The Ethics of Patenting Genetically Modified Organisms

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8/17/2007

TABLE OF CONTENTS

ACKNOWLEDGMENTS

I'd like to extend my many thanks to Professors Jon Merz and Michael Weisberg, of the University of Pennsylvania Center for Bioethics and philosophy department, respectively, for their invaluable help on this paper. Thanks also to Professor Autumn Fiester, also from the UPenn Center for Bioethics, for the invigorating classes.

INTRODUCTION

Genetic engineering and cloning present unique philosophical and moral questions, and law—particularly patent law—is slow to catch up with and address these questions. For this paper, I examine the ethical questions surrounding patenting genetically modified organisms (GMOs). I discuss some of the important legal cases of the past thirty years that touch upon the issue of patentability of "life," and give the positives and negatives of such patent law, presented from the two prominent schools of philosophy. Ultimately, I am persuaded by the consequentialist school, and I present my reasoning for siding there as stemming from the original intent of patent law in the United States.

OF FRANKENPETS AND THE "YUCK" FACTOR

One of the concerns about GMOs is the so-called "yuck" factor.[1] This is characterized by an often uncontrollable distrust of or repulsion with GMOs. These organisms are considered unnatural or otherworldly, and are as such distrusted. Yet, these fears are often unfounded, and admittedly so; it is difficult for even the most rational of people to cast aside their preconceived notions and prejudices. That GMOs are often portrayed in a negative light in the mainstream media and in science-gone-awry horror flicks does not help matters. Indeed, out-of-control scientists concocting genetic horrors (e.g., "The Fly") make for engrossing stories, but hardly does justice to the subject.

What the "yuck" factor boils down to is a fear of scientists playing God when they ought not. That is, regardless of any religious beliefs, "playing God" consists of meddling with the

[1] First used by Arthur Caplan in 1994. See generally Fethe, Charles, *The Yuck Factor*, Philosophy Now (October/November 2000), p. 30.

bounty of nature in order to create so-called "unnatural" organisms.[2] What "unnatural" means is at first vague. Indeed, humans have been "playing God" for centuries, employing cross-breeding techniques on plants and many animals. These hybrids (pigeons, for instance, have been selectively bred for centuries[3]) are "unnatural" in the sense that they are manufactured by humans, yet perhaps the reason they are not as reviled as GMOs is because they were manufactured through "natural" hybridization methods, and not in a laboratory. The biggest distinction between the two means of hybridization is that cross-breeding is theoretically possible in nature without human intervention, but laboratory genetic modification may not be. This brings us back to the concerns about "playing God": in a laboratory, humans may create organisms that are not possible in nature through simple cross-breeding.

The question then becomes, do we care about this distinction? The horror-story fear that often animates the "yuck" factor is often animated by so-called Frankenpets, or chimeras.[4] These organisms are the by-product of hybridization between multiple animals, or between animals and humans. Wild imaginations often portray these hybrids as mythical creatures—e.g., the Greek Chimera, or the Centaur—that are at once both human and animal, and yet neither fully. These fears can be equated with the Uncanny Valley phenomenon[5]: as robots take on more and more recognizable human characteristics, people have more and more positive reactions to the robots.[6] Yet at a certain point when the robot is nearly human, but slightly "off,"

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[2] Fiester, Autumn. "Clones, Chimeras, and Frankenpets: Justifying a Presumption of Restraint in Animal Biotech Research," American Journal of Bioethics, January 2008, p. 4.
[3] See generally the National Pigeon Association (http://www.zyworld.com/NPA/).
[4] Fiester, supra, n. 2, at p. 1.
[5] Mori, Masahiro, *The Uncanny Valley*, Energy 7(4), 33-35, 1970.
[6] *Id*.

peoples' favorable reactions plummet and are replaced with a feeling of strangeness and "horror,"[7] before rising again once the robot is indistinguishable from a human.

In genetic engineering terms, we can imagine half-human-half-horse GMO hybrids; the visceral reaction is negative because the GMO approaches recognition as a human, but is "off." I am sympathetic to this reaction against such a creature: it is not hard to imagine sentient human-animal GMO hybrids, engineered for slave labor. Yet, for our current technology, these concerns are generally moot. Eventually we may have the capacity to engineer a centaur, but it seems unnecessary to ban such a practice when it is not even currently feasible. (Further, just because something makes us uneasy doesn't necessarily make it bad.) Instead, more immediate targets of genetic engineering are much more minimal in scope. The Omega-3 pig is one famous example.[8] The Omega-3 fatty acid, which is often found in fish oil, was transgenically inserted in vitro into pigs so that consumers could enjoy the benefits of Omega-3 while eating pork. Though the merits of the research appear dubious at first blush, it appears in actuality to be a cogent response to dwindling marine food supplies:

> So far, the only way to enrich the tissues of mammals with *n-3* fatty acids has been dietary provision of *n-3* fatty acids. Thus, the food industry must feed animals with flaxseed, fish meal or other marine products. In view of the decline in marine fish stocks and the potential contamination of fish products with mercury and other chemicals, alternative, land-based dietary sources of *n-3* fatty acids are needed. Generation of *fat-1* transgenic livestock that produce *n-3* fatty acids may be an economical and sustainable strategy to address this need.[9]

Omega-3 pigs make additional sense from a utilitarian perspective, in that the pork makes more prevalent the fatty acid, which has been found to have positive health benefits. Consumers who

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[7] *Id*., at p. 35.
[8] Lai, Liangxue, et al*., Generation of Cloned Transgenic Pigs Rich in Omega-3 Fatty Acids*, Nature Biotechnology 24, 435-436, 2006.
[9] *Id*., at 436.

do not eat seafood might otherwise be precluded from getting the positive health benefits of the fatty acid.

The Omega-3 pig is also a far cry from, *e.g.*, a griffin in terms of questionable genetic engineering practices. Furthermore, it is realistic to assume that GMOs going forward will mimic the Omega-3 pig in terms of capitalist utility: someone has to pay the bills for the research, after all, and a GMO without the means to bring a return on the (currently) sizeable investment is unlikely to be green lighted. With this in mind, the question changes to are we comfortable with GMOs as capitalist endeavors?

The answer is unclear. A Food and Drug Administration (FDA) report in 2003 declared that no health risks were found in food and milk from cloned animals, yet FDA has been reluctant to issue any ruling on the permissibility of allowing cloned animals into the general food supply, citing the need for further testing.[10] A Pew Initiative poll from 2005 found that 66% of Americans were uneasy about eating food or drinking milk from cloned animals.[11] Similarly, a ViaGen, Inc. poll found that a plurality (35%) of respondents would "never buy" cloned food.[12] This is a strong showing for the "yuck" factor, and on as "mundane" a subject as cloned animals; it is likely that the negative reactions would be even higher if the question asked about allowing chimeras or GMOs into the food supply. Yet, the existence of the Omega-3 pig indicates that there is some market for GMOs as food. The difference is that whereas the cloned food would have been added to the general food supply, unlabelled and along with the "normal" food, the Omega-3 pork draws attention to itself as genetically-altered and "improved." Like the

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[10] Gillis, Justin. "Clone-Generated Milk, Meat May Be Approved." The Washington Post. October 6, 2005. (<http://www.washingtonpost.com/wpdyn/content/article/2005/10/05/AR2005100502074.html>)
[11] Gillis, Justin. "Shoppers Uneasy About Cloning." The Washington Post. November 16, 2005. (<http://www.washingtonpost.com/wp-dyn/content/article/2005/11/15/AR2005111501617.html>)
[12] *Id*.

"organic" label, transgenic animals such as the Omega-3 pig aim to invade the luxury food space. Their success or failure will largely determine the future prospects of such research.

The fear of the "unnatural" is palpable, but ought we to include it in the ethical calculus? Facially, I would say no. After all, as mentioned, people have long been creating hybrid plants and animals, and extracting and synthesizing products from them, yet there is no cry for legislation to ban the breeding of mules or the synthesis of insulin. Furthermore, certain GMOs such as the Omega-3 pig seem to have found a niche in the luxury food market, although not uncontroversially. This perhaps speaks to a fear of the "unnatural" approaching the "natural"; kept in a separate, distinct sphere, the "unnatural" is acceptable. If this is true, then the fear of GMOs has less to do with their existence altogether (and scientists "playing God"), than with a fear that they will escape laboratory control and enter the "natural" sphere unchecked—which is, again, a common science-run-amok storyline.

That is not to say, however, that this fear is unfounded. Quite the contrary: because genetic engineering is a relatively new technology, and GMOs more so, we have not adequate data to say with certainty that cross-breeding with their progenitors is impossible, or even what the results would be. Certainly it is a valid concern that a GMO, escaped into the wild, would have a genetic advantage over its "natural" brethren in terms of acquiring food and reproducing. However, this concern, like all others laid out here save the "playing God" fear, is moot for the question of whether GMOs are patentable. Yet it is important to lay out here these concerns, because general unease with GMOs is often conflated with unease about their patentability. However, the U.S. patent system attempts to ignore ethical considerations in all but the most

extreme of cases[13] and courts have ruled that GMOs as presently construed are patentable. We shall proceed with the rest of the paper from this perspective.

[13] Anything illegal is exempt from consideration for patentability. It can be argued that ownership of a patent on a GMO human is akin to slavery, which is prohibited under the Thirteenth Amendment to the U.S. Constitution. See *intra*, n. 62, and more generally the Utility section herein.

PATENTABILITY

The U.S. Patent Act states that

> 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.[14]

This gives inventors a temporary monopoly on either the process of manufacturing the new invention, the product itself, or both. A process patent is weaker than a product (or, utility) patent because the former only gives a monopoly on the particular process outlined in the patent, whereas the latter provides a monopoly for the inventor on the creation of the invention itself, regardless of how it is produced. This is an important distinction because many inventions—pharmaceuticals for instance—are capable of being created in multiple ways. An invention that is deemed by the U.S. Patent & Trademark Office (PTO) to be sufficiently "new and useful" is often given a product patent, which covers not only the inventor's process of manufacturing the invention, but also covers other, alternative means of producing the invention. This precludes "knock-offs" that achieve the same result as, but are manufactured differently than, as the original drug.

Alternatively, a process patent may be given to an invention that does not by itself meet the "novelty" requirement, but its process of manufacture does:

> A patent may not be obtained…if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.[15]

That is, an invention that is deemed obvious—i.e., obvious to a person of "ordinary skill in the art"—is precluded from obtaining a patent on the product; however, it may still be eligible for a

[14] 35 USC 101.
[15] 35 USC 103 (a).

patent on the process for manufacturing said non-obvious invention, if the process is deemed novel and non-obvious. Discoveries and products of nature fall under the "obvious" umbrella, and are not considered eligible for product patents.

In real-life terms, process patents are considerably less valuable than product patents, because they do not prevent anyone from manufacturing the product itself—only the specific means outlined in the patent of producing it. That is, product patents protect the end result, whereas process patents protect only particular means of achieving the end result. For instance, a new pharmaceutical drug that is protected only by a process patent would be vulnerable to imitators that are produced using a modified process, but are otherwise identical in their final form. However, for a product patent, these same imitators would have to wait until the patent expires—and is therefore considered to be part of the public domain—to be released. Because the term of a patent lasts 20 years from the date of the application filing[16], receiving a product patent over a process patent is significant.

For much of the PTO's existence, the question of what was eligible for patentability was not in doubt. "Products of nature" were excluded because they were considered neither non-obvious nor manufactures. With advances in plant breeding came the 1930 Plant Patent Act[17] (PPA), which allowed for patents to

> Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.[18]

[16] 35 USC 154 (a)(2).
[17] 35 USC 161-164.
[18] *Id*. § 161.

Although this was meant to be more equitable to plant breeders, the limitation of patentability to asexually reproducing plants meant that "it is not the organism itself that receives review but the method of its creation."[19] That is, the process by which the plant was cultivated was more important than the end product.[20] It was not until 1970, when Congress passed the Plant Variety Protection Act[21] (PVPA), that sexually reproducing plants were eligible for patentability. (A major change with PVPA is that it is administered by the U.S. Department of Agriculture (USDA), not the PTO.[22] USDA can issue a "Certificate of Plant Variety Protection" that grants limited monopoly rights, which are similar but distinct from patents.[23] For instance, Certificate holders are required to license their technology, and may not exclude at will.[24] Furthermore, Certificates operate using a sort of fair use doctrine, where research on any certified plant negates exclusive protection.[25])

Both plant acts were important to the development of patent law in the U.S. because they opened the door to the possibility of patenting other forms of life. Indeed, the Acts make moot any claims that products of nature are excluded from patentability. However, it was not until the late-1970s that non-plant life forms became eligible.

LEGAL CHALLENGES

IN RE BERGY

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[19] Iwasaka, 109 Yale Law Journal 1514, 1999-2000.
[20] *Id*.
[21] 7 USC 2321-2582.
[22] Iwasaka, supra n. 18, at 1515.
[23] 7 USC 2483.
[24] *Id*. § 2404.
[25] *Id*. § 2544.

In re Bergy[26] was an appeal to the U.S. Court of Customs and Patent Appeals (CCPA) regarding the rejection of a claim in a patent application. The claim was for the microorganism Streptomyces vellosus, a biologically pure culture that did not exist in nature, and that was capable of producing certain antibiotics. Despite the fact that the appellants "cited a number of precedents for holding that a pure product could be patentable over a known impure product of similar kind,"[27] it was "rejected under 35 USC 101 as non-statutory subject matter,"[28] because it was a product of nature.

On appeal, CCPA overturned the rejection, writing that "since 35 U.S.C. 101 does not expressly exclude patents to living organisms, … living organisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute."[29] Noting that the biologically pure culture "is man-made and can be produced only under carefully controlled laboratory conditions,"[30] qualified it as a "manufacture" under the statute. Furthermore, the court noted the contradiction in application of the statute by the patent examiner, as "the statute makes no distinction between manufactures and compositions on the one hand and processes on the other. If the board is right in excluding products because there is life in them, then logic dictates that it should take the same position with regard to processes. But it does not do so."[31] That is, the position taken by opponents of patenting living organisms is that the organisms, as "products of nature," necessarily do not qualify for a product patent. Yet, the PTO has no difficulty in giving out process patents for living organisms. Thus, the characteristic of life is not in and of itself enough to negate a patent.

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[26] *In re* Bergy, 563 F.2d 1031 (U.S. Court of Customs and Patent Appeals, 1977).
[27] *Id*., at 1033.
[28] *Id*., at 1032.
[29] *Id*., at 1034.
[30] *Id*., at 1035.
[31] *Id*., at 1037.

Yet, however much progress in patent law came from *In re* Bergy, the decision was explicit in its desire to be seen as limited:

> We are not deciding whether living things in general, or, at most, whether any living things other than microorganisms, are within § 101. These questions must be decided on a case-by-case basis and anything said herein is to be taken as said in the context of a discussion of the subject matter of claim 5 and § 101. … The nature and commercial uses of biologically pure cultures of microorganisms…are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses.[32]

That is, In re Bergy was an important step in shifting the debate from the question of whether living things (*i.e.*, "of nature") were patentable to the question of whether they are "new and novel." Are they "manufactures"?

DIAMOND V. CHAKRABARTY

This question was answered more definitively in the landmark *Diamond v. Chakrabarty*[33] case, where it was held that "a live, human-made micro-organism is patentable subject matter under 35 USCS 101, such a micro-organism constituting a 'manufacture' or 'composition of matter' within the meaning of 101."[34] Chakrabarty, the inventor, "discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single … bacterium, which itself has no capacity for degrading oil."[35] Chakrabarty's patent made claims of three types: (1) process claims for the method of which the bacteria were produced; (2) claims on an inoculum "comprised of a carrier material floating on water, such as straw, and the new bacteria; and (3) claims on the bacteria.[36] Claims of the first

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[32] *Id*., at 1039.
[33] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
[34] *Id*.
[35] *Id*. at 305.
[36] *Id*. at 306.

two categories were accepted, but the patent examiner rejected the claims for the bacteria themselves, citing (1) that such organisms are "products of nature"; and (2) that 35 U.S.C. 101 excludes living things as patentable subject matter.[37]

This was the same rationale used by the PTO in rejecting the patent that brought the *In re* Bergy case, and as such the Supreme Court in Chakrabarty cited *In re* Bergy's decision that, for purposes of patent law, "the fact that microorganisms … are alive … [is] without legal significance."[38] Like in *Bergy*, the Court weighed more heavily the issue of whether living organisms constituted "manufactures" or "compositions of matter," rather than whether "products of nature," in and of themselves, are patentable subject matter. And like in *Bergy* (though extending it further), the Court favored a more expansive interpretation, and ruled that the key to patentability was the creation of something "new."[39] Meeting that requirement—no bacteria in nature contained the same four plasmids, nor the same functionality, as Chakrabarty's bacteria—the Court affirmed CCPA's reversal of the initial patent application rejection.

One of the dissents' main arguments against the decision was that 35 USC 101 does not explicitly allow for the patenting of living organisms. This is bolstered by the observation that Congress enacted two acts—the PPA and the PVPA—specifically to allow patent-like protection for plants. Addressing the first argument the Court noted, "a rule rendering unanticipated inventions unpatentable per se would conflict with the core concept of the patent law that

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[37] *Id*.
[38] *In re* Bergy, supra n. 25.
[39] The Court quoted from *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S., at 131 (1948), in rejecting a patent claim on bacteria: "Each species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infect. *No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility*. Each species has the same effect it always had. The bacteria perform in their natural way." [Emphasis added.]

anticipation undermines patentability."[40] Indeed, the statute is purposely vague in order to allow for as many inventions as possible—or, more specifically, to ensure that inventions are not prohibited by mistake. Congress itself even made explicit its intentions in this regard, as Committee Reports from the 1952 Patent Act revision cite "anything under the sun that is made by man" as subject for patentability.[41] With *Chakrabarty*, this now included genetically engineered bacteria that were not found in nature.

Addressing the second claim—that because Congress had enacted PPA and PVPA to allow for patent rights on plants—the Court noted House and Senate Reports, made during consideration of the 1930 PPA, which read:

> There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man. … On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature*, nor can it be reproduced by nature unaided by man*. …"[42] [Emphasis added.]

At this, the Court remarked that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[43] Indeed, the reason why sexually reproduced plants were initially excluded from patentability under the 1930 PPA was because plant breeding technology had not advanced to the point where "true-to-type" reproduction was possible.[44] Further, the Court noted that PTO had already granted patents for bacteria under § 101, which countered the suggestion that prior to PPA living

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[40] *Id*.
[41] S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).
[42] S. Rep. No. 315, 71st Cong., 2d Sess., at 6 (1930); H. R. Rep. No. 1129, 71st Cong., 2d Sess., at 7 (1930).
[43] *Chakrabarty*, supra n. 32, at 313.
[44] *Id*.

things were unpatentable.[45]

HARVARD V. CANADA (THE ONCOMOUSE)

[Note: although the focus of this paper is on U.S. patent law, the following Canadian case is included for analysis because of (1) its importance to the discussion of patentability of higher life forms; and (2) the similarities between U.S. and Canadian patent law. In all other sections, any mention of patent law will—unless otherwise noted—refer to the U.S. system.]

After *Chakrabarty*, the consensus in the U.S. was that higher life forms were now patentable. In 1988, Harvard College was granted a patent on what has become known as the oncomouse. Harvard developed a process whereby oncogenes—which make an organism susceptible to cancer, and thus valuable for laboratory research—were inserted into the genetic code of developing mice.[46] Despite the ruling in *Chakrabarty*, Harvard's patent was surprisingly not challenged in the U.S.; however, the patent ran into trouble upon application in Canada.

The Canadian patent examiner granted Harvard patents on the method of the genetic modification, but rejected patents on the transgenic mice themselves.[47] The Federal Court Trial Division (FTD) upheld the decisions of the patent examiner and commissioner, and ruled that "although the definition of 'invention' in the [Canadian] Patent Act had been previously extended to include lower life forms (e.g., yeast), it was inappropriate to stretch it even further to include higher life forms (e.g., transgenic animals) because of the level of control over the

[45] *Id*. at 314, n9: "In 1873, the Patent Office granted Louis Pasteur a patent on 'yeast, free from organic germs of disease, as an article of manufacture.' And in 1967 and 1968, immediately prior to the passage of the Plant Variety Protection Act, that Office granted two patents which, as the petitioner concedes, state claims for living micro-organisms."
[46] U.S. patent nos. 4,736,866 and 5,087,571.
[47] *Canadian Biotechnology Advisory Committee (CBAC) Advisory Memorandum: The Federal Court of Appeal's Decision Against the Commissioner of Patents on the Harvard Onco-mouse Case*. September 8, 2000, p. 1.

inventive subject matter."[48] That is, because higher life forms, by their nature, are complex and their entire compositions are less controllable than microorganisms, they cannot be considered to have been "manufactured."[49]

This became the dominant argument against patentability used by the majority in *Harvard*. Explaining the opinion of the FTD in upholding the original patent rejection, the opinion in *Harvard* noted that "[t]he presence of the [onco]gene only transfers with the natural rate of inheritance, the 'Mendelian ratio.' After the gene has been introduced, the gene passes with a normal breeding process. … [T]he respondent can make no claim to being able to reproduce the mammal at will by doing anything other than ordinary breeding."[50] Thus, the Court returned the question at hand to whether or not the organism is a "product of nature." Seen in this way, where the entirety of the organism must be controllable to be patented, then multicellular organisms indeed have a difficult time meeting the criteria for patentability. However, this may be overly restrictive. Indeed, as the dissenting opinion notes, there should be nothing intrinsic about using the "laws of nature" as to exclude an organism from patentability:

> Once it is acknowledged, as does the majority of this Court, that the fertilized, genetically altered oncomouse egg is an invention under the Patent Act, there is no basis in the statutory text to conclude that the resulting oncomouse, that grows from the patented egg, is not itself patentable because it is not an invention.[51]

Furthermore, other inventions, such as pharmaceuticals, make use of the "laws of nature":

> As to the contention that growth from a single fertilized cell to the complete mouse has nothing to do with the inventors and everything to do with the "laws of nature," it must be said that the "laws of nature" are an essential part of the working of many and probably most patented inventions. Pharmaceutical drugs utilize the normal bodily processes and functions of animals and humans are not

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[48] *Id*.
[49] *Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 2002 SCC 76 (CanLII)*, at para. 130.
[50] Id. at paras. 133-134.
[51] *Id*. at *A. Statutory Interpretation*.

> on that account regarded as less patentable. Medications, like the oncomouse, could not be brought into existence without reliance on the "laws of nature" in general and the processes of biochemistry in particular.[52]

Put another way, the modifying of the oncomouse's genome was "like adding a new and useful propeller to a ship."[53] Likewise, it matters not that the oncomouse has additional characteristics that may be unknown and unknowable after the oncogene has been inserted into the egg, because "[t]he utility of the invention has nothing to do with the length of the mouse's whiskers. Its value, in terms of the patent, appears to reside wholly in the oncogene."[54]

Similarly, Canada's Patent Act was "essentially taken from the United States *Patent Act* of 1793."[55] Despite the similarities in structure between the Canadian and U.S. Patent Acts, and the decision in *Chakrabarty* twenty-two years earlier, the Court in *Harvard* nonetheless ruled that higher life forms were not subject to patentability because such a power was not enumerated explicitly in the Patent Act,[56] largely mimicking the dissenting opinion in *Chakrabarty*. Yet, despite these similarities in structure between the two patent acts, *Chakrabarty* and *Harvard* were nonetheless decided quite differently—the former widening the scope of patentability, and the latter narrowing it. However, the *Harvard* decision was less a decisive blow against the conception of patenting higher life forms as it was an insistence by the Court to defer to Parliament.[57]

This call to deference in the opinion mirrored the call to deference from the Canadian

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[52] *Id*. at *C. The Line-Drawing Exercise*.
[53] *Id*. at para. 68.
[54] *Id*. at para. 84.
[55] *Id.*, at para. 4.
[56] "The current Act does not clearly indicate that higher life forms are patentable." *Id*.
[57] "Since patenting higher life forms would involve a radical departure from the traditional patent regime, and since the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues, clear and unequivocal legislation is required for higher life forms to be patentable." *Id*. at B. (1) The Words of the Act.

Biotechnology Advisory Committee (CBAC), which was commissioned in 2000 to write a memorandum on the recent Federal Court of Appeal's overturning of the Patent Commissioner's rejection of the Harvard oncomouse patent.[58] In the memorandum, CBAC advised that the Canadian government "stop the clock"—that is, halt patents on higher life forms—pending Parliamentary action.[59] While it is certainly true that in a democracy, a country's "laws must reflect the values [its citizens] share,"[60] and that a country's legislature—after listening to its constituents—ought to be tasked with writing into law appropriate statutes that reflect the country's will, the CBAC report and its recommendations did little to advance the issue of patentability of higher life forms past the limbo it resided in prior to *Harvard*. That is, despite CBAC's insistence that "Parliament, not the Courts, should determine Canada's policy with respect to patenting of higher life forms (and the distinction between 'lower' and 'higher' life forms),"[61] the fact of the matter is that Canada's Parliament punted on the issue for twenty years (and still counting) between the *Chakrabarty* decision in 1980 and the CBAC memorandum in 2000. Considering the similarities between U.S. and Canadian patent law, the granting to Harvard of a U.S. patent on its oncomouse in 1988, and Harvard's concurrent application for a Canadian patent on the oncomouse, it is impossible for Parliament to have been ignorant of the likelihood that it would one day be asked to rule on the issue of patentability of higher life forms. Ignoring the possibility of negligence, this refusal to act by Parliament—much like how the U.S. Congress has refused to act on the issue—can only be taken as an implicit acceptance of the legality of patenting such life forms.

Despite CBAC's and the Court's insistence to the contrary, Parliament has still to this

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[58] *CBAC*, supra., n. 46.
[59] *Id*. at p. 5.
[60] *Id*. at p. 4.
[61] *Id*.

day passed on legislating the issue of patentability of higher life forms. It is entirely reasonable to assume that Parliament may have ignored CBAC's calls because of the impending appeal of the *Harvard* case to the Canadian Supreme Court; its continued ignoring of the issue may certainly now be an acceptance of the Court's decision. This is perhaps a dereliction of duty by the respective legislatures of the United States and Canada, but it is not an unexpected one given the long history of ignoring this issue.

Yet, the CBAC recommendation also ignores the fundamental role of the judiciary in the U.S. and Canadian systems of government: namely, interpreting laws. The Patent Act was construed broadly so as not to prohibit unnecessarily applications that met the requirements. Forcing the legislature to amend laws every time a tough decision comes up is inefficient, however constitutional. Instead, legislatures ought to be free to react as they may (or may not, as the case is), but "stopping the clock" would be tantamount to preemptively negating the judiciary's Constitutional role.

Regardless, *Chakrabarty* and *Harvard* decisions currently remain standing in the U.S. and Canada, respectively, and define the limits of patentability of life there. Considering the reluctance by the respective legislatures to address the issue, it is unlikely that either legislature will readily do so in the future, until and unless another difficult biotechnology issue arises. However, because of the volatile nature of the issues, it is still more likely than not that the legislatures will continue to pass on acting, content to follow the decision of the judiciary and leaving the language of the Patent Act as is.

PHILOSOPHY

UTILITY

The utility of a patent is largely the determining factor in its patentability (it is unsurprising, then, that product patents are also known as "utility" patents). As stated above, the U.S. Patent Act notes that patents may be issued to "any new and useful" invention or improvement.[62] In the U.S. Constitution, Congress is empowered to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[63] Taken together, these show the strong consequentialist current that runs through the U.S. patent system. By noting first that an invention must first be "useful," and that Congress is empowered to "promote the progress of science and useful arts," it is clear that the purpose of granting patents is to raise utility—specifically, to advance the "progress of science and the useful arts" in a way that gives society a net benefit. That is, the granting of a short-term negative (a monopoly over an invention) will result in greater positives ("progress") because of the public disclosure of the patented invention, and the ability to profit during a period of exclusivity will motivate investment and innovation.

This is the *quid pro quo* that is at the heart of intellectual property laws. Thus, in terms of granting patents, deontology matters little. Deontology (or Kantianism) is concerned with the nature of duties and obligation, with consequences to actions largely ignored.[64] In terms of patent law as written, duties hold some import—anything illegal is exempt from patentability—but are otherwise inconsequential.[65] Yet, there are very real concerns (and imagined myths)

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[62] 35 USC 101, supra n. 13.
[63] Article 1, § 8, Clause 8, U.S. Constitution.
[64] See generally Kant, Immanuel, Groundwork of the Metaphysics of Morals, Cambridge University Press: 1997.
[65] *Id*.

about how patent law as written can be exploited today, and whether it is able to deal adequately with ethical issues of modern technology.

One such issue that misunderstands patent law is the question of ownership of a living organism. That is, a popular cry against patenting GMOs, especially those with some human genes, is that it is tantamount to slavery. Yet, this is not only factually inaccurate, but also misleading. The owning of human beings is prohibited under the Thirteenth Amendment to the U.S. Constitution[66]; by itself, this renders ineligible for patentability anything that is construed as "slavery." Noting this, the Office of Technology Assessment (OTA) has ruled that patent "claims directed to or including a human being will not be considered."[67] This buys into the frame that owning a patent is equivalent to, say, owning a ladder or some other physical object. This is not a valid comparison, as "owning" a patent does not necessarily entail hoarding an object or keeping it in your possession, as you would a ladder. Admittedly, this does not address the question of whether human-animal hybrids or human embryos are patentable subject matter (these will be addressed later), because embryos and hybrids are not constitutionally recognized as human beings.

Yet for the immediate question of whether, *e.g.*, a cloned human is patentable, the answer is simply that "ownership" of intellectual property is not akin to ownership of an actual object:

> Patents do not confer ownership of the thing patented. No particular thing or class of things belongs to a patentee by virtue of her patent. If a person owns a bicycle then a particular bicycle belongs to her, but if a person has a patent on a bicycle, it is entirely possible that no bicycles belong to her. It is not the case that all bicycles covered by the patent belong to her. … Analyses of the ethics of patenting should examine whether the right to exclude which is conferred by patents undermines other rights, conflicts with particular interests, conflicts with

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[66] U.S. Constitution, Amendment XIII, § 1. "Neither slavery nor involuntary servitude … shall exist within the United States…."

[67] Office of Technology Assessment, U.S. Congress, Pub. No. OTA-BA-370, New Developments in Biotechnology: Patenting Life – Special Report, 93 (1989).

> important values, or interferes with utility maximization.[68]

Indeed. Despite the fact that Harvard's patent on the oncomouse is titled "Transgenic non-human mammals,"[69] it is not the case that "Harvard owns *any mammal* with *any recombinant cancer-causing gene*"[70] (emphasis in original). Rather, Harvard's patent gives them monopoly rights on not only the process by which the oncomice were created, but also rights to exclude others from bringing the same invention into the market:

> To say that a biotechnology firm has a patent on, for example, a gene that causes breast cancer is to say that the firm has a patent on the gene *type* and can get legal protection for, say, a diagnostic test that can identify who has the gene. It is not to say that the firm has a property right in all *tokens* of that type, such that individual who have the gene are somehow committing patent infringement"[71] (emphasis in original).

This last point is especially important in understanding what ownership of a gene or a GMO entails. Furthermore, "[p]atents on human DNA cannot be used to exclude a person from 'using' her own DNA—they do not prevent a person from replicating new cells or having children."[72] The issue, then, is wholly different from physical ownership of an object or an organism. Digging deeper, there is the issue of respect for life (or personhood)—a fundamentally deontological concept—underlying criticisms of patenting life.

BIOCENTRISM AND DEONTOLOGICAL CRITICISMS

Behind the deontological criticisms of patenting living organisms is the concept of biocentrism,

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[68] Ossorio, Pilar. *Legal and Ethical Issues in Biotechnology Patenting*. A Companion to Genethics. Burley, Justine and Harris, John (eds.). Blackwell Publishing: New York. 2002, p. 411.
[69] U.S. patent no. 4,736,866.
[70] Hettinger, Ned. *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, 22 Boston College Environmental Affairs Law Review 267 (1995), at 277.
[71] Munzer, Stephen R. *Property, Patents, and Genetic Material*. A Companion to Genethics. Burley, Justine and Harris, John (eds.). Blackwell Publishing: New York. 2002, p. 441.
[72] Ossorio, *supra*, n. 67, at p. 412.

which "holds that all living beings possess morally-considerable interests that we ought to respect."[73] Thus, all living beings—regardless of sentience—qualify for, and demand, respect. That is, "living beings possess goods of their own or welfare interests, and thus may be benefited or harmed without reference to the good of any other being. For example, crushing the roots of a tree with a bulldozer harms the tree itself; this is a setback for the tree's welfare and is not bad simply for the interests of the homeowner who wants the tree's shade."[74] To put this particular argument into a more Kantian vein, even a tree is an end in itself, and must be treated as such, rather than be treated as merely a means to a particular end—for example, creating shade for a homeowner.

Biocentrism here is somewhat at odds with the concept of species interests, which will be discussed below. Suffice it to say, biocentrism is on the far end of the continuum of respecting animal rights versus ignoring animal rights; this is no criticism of animal rights *per se*, but rather to note that taking interests of sentient being into account, rather than this advocacy for the rights of anything living—disregarding sentience—is a much more moderate proposal. It will be discussed later, in the Gene Migration section.

Looking at patent law through a lens of biocentrism inextricably leads one to the conclusion that multicellular—and perhaps even monocellular—organisms ought to be precluded from patentability. Or, rather, that if patents are to be issued, then the "true" owner of the genetic data ought to own the patent. Thus, John Moore—a patient whose leukemia-infected spleen was removed and subsequently patented by the university-run hospital[75]—would be the "true" owner of the patent of the pharmaceutical that was derived from his spleen. Further,

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[73] Hettinger, *supra*, n. 69, at 281.
[74] *Id*., at 282.
[75] *Moore v. Regents of the University of California*, 793 P.2d 479, 488-93, 271 Cal. Rptr. 146 (Cal. 1990).

"[t]he DNA in a bacterial cell naturally belongs to that bacterium and not to the researcher; the trunk of a tree is something to which the tree, not the lumber company, is naturally entitled; the calf, not the rancher, naturally owns the flesh of its body."[76] Similarly, "the proper functioning of the system that allows a tobacco plant to glow in the dark—after a firefly gene has been inserted into it—does not specify the plant's own good."[77] This echoes Kantian sentiments that organisms must be ends in and of themselves, rather than a "utilitarian artifact," or a means to an end:

> Animals who feel pain and possess preferences are clearly not mere resources to which people may be naturally entitled. To conceptualize a sentient animal as a mere resource would be to conceive of it as morally analogous to a utilitarian artifact. On this view, the moral issues involved when a neighbor pounds his pet dog with a hammer are the same as when he pounds his step ladder with a hammer.[78]

It is undoubtedly true that sentient beings deserve to have their rights recognized, but it is perhaps unfair to compare beating a dog as morally equivalent to hammering a ladder. This speaks to the deontological/utilitarian divide that is at the center of many bioethics debates: on the one hand, if sentient (or, sometimes even non-sentient) animals are given equal consideration, then research on them is neigh-indefensible; however, if attempts are made to minimize pain and suffering, and the research may lead to important medical breakthroughs that would otherwise not happen without animal research, then the research may be legitimate. Yet, this issue is moot for the purposes of this paper, as the real question concerns—accepting animal testing and research as unavoidable and perhaps even necessary—whether the issuance of patents on the biotechnology products is ethical.

Taking a utilitarian tact, I argue that it is. As explained above, patent law in the U.S. has

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[76] Hettinger, supra, n. 69, at 281.
[77] *Id*., at 282.
[78] *Id*., at 285.

always been consequentialist in nature, favoring the "progress of science and useful arts"[79] over most other concerns. That is, the potential benefits of a breakthrough in cancer research stemming from the oncomouse, in my calculus, far outweighs the negatives from using the oncomice as means to an end. A more pertinent question for the consequentialist, then, is how much pain and suffering are the research animals subject to? Unfortunately, and this is a valid criticism of utilitarianism, there is no bright-line ruling, where on one side it is too much pain and suffering, and on the other it is an acceptable level. Indeed, "a major use of animal biotechnology involves the deliberate production of diseased animals,"[80] and "[b]iopatents are certainly not a mechanism for insuring that biotechnology leads to overall decrease in suffering."[81] Yet, this implies that patents are the cause of such suffering, when in reality patents are just a byproduct of the research that causes the suffering. That is, "[w]hile the oncomouse is deliberately designed to grow painful malignant tumours, animals will continue to be used in laboratories for scientific research whether patented or not."[82] Furthermore, "[p]atentability addresses only the issue of rewarding the inventors for their *disclosure* of what they have done"[83] (emphasis in original). In fact, patent law has no bearing on whether or not the research will continue; however, patent law more strongly encourages utilitarian research (to promote the progress of science). Further, measures can be taken to help ensure that the animals' pain and suffering is minimized to where it is at an "acceptable" level.

A few criticisms of biotechnology patents arise from consequentialist concerns, including the unjust enrichment of the patent holders, migration of genes, and harms to the environment.

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[79] U.S. Constitution, *supra*, n. 50.
[80] Hettinger, *supra*, n. 69, at 297.
[81] *Id*., at 298.
[82] *Harvard*, *supra*., n. 48, at (4) E. Other Objections.
[83] *Id*., at para. 103.

They will each be considered in turn.

CONCERNS WITH PATENTABILITY

UNJUST ENRICHMENT

This often returns us to the issue of whether "natural" products—albeit perhaps with some modification—are subject to patentability. The oncomouse is, after all, just a mouse whose DNA has been modified to make it more susceptible to cancer. One can make the argument that while Harvard ought to be granted a patent on the process by which the mouse's DNA is modified, it ought not be granted a patent on the organism itself, which, in theory, could be found in nature. That is, is the oncomouse not facially identical to a "normal" mouse that contracts cancer?

In a similar vein, an applicant in 1941 sought a patent for not only a process to remove the head and sand vein of shrimp, but also on the byproduct itself: headless and veinless shrimp.[84] Despite the acknowledgement that such headless and veinless shrimp do not occur in nature, the court ruled nonetheless that they were still products of nature. What is it about headless and veinless shrimp, or pure tungsten—neither of which occurs naturally—that renders them unpatentable?[85] The thinking seems to be that, although such shrimp or refined metals are, essentially, "unnatural," they are derived from something natural, and therefore are not the "products" of man. Thus, man may claim no ownership or credit for the "invention." Therefore, to grant a patent for such a product—and in so doing give monopoly rights to the patent holder—is to unjustly enrich the patent holder for something that he merely "discovered" from nature. That is, "[w]hy should Harvard appropriate to itself the whole value attributable to the 'platform'

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[84] *Ex parte Grayson*, 51 U.S.P.Q. (BNA) 413 (PTO Bd. App. 1941).
[85] Sagoff, Mark. *Are Genes Inventions?* A Companion to Genethics. Burley, Justine and Harris, John (eds.). Blackwell Publishing: New York. 2002, p. 424.

when all it contributed is an improvement to that platform?"[86]

A similar argument is made against patenting genes themselves: that because DNA is derived from a living organism, it therefore is a "product of nature." This is true in a sense, because genes still in our cells, unmodified, cannot be said to be inventions because no work has been done on them. In this regard, "natural" genes can be thought to be "products of nature," or discoveries, and therefore are unpatentable. Yet, this line of reasoning misses the crucial point that genes and DNA lines that today are being patented *are* modified, and isolated from their original cells. That is,

> Purified and isolated genes, however, are quite patentable, because they are chemicals, or in the patent vernacular, compositions of matter. Purified and isolated compositions of matter have been patentable for more than 100 years. For example, insulin isolated and purified from blood is patentable, as is recombinant insulin, made from human genes. Isolated and purified genetic materials differ from nongenetic compositions of matter only in their source of raw material, and the source is irrelevant for the purposes of U.S. patent law.[87]

That is, if we think about genes as simply the chemicals that they are composed of, it is easier to understand how analogous they are to other, patentable chemicals.

Further, the argument against headless and veinless shrimp is about what are perceived as frivolous patents—what do not, in some eyes, make progress—not against whether patenting GMOs *per se* is ethical. After all, "[t]he inventor of the frisbee [sic]…would also, no doubt, be thought by some critics to have been excessively rewarded."[88] Indeed, an argument can be made that even the Frisbee is a "product of nature" in that it is a natural shape (circle), and has physical properties akin to natural entities. Further, it is unclear what advances to science the Frisbee makes; yet there are no arguments that it ought not to have been patented. Yet, even if the

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[86] Harvard, *supra*, n. 48, at para. 94.
[87] Merz, J.F. Some thoughts on *Chakrabarty*. Penn Bioethics, 9(4):3, 2002.
[88] *Id*., at para. 95.

oncomouse is considered a "discovery," it does not necessarily follow that it still ought not be subject to patentability:

> It is usually said that one cannot patent laws of nature, such as $F=ma$ or $E=mc^2$. … Still, the DNA sequence of a gene is not a law of nature—at least not in the same sense that $F=ma$ or $E=mc^2$ is a law of nature. The DNA sequence is, rather, a partial description of the structure of a complicated molecule, and in that respect is like the structural formulae for glyburide and paclitaxel in pharmaceutical chemistry."[89]

Absent strong legislation to ban genetic research that may lead to patents—and it is my opinion that such a ban, unfeasible to begin with, would prove to undermine science and prevent important breakthroughs and cures—the genie is out of the bottle, so to speak, and genetic research of the kind that led to the oncomouse will continue apace. Thus, to limit or prohibit patentability on GMOs like the oncomouse will do nothing to prevent their construction:

> If the claim for the patent on the oncomouse itself is refused, the result will *not* be that Harvard is denied the opportunity to make, construct, use and sell the oncomouse. On the contrary, the result will be that *anyone* will be able to make, construct, use and sell the oncomouse. The only difference will be that Harvard will be denied the *quid pro quo* for the disclosure of its invention.[90] (emphasis in original)

And if patents on GMOs are revoked or prohibited, it will simply lead to stronger and more counterproductive measures on behalf of the researchers to protect their intellectual property—namely, trade secrets. Like the name implies, trade secrets are held secret from others, and offer no *quid pro quo* of protection in exchange for disclosure. Thus, bereft of patentability for GMOs, researchers would likely file for trade secrets on their inventions, and, like Coca-Cola, the formula for the creation of such GMOs—and with it, the open disclosure of information that others may build on, to "progress" science—will remain hidden. From an utilitarian/consequentialist perspective, this is fundamentally counter to the expressed goal of

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[89] Munzer, *supra*, n. 70, at 442.
[90] *Harvard, supra,* n. 48, at para. 100.

patent law, and is therefore unpalatable.

GENE MIGRATION

A second legitimate consequentialist concern is the migration of genes outside of GMOs.[91] Problems arise with bioengineering in regards to keeping the engineered genes "caged" in to the GMO, and to prevent the genes from "escaping" into the wild. The migration of altered DNA has as a strong negative side effect the potential to harm ecosystems, by introducing organisms that are perhaps evolutionarily stronger than their "natural" brethren as a result of the bioengineering. That is, if a fish that were genetically engineering to be forty percent larger was introduced into the same ecosystem as the non-genetically engineering fish, the larger GMO would likely have an evolutionary advantage over the other, smaller fish, and would be able to dominate them for food.[92] Yet, like with many of the arguments against bioengineering, this has little to do with patent law. While it is undoubtedly true that ecosystem balance is an important issues, the introduction into ecosystems of evolutionarily superior GMOs has nothing to do with whether such GMOs ought to be subject to patentability. Indeed, this issue also crops up in cross- and selective breeding, and even when "natural" foreign animals are introduced into a new ecosystem.[93]

Ironically, bioengineering may actually hold an answer to this concern in that GMOs can be engineered to be sterile, and thus incapable of breeding outside of a laboratory. Yet, while

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[91] Hettinger, *supra*, n. 69, at 300.
[92] *Id*.
[93] See Fahrenthold, David A. and Partlow, Joshua, "Snakeheads May Be Making Home in Potomac," Washington Post, June 30, 2004 (http://www.washingtonpost.com/wp-dyn/articles/A16016-2004Jun29.html). The northern snakehead, an Asian fish that found its way into the Potomac near Washington, DC after being released, posed a direct threat to the ecosystem because it had no natural predators in the Potomac.

this would be a positive solution to the problem of GMOs being released into the wild and having their altered DNA get into the general gene pool, creating sterile GMOs would pose at least two problems: (1) the cost to produce them, solely from a laboratory, is currently prohibitive; and (2) it would "prohibit farmers from the common practice of saving and using seeds from previous crops or from breeding animals."[94] As to the first problem, this also has little to do with the ethics of biotech patents. If such a solution were undertaken, the costs would likely be transferred onto the consumer—and while this in itself may be a tactic of dubious worth, it is facially no different than the high cost of prescription pharmaceuticals that companies pass along to consumers to defer the cost of research and development. The second issue is more problematic, in that sterile GMOs would "squeeze small farmers and increase the power and wealth of giant agribusinesses who are likely to own the new biopatents."[95]

The consequences of "squeezing" smaller farmers out of the industry by virtue of their inability to afford to purchase new crops and animals with each generation is legitimate, as the disappearance from the agriculture industry by everyone but a few large farmers would ensure long-term monopolies, rather than the short-term monopolies given to patent holders. To combat this, however, a sort of fair use doctrine could be instituted in order to protect smaller farmers from the prohibitive costs of buying "new" crops and animals with each generation, or by allowing smaller farmer a fair use license to breed successive generations of such GMOs, if they are not made inherently sterile. Such a fair use standard exists with regard to plant research[96], and it would be easy enough to apply it to small farmers, and others deemed eligible.

Interestingly, another way of looking at this issue is the problem that biopatents pose for

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[94] Hettinger, *supra*, n. 69, at 278.
[95] *Id*., at 301.
[96] See the discussion about Certificates above, in the *Patentability* section. More generally, see 7 USC 2544.

patent holders—namely, the difficulty in enforcing the monopoly. It is easy enough for Boeing to maintain its patent monopolies on airplane parts because an infringer would have to proactively go out of his way to replicate, or pirate, such a part. However, living organisms are naturally able to reproduce; if any oncomice were to escape from a laboratory, they would likely reproduce on their own, thus "violating" the patent holder's monopoly rights.[97] Thus, holders of biopatents have a vested interest in prohibiting their patented GMOs from breeding, or letting others breed them. This likely would lead to patent holders either creating licensing deals with purchasers—stipulating how the purchasers may use (and potentially breed) the GMOs[98]—or engineering into GMOs a way to block reproduction, like, as mentioned above, GM crops are often made sterile—thus forcing farmers to continuously buy new seeds for each generation.

While it is undoubtedly true that "if DuPont sold oncomules, they would not have to worry about restrictive licenses"[99] because of the mules' sterility, deliberately generating sterile GMOs is, from a consequentialist perspective, questionable for at least two reasons. The first is that although a patent will expire twenty years after its application is submitted, a line of GMOs that is engineered to be sterile will last forever, potentially longer than the length of the patent. That is, even after the patent expires and the GMO enters the public domain, the general public's access to the GMO will still be restricted by virtue of the fact that the GMOs must still be created in a lab somewhere, instead of allowing anyone to breed them. This gives undue power and influence to patent holders, and creates *de facto* permanent monopolies.

The second issue to make a consequentialist uneasy is that engineering GMOs to be sterile

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[97] Merz, supra, n. 86, at p. 4.
[98] *Id*., at p. 3.
[99] *Id*., at p. 4.

would likely violate the organisms' interests.[100] That is, sentient organisms are able to feel pleasure and pain of varying degrees. These sensations constitute their interests: they are inclined to want to seek pleasure and avoid pain. It may be said that the natural desire to reproduce is a type of pleasure, or at least that the prohibition on reproducing is a type of pain. This is undoubtedly true when considering humans, as castration and forced sterility are seen as barbaric punishments because of the physical and psychological pain they inflict. Even if we grant that non-human organisms feel less pain than humans at being sterilized, it is clearly against the organisms' interests to be prohibited from reproducing. This, along with the questionable big-business threat of squeezing out the small farmer, ought to give consequentialists pause.

ENVIRONMENTAL HARM

As mentioned above, the escape into the wild of GMOs would potentially pose dire hazards to ecosystems that are unable to cope with the new "super organisms." Similarly, it is always possible for a GMO to escape captivity and migrate into the wild, no matter how good a cage it might be in. This is especially true for plants, for which research has shown that "crops can readily mate with related weeds over a thousand yards away."[101] Similarly, genetically altered animals could always escape into the wild, and wreck ecosystems or interbreed with the "normal" animals. These are serious concerns, but, like with many of the other issues presented in this paper, have little to do with patenting *per se*, and more to do with concerns about bioengineering.

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[100] See generally Singer, Peter. *All Animals Are Equal,* Animal Rights and Human Obligations. Regan, Tom & Singer, Peter (eds.) New Jersey: Prentice-Hall, 1989, pp. 148-162.

[101] Ellstrand, Norman, *How Ya Gonna Keep Transgenes Down on the Farm?* The Amicus Journal, Spring 1993, at 31.

Potential solutions to this problem are, as mentioned above, engineering GMOs to be sterile, or, alternatively, engineer in them a reproduction-blocker that is lifted only with doses of a serum in a laboratory setting. In a laboratory, the serum would allow GMOs to breed, but in the wild, without the serum, the GMOs would revert to sterility. Of course, this poses in itself ethical issues about harm to the animals, and their suffering if they are made to be "unnaturally" sterile. I make no endorsement for or against any of these solutions, but rather offer them as rejoinders to the problem of escaping DNA.

CONCLUSION

Since *In re* Bergy first opened the doors to patenting living organisms, with *Chakrabarty* following in its footsteps, patent law has struggled to adapt to change. Congress in the U.S. and Parliament in Canada have been neigh-derelict in their duties to respond to such an important and controversial issue, instead standing silent as the courts attempt to translate intellectual property laws that are over one hundred years old into something that makes sense in today's technological landscape. The legislatures perhaps are content to leave the issue up to the courts—after all, if they take no action, they have no record for which an opponent may run against—but the silence from the legislatures only strengthens the controversy. Instead of finding and enacting laws that represent a consensus among the population (or as much of one as there can be), what in fact is happening is both sides of the issue are digging in and holding ground, each claiming to represent a majority, and neither getting anywhere.

This represents the perhaps intractable nature of patenting GMOs (or life, more generally), and the political discourse mimics the philosophical. Consequentialist theory is, in

my view, more appealing and answers better the difficult questions raised by patenting life. However, it is not without its flaws, which deontologists are quick—and sometimes accurate—to point out. Yet, no philosophical theory is perfect, nor does any ever answer satisfactorily all questions. As relates to patent law, a pragmatic consequentialism is better able than deontology to deal with the difficult issues, and indeed U.S. patent law (and U.S. law in general) has long relied to consequentialist theory to shape and mold laws. A radical shift away from this precedent would be damaging to patent law, and would undermine the authority of courts in interpreting law.

Genetic engineering and cloning are undoubtedly controversial issues, as recent polls have shown, and they are issues that are unlikely to be resolved completely in the near future. And indeed, the court rulings that opened up patentability to living organisms may have in fact exacerbated things. Yet, there appears to be a softening of the uneasiness among the general populace with the concept of GMOs in and of themselves: if niche products like the Omega-3 pig are able to take off and become popular—perhaps, ironically, competing against organic food for the health market—then clearly the general populace agrees on principle with consequentialism, and will buy products that are "beneficial," even if it means holding their noses while they eat the pork. This is far from decided, and the technology behind GMOs still has not been tested enough to convince most people of its safety and accuracy. However, progress on the public relations front is being made, and often, simply giving people more information is enough to make them rethink their views on seemingly intractable issues. Whether this shift is actually happening, or if it is merely a mirage, is yet to be known. But it is not inconceivable that in the near future we will have GMO-food stores to compete with health-food stores; and headless

Frankenpet chickens competing for top dollar against free-range. This is perhaps a nightmare, horror-film scenario, but just because Hollywood might imagine it, does that *necessarily* make it wrong?

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1. 35 USC 101.
2. 7 USC 2321-2582.
3. Amendment XIII, § 1, U.S. Constitution.
4. Article 1, § 8, Clause 8, U.S. Constitution.
5. S. Rep. No. 315, 71st Cong., 2d Sess., at 6 (1930); H. R. Rep. No. 1129, 71st Cong., 2d Sess., at 7 (1930).
6. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).