, vol. 74 (1988); *Official Gazette of the U.S. Patent and Trademark Office*, vol. 8 (1987); Reid G. Adler, "Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting," *Harvard Journal of Law and Technology*, vol. 1 (1988); "New Animals Will Be Patented," *New York Times* (April 17, 1987); Neil D. Hamilton, "Why Own the Farm if You Can Own the Farmer (and the Crop)?" *Nebraska Law Review*, vol. 73 (1994); "Transgenic Crops Head to Market," *Chemical Week* (Sept. 27, 1995); Richard D. Land, quoted in Bruce Rubenstein, "Genetic Patents Pit Clients, Religion, Government," *Corporate Legal Times* (Sept. 1995); Reginald Rhein, "Gene Patent Crusade Moving from Church to Court," *Biotechnology Newsweek* (June 5, 1995).