Creating Life from Scratch: The Patentability of Synthetic Organisms

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I. INTRODUCTION

Published in May 2007, U.S. application no. 20070122826 (Venter patent) describes a minimally operative genome of the bacterium *Mycoplasma genitalium* consisting of 381 genes, which the inventors believe to be essential for the survival of the bacterium in an environment containing all the necessary nutrients and free from stress.[1] However, the team of inventors from the J. Craig Venter Institute is trying to accomplish something more than just the usual patenting of genes; they intend to create and patent the world's first artificial organism.

The team has already cleared two of the three major hurdles on its way to constructing this first synthetic organism. In January 2008, they announced completion of the second step, the laboratory synthesis of the entire 582,970 base pairs of the genome described in the patent above.[2] What remains is the third and final step of inserting this human-made genome into a bacterial cell chassis and "booting up" the organism.[3]

Craig Venter and Hamilton Smith, lead researchers on the team have been discussing the creation of synthetic life since 1995, when their team published the first complete genome sequence of a living

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1. U.S. Patent No. 2,007,122,826 (filed Oct. 12, 2006). U.S. Patent Appl. No. 2,007,122,826 (filed Oct. 12, 2006).

2. Roger Highfield, Artificial Life Being Created, Telegraph, (Jan. 24, 2008), http://www.telegraph.co.uk/earth/main.jhtml;j?xml=/earth/2008/01/24/sciventer124.xml.

3. *Id.*

organism.[4] Dr. Venter is perhaps best known for his involvement in the human genome project and for being the first to sequence the entire genome of a single person.[5] His institute's effort is part of a larger and growing field called synthetic biology, which "takes as its mission the construction, and 'reconstruction,' of life at the genetic level."[6]

As Sapna Kumar and Arti Rai have recently written regarding the field: "[t]he scale and ambition of synthetic biology go well beyond traditional recombinant DNA technology. Rather than simply transferring a preexisting gene from one species to another, synthetic biologists aim to make biology a true engineering discipline."[7] Moreover, they explain:

> The possibility of low-cost production of "green" fuels such as cellulosic ethanol has particularly caught the attention of prominent venture capitalists. Even more apparently whimsical applications, such as programming bacteria to take photographs or to form visible patterns may be useful for detection of environmental pollutants. Similarly, programming cells to implement digital logic could have large numbers of medical and computational applications.[8]

While only one part of the larger field of synthetic biology involves the creation of wholly synthetic organisms, Craig Venter's goals and those of other synthetic biologists have reinvigorated the debate over the morality of patenting life.[9] This controversy extends back most notably to the United States Supreme Court ruling in *Diamond v. Chakrabarty* and the debate over the patenting of the Harvard Oncomouse in Europe and Canada.[10]

It is therefore reasonable to think that with the growth of the field of synthetic biology and the imminent creation of artificial life, ethical questions, similar to those raised in *Chakrabarty* and with the Harvard Oncomouse, will be raised again. In order to properly evaluate how courts will approach the new ethical considerations accompanying the

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4. *See Nearly There*, ECONOMIST, June 26, 2008, at 76.

5. *See Patent Pending*, ECONOMIST, Jan. 16, 2007, at 76.

6. Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1745 (2007).

7. *Id.*

8. *Id.* at 1756.

9. *See* Venter Institute Builds Longest Sequence of Synthetic DNA (That Doesn't Work), ETC Group (Jan. 24, 2008), http://www.etcgroup.org/upload/publication/pdf_file/670.

10. Diamond v. Chakrabarty, 447 U.S. 303 (1980); Harvard College v. Canada (Comm'r of Patents), [2002] 4 S.C.R. 45 (Can.); Case T315/03, Harvard/Transgenic Animal, [2005] E.P.O.R. 271 (Technical Bd. App. 2004), *available at* http://legal.european-patent-office.org/dg3/pdf/t030315ex1.pdf.].

patenting of synthetic organisms, this Comment will survey these past decisions.

First this Comment will review the Supreme Court decision leading to the patenting of Chakrabarty's bacterium in the United States. Next it will similarly review the decisions leading to the patenting of the Harvard Oncomouse in the United States and European Union (applying rule 6.1(b) by analogy) and the denial of that patent in Canada. Then it will examine the ethical implications of synthetic biology and the Venter patent through the lens of these controversies and make predictions for the future.

II. PATENTING MICROBIAL LIFE—CHAKRABARTY

In the early 1970s, Ananda Mohan Chakrabarty developed a bacterium that could digest crude oil, an ability no naturally occurring bacterium possessed.[11] Specifically, the invention was "a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway."[12] Chakrabarty's invention inserts two different plasmids into the *Pseudomonas* bacterium, one that confers the ability to breakdown camphor and another which breaks down octane; both of which are major parts in crude oil production.[13]

Plasmids are small circular double-strands of DNA that are commonly found within bacterial cells and which often bestow selective advantages to their holders.[14] In nature bacteria often replicate and transfer plasmids between one another as a means of sharing beneficial traits.[15]

In 1972, Chakrabarty filed his patent application in the United States, assigning the invention to his employer General Electric.[16] In his application he filed three types of claims: (1) a process claim for the method of creating the new genetically modified bacterium, (2) "claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria," and (3) claims to the living bacterium itself.[17]

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11. *See Chakrabarty*, 447 U.S. at 305.
12. *Id.* (citing U.S. Patent No. 4,259,444 (filed June 7, 1972).
13. *See id.* at 305 n.1.
14. *See* Plasmid, http://dictionary.reference.com/browse/plasmid (last visited Sept. 13, 2008).
15. *See id.*
16. *Chakrabarty*, 447 U.S. at 305.
17. *Id.* at 305-06.

The patent examiner granted the first two types of Chakrabarty's claims, but rejected the third, stating "1) that micro-organisms are 'products of nature,' and 2) that as living things they are not patentable subject matter under 35 U.S.C. § 101."[18] Chakrabarty then appealed the rejection of his third set of claims to the Board of Patent Appeals, which upheld the rejection by the examiner on the basis that living things are not patentable subject matter.[19] But notably, the Board of Patent Appeals rejected the reasoning of the examiner that the micro-organisms were "products of nature" because *Pseudomonas* bacteria containing the crude-oil digesting plasmids did not naturally occur.[20]

Chakrabarty then appealed again, this time to the Court of Customs and Patent Appeals, which, by a divided vote, overturned the judgment of the Board of Patent Appeals relying on its recent opinion in *In re Bergy* wherein the court stated: "'the fact that microorganisms . . . are alive . . . [is] without legal significance' for purposes of the patent law."[21] Commissioner Diamond of the Patent and Trademarks Office then sought and was granted certiorari with the Supreme Court.[22]

In a landmark decision, the Supreme Court upheld the judgment of the Court of Customs and Patent Appeals, interpreting 35 U.S.C. § 101 very broadly and finding that microorganisms fit within the definition of a "manufacture" and "composition of matter" for purposes of the Patent Act.[23] The Court then famously followed the language of the Committee Reports accompanying the 1952 Patent Act (drafted before the age of genetic engineering) where it was declared that section 101 was meant to "include anything under the sun that is made by man.[24]

The court made clear that this does not mean that section 101 has no limits, but rather that those limits are not drawn between living and nonliving matter.[25] They reiterated that "laws of nature, physical phenomena, and abstract ideas" are not patentable.[26]

The court then rejected both of Commissioner Diamond's primary arguments against patentability.[27] The commissioner first contended that

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18. *Id.* at 306.
19. *Id.*
20. *Id.* at 307 n.3.
21. *Id.* at 306 (citing *In re* Bergy, 563 F.2d 1031, 1038 (C.C.P.A. 1977).
22. *See Chakrabarty*, 447 U.S. at 307.
23. *Id.* at 308.
24. *Id.* at 309.
25. *See id.*
26. *Id.* (citing Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.").
27 *See id.* at 310.

Congress did not intend for living organisms to be patentable under section 101 because it felt it necessary to create the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act (PVPA), "which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection."[28] Therefore, according to the commissioner, if Congress had intended section 101 to include living matter, the PVPA would have been unnecessary.

The court rejected this argument, reasoning that the PPA and the PVPA were thought by Congress to be necessary not because plants are living subject matter, but because (1) bred plants, though artificially fertilized, were thought to be "products of nature" (and, as the Board of Patent appeals noted above, Chakrabarty's bacterium is not); and (2) because it would be very difficult for patentees to satisfy the written description requirement when patenting plants under the normal filing methods.[29]

Reasoning in the negative, the court instead articulated that that section 101 was meant to include living subject matter because there were two other justifications for the creation of the PVPA and PPA and because there was no mention in the legislative record that they were being created because section 101 was not meant to include living subject matter.[30]

In the United States, *Chakrabarty* is still followed and patents on living organisms, including multicellular ones, continue to be regularly granted due to the broad language of the *Chakrabarty* decision.[31]

The European Union has largely adopted the *Chakrabarty* standard for the patenting of genetically engineered bacteria, and presently, the E.U. Directive expressly allows for the patenting of plants and animals, but not animal varieties.[32] However, unlike the United States, member nations of the European Patent Convention (EPC) consider questions of morality in making determinations of patentability. This includes a balancing of the potential for animal suffering and environmental risks linked to the patented organism against the "invention's usefulness to

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28. *Id.* at 311.

29. *Id.* at 310-15.

30. *See id.*

31. *See, e.g.*, Classification Definitions: Class 800, Multicellular Living Organisms and Unmodified Parts Thereof and Living Processes, United States Patent Office, Dec. 2000, http://www.uspto.gov/go/classification/uspc800/defs800.pdf; Yvonne Cripps, *Aspects of Intellectual Property in Biotechnology: Some European Legal Perspectives*, *in* PROTECTION OF GLOBAL BIODIVERSITY: CONVERGING STRATEGIES 316, 318 (1998).

32. *See* Samantha Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AIPLA Q.J. 193, 247-48 (2007).

humankind."[33] While this has not yet led to any significant differences in the granting of patents on living organisms between the United States and the EPC member nations, such departures may appear in the future.[34]

The Canadian patent office has also allowed patents on lower-level life forms basing their judgment on the decision of *Chakrabarty* in the United States. The Canadian Patent Office similarly allows the patenting of lower-level life forms based on the same reasoning as in *Chakrabarty* and the prior practices of other nations such as Germany, Australia and Japan. In enacting this rule, the Canadian Patent Board of Appeal overturned the rejection of the *Abitibi* patent in 1982, which claimed "a microbial culture that was used to digest, and thereby purify, a certain waste product that emanates from pulp mills."[35]

Since the time of the *Chakrabarty* decision, the public debate surrounding the patenting of genetically modified organisms continues in Europe.[36] This debate has been most notable in regards to the patenting of the Harvard Oncomouse, which received a European Patent on May 13, 1992.[37] The same patent on the Harvard Oncomouse was denied in Canada and was only upheld in the European Patent Office after more than a decade of litigation.[38]

III. PATENTING MULTICELLULAR LIFE—HARVARD ONCOMOUSE

In 1988 U.S. patent no. 4,736,866 was granted on the Harvard Oncomouse, which claimed "a transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal."[39] An oncogene is any gene known to be involved in the transformation of a normal cell to a cancerous one.[40] These engineered mice are therefore useful as a dependable animal cancer model for scientists to employ as a test subject in experimental cancer treatments.[41]

Despite the relative ease by which the U.S. patent was granted, it is clear that ethical issues were considered in the U.S. patent application

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33. *Id.* at 247-48.
34. *See id.* at 245.
35. Harvard College v. Canada (Comm'r of Patents), [2002] 4 S.C.R. 45, 146 (Can.).
36. Case T315/03, Harvard/Transgenic Animal, [2005] E.P.O.R. 271, 290 (Technical Bd. App. 2004).
37. *See id.* at 279.
38. *Id.* at 331; Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45 (Can.). *See id.*
39. U.S. Patent No. 4,736,866 (filed June 22, 1984).
40. Oncogene—Definition, http://dictionary.reference.com/browse/oncogene (last visited Mar. 28, 2008).
41. *See* U.S. Patent No. 4,736,866 (filed June 22, 1984).

because the language of the U.S. patent only claimed *nonhuman* mammals.[42]

In contrast to the relative lack of public controversy in the United States in 1992, the European Patent Office (EPO) granted European Patent No. EP-B-0169672 for Harvard Oncomouse, and consequently received a strong reaction from European animal rights groups.[43] "This triggered one of the most complicated cases in the history of the EPO, as the grant was opposed by a large number of political parties, [non-governmental] organizations [sic], religious groups and individuals."[44] Twenty-three separate groups voiced opposition against the issuance of the Harvard Oncomouse patent, arguing that "balancing morality against usefulness is not a fit basis for patenting animals."[45] They also argued, in the alternative, that the patentees were overstating the usefulness of the mice while understating the animal suffering it would cause.[46]

The opponents to the patent based their arguments on article 53(a) and 53(b) of the European Patent Convention (EPC 1973) which lists the European exceptions to patentability.[47] Article 53 allows for the patenting of biotechnology generally, but states that inventions contrary to the *ordre public* or morality are excluded from patentability.[48]

When considering the patentability of the Oncomouse, the Technical Board of Appeals favored granting the patent on technical grounds, but referred a list of moral considerations to the Examination Division before allowing the patent to grant.[49] Among these relevant moral considerations: (1) whether animals were being regarded in the application as objects, (2) [the] likelihood of descendants of transgenic animals escaping into the environment and spreading malignant foreign genes through mating, and (3) whether the claimed patent was drastically interfering with evolution.[50]

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42. *Id.*

43. European Patent Office, Biotechnology in European Patents—Threat or Promise? (Mar. 25, 2008), http://www.epo.org/topics/issues/biotechnology.html.

44. *Id.*

45. Deborah MacKenzee, Activists Join Forces Against the Onco-Mouse, NEWSCIENTIST, Jan. 16, 1993, http://www.newscientist.com/article/mg13718560.900-activists-join-forces-against-the-oncomouse-.html.

46. *See id.*

47. *Id.* at 288-94, 301-02.

48. *See* Convention on the Grant of European Patents, art. 53(a)-(b), Jan. 11, 1978, 1065 U.N.T.S. 255, http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar53.html [hereinafter European Patent Convention].

49. *See* Cripps, *supra* note 31, at 318.

50. *Id.* at 319.

These moral issues having been considered by the Examination Division, the patent was granted in 1992, but then again appealed. A final decision was not rendered until 2004.[51] In its final opinion the Technical Board of Appeals at the European Patent Office held that Rule 23(d) EPC applied to this case, even though Rules 23(b) through 23(e) EPC had only been adopted while challenges to the Harvard Oncomouse patent were still being reviewed.[52] These rules clarified the application of article 53(a) to genetically modified animals in barring the patent grants on moral grounds.[53]

"Rule 23d(d) EPC excludes from patentability inventions relating to processes for modifying the genetic identity of animals (or animals produced by such processes) in which the suffering to the animal is not outweighed by the substantial medical benefit to mankind or animals."[54] The T19/90 test, which weighs the suffering of the patented animal against its usefulness to humans, was also applied.[55]

Additionally, the 2004 opinion confirmed that transgenic nonhuman animals and plants did not invoke the article 53(b) bar on patenting plant and animal "varieties" and noted that exclusions to patentability are to be construed narrowly.[56] The board also noted that evidence as to the public's perception of moral issues will be closely examined and, if found to be convincing, could be influential to the board's decision-making.[57]

Interestingly, because the original European patent application on the Harvard Oncomouse was filed in 1985 and the matter of patentability was not resolved until 2004, the controversy lasted almost the entire patent term, leaving little remaining time for Harvard to exploit the patent. Nevertheless, the decision "was fundamental and has provided some landmark guidance in the EPO to parties interested in the field of biotechnology."[58]

Patents were eventually granted on the Harvard Oncomouse in Europe, the United States, and Japan, but were denied in Canada until 2000.[59] In August 2000, the Canadian Federal Court of Appeals granted

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51. *See* Case T315/03, Harvard/Transgenic Animal, [2005] E.P.O.R. 271 (Technical Bd. App. 2004) (decided July 6, 2004).

52. *Id.* at 321-24.

53. *Id.*

54. Harvard/Oncomouse—EPO Decision (T315/03), Kilburn & Strode, May 17, 2005, http://www.kstrode.co.uk/news/NewsDet.asp?RID=174&NewsType=Current.

55. *Harvard/Transgenic Animal*, [2005] E.P.O.R. at 338-40.

56. *Id.* at 338-40.

57. *See id.* at 331-36.

58. Harvard/Oncomouse—EPO Decision, *supra* note 54.

59. Erika Check, *Canada Stops Harvard's Oncomouse in Its Tracks*, NATURE, Dec. 12, 2002, at 593.

a patent on the Harvard Oncomouse as a "composition of matter" or "manufacture" thereby reversing longstanding Canadian precedent of denying patent protection to animals.[60] In a five to four decision, the Canadian Supreme Court soon overturned the lower court on December 5, 2002, holding that "the 'Harvard mouse,' being a higher animal life form, is not a patentable 'invention' in Canada."[61] In the majority opinion Justice Bastarache stated:

> I do not believe that a higher life form such as the oncomouse is easily understood as either a "manufacture" or a "composition of matter". For this reason, I am not satisfied that the definition of "invention" in the Patent Act is sufficiently broad to include higher life forms. This conclusion is supported by the fact that the patenting of higher life forms raises unique concerns which do not arise in respect of non-living inventions and which are not addressed by the scheme of the Act. Even if a higher life form could, scientifically, be regarded as a "composition of matter", the scheme of the Act indicates that the patentability of higher life forms was not contemplated by Parliament.[62]

The dissenting Canadian Supreme Court justices felt that the term "invention" was intended to be very broad as new and useful inventions will necessarily push into previously uncharted territories, therefore they reasoned that the exploration of biotechnology should be treated no differently from any other technological advancement deserving of patent protection.[63]

Divergences in patentable subject matter, as seen in Canada, and which might later appear between Europe and the United States, could have large effects on the incentives to create synthetic organisms.[64] While the promising technologies of the emerging field of synthetic biology deserve to be incentivized, there is also good reason to be cautious.

IV. IMPLICATIONS FOR SYNTHETIC BIOLOGY

A. Single-Celled Synthetic Organisms

Several public watchdog groups including the Canada-based ETC group (Action Group on Erosion, Technology and Concentration) have

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60. Harvard College v. Canada (Comm'r of Patents), [2002] 4 S.C.R. 45 (Can.).

61. *Harvard Onco-Mouse Not Patentable in Canada*, BARRISTERS & SOLICITORS, Dec. 5, 2002 (Special Report), http://www.barrigar.com/harvard0212.pdf.

62. *Harvard College*, [2002] 4 S.C.R. at 122.

63. *Id.* at 8-12.

64. *See* Robert M. Sherwood, *Why a Uniform Intellectual Property System Makes Sense for the World*, *in* GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 66-68 (Mitchell Wallerstein et al. eds., 1993).

called for a moratorium on the release and commercialization of synthetic organisms.[65] They argue that, despite the technological advance made by the Venter Team in constructing a genome-length piece of synthetic DNA, the focus should not be on the extraordinary length of this man-made molecule, but on the good sense of conducting this research at all.[66] Says Jim Thomas, Research Program Manager at ETC Group:

> While synthetic biology is speeding ahead in the lab and in the marketplace, societal debate and regulatory oversight is stalled and there has been no meaningful or inclusive discussion on how to govern synthetic biology in a safe and just way. In the absence of democratic oversight profiteering industrialists are tinkering with the building blocks of life for their own private gain. We regard that as unacceptable.[67]

Barring some legislative action, such calls for moratoria are unlikely to be persuasive on the U.S. Patent Office. As pointed out by the Supreme Court in *Chakrabarty*, it is true that the judiciary "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress."[68] The Supreme Court has put its foot down on the issue of patentability in the United States, citing *Marbury v. Madison*, and stating that it is their role to determine what the law is under section 101.[69]

Because the holding in *Chakrabarty* circumscribes such a great area of patentable subject matter it is foreseeable that virtually all synthetic organisms will be patentable in the United States.[70] The U.S. Patent Office and the lower courts are therefore very likely to grant and uphold the Venter Patent and others similar to it.

This is not to say that the U.S. government and U.S. based synthetic biologists are not concerned about the potential hazards of the new technology.

> From its inception, commentators have raised issues ranging from bioethical and environmental worries to fears of bioterrorism. The successful in vitro creation of a complete [poliovirus] genome "using mail-order segments of DNA and a viral genome map that is freely available on the Internet" provided a focal point for these concerns. The worry has been sufficiently great that the synthetic biology community recently released a

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65. *See* ETC Group, *supra* note 9.
66. *See id.*
67. *Id.*
68. Diamond v. Chakrabarty, 447 U.S. 303, 314-15 (1980) (citing Parker v. Flook, 437 U.S. 584, 596 (1978)).
69. *See id.*
70. *Id.* at 309.

> declaration publicly committing itself to improving the software that checks DNA synthesis orders for sequences encoding hazardous biological systems.[71]

By contrast, article 35(a) of the EPC requires the European Patent Office to examine morality in its determinations of patentability.[72] Application of this rule can be seen in the EPO's Harvard Oncomouse case, where the board applied a balancing test between the suffering of the animal and the possibility of environmental contamination by the modified genes versus the invention's utility and medical benefit.[73]

Because the possibility of environmental contamination by synthetic microorganisms is potentially much greater than with transgenic mice, this factor will be accorded greater weight in the assessment of the moral concerns surrounding such environmentally pertinent synthetic organisms.[74]

In fact, the European Union, in its sixth E.U. Framework Program for Research and Technological Development (FP6), has enacted a €215 million New and Emerging Sciences and Technologies Program (NEST).[75] As part of this effort, in 2007, a large-scale targeted NEST Pathfinder Project was initiated to investigate the newly emerging field of synthetic biology.[76] This project, entitled Synbiosafe, "set out to create a framework for ethics, safety, and public opinion within which Europe's developing synthetic biology community . . . can flourish."[77] The main objectives of these projects are to make determinations as to how synthetic biology research and industry should be regulated to prevent the creation of dangerous compounds or organisms and to educate and receive feedback from the public on their perceptions of this emerging technology.[78]

This information, particularly the public opinion data, could be highly relevant to *ordre public* determinations of the moral propriety of

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71. Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1745 (2007) (citing Philip Ball, *Starting from Scratch*, NATURE, Oct. 6, 2004, at 624; Declaration of the Second International Meeting on Synthetic Biology (May 29, 2006), http://dspace.mit.edu/bitstream/1721.1/32982/1/SB.v5.pdf (revised public draft)).

72. European Patent Convention, *supra* note 48, art. 53(a).

73. *See* Case T315/03, Harvard/Transgenic Animal, [2005] E.P.O.R. 271, 290, 321-24 (Technical Bd. App. 2004).

74. *See* Cripps, *supra* note 31, at 319.

75. European Comm'n, Sixth Framework Program in Brief (2002-2006), http://ec.europa.eu/research/fp6/pdf/fp6-in-brief_en.pdf.

76. Safety and Ethics of Synthetic Life, Synbiosafe, 2007, http://www.synbiosafe.eu/uploads/pdf/Synbiosafe.pdf.

77. *Id.*

78. *See id.*

granting a patent on synthetic organisms in Europe.[79] Should public opinion grow against the development of synthetic organisms in Europe, as it did with the European reaction against genetically-modified food, divisions in patentable subject matter may soon emerge between the European Union and the United States.[80] If this occurred, it would reduce the incentive to invest in synthetic biology technology globally, because inventors would not be able to exploit their inventions in the European market.[81]

B. Multicellular Synthetic Organisms

Perhaps the wider philosophical implications of the Venter patent and the creation of synthetic organisms in general is that, if living organisms can be created de novo, then what meaningful distinction will remain between life and nonlife. In fact, this dilemma has long been recognized in scientific and legal circles, as noted in the amicus brief by Drs. Hood et al. to *Chakrabarty*:

> The prevailing view among scientists is that the essential characteristic of "living" matter is nothing more than its complexity. "Life is not one of the fundamental categories of the universe, like matter, energy and time but is a manifestation of certain molecular combinations." N.H. Horowitz, F.D. Drake, S.L. Miller, L.E. Orgel and C. Sagan, "The Origins of Life" from *Biology and the Future of Man*, 165 (P. Handler, Ed. 1970).
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> Nobel Laureate Erwin Schrodinger argues that the transition from atoms to molecules, to giant molecules such as enzymes, to simple viruses and on up to bacteria is a continuum. At some arbitrary level the aggregates take on sufficient complexity that they are regarded as living. E. Schrodinger, *What Is Life* (1958).[82]

With synthetic organisms, the life/nonlife gray zone described in the Hood brief has the potential to extend up the tree of life. If, as is likely within the coming decade, entire genomes of higher-order organisms such as mice and humans can be created synthetically and "booted up" within the husks of empty cells, the boundaries of our ethical treatment of living organisms may be further challenged. According to the ETC Group:

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79. Case T315/03, Harvard/Transgenic Animal, [2005] E.P.O.R. 271, 331-36 (Technical Bd. App. 2004).

80. *See, e.g.*, John Pikrell, *Instant Expert: GM Organisms*, NEWSCIENTIST, Sept. 4, 2006, http://www.newscientist.com/channel/life/gm-food/dn9921.

81. Sherwood, *supra* note 64, at 68-88.

82. Brief for Dr. Leroy E. Hood et al. as Amici Curiae Supporting Petitioner, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (No. 79-136), *available at* 1980 WL 339764.

> In 2004 Craig Venter predicted that "engineered cells and life forms will be relatively common within a decade." According to synthetic biologist Drew Endy of Massachusetts Institute of Technology (MIT): "There is no technical barrier to synthesising plants and animals, it will happen as soon as anyone pays for it." Indeed, in a recent interview (November 2006) Endy predicted that it should be possible to synthesise an entire human genome within a decade.[83]

Some may fear that, by constructing life out of nonliving parts in the lab, less respect will be accorded to such synthetically engineered organisms. Similar suspicions have been seen in concerns over human cloning. In response to such worries European Union has enacted laws barring such cloning, which have been incorporated into the European Patent Convention as Rules 23d EPC.[84] In the United States, legislative proposals have passed the House of Representatives several times, but as of yet, no outright ban on human cloning has been passed.[85] Hollywood has even addressed these worries with several films including *The 6th Day* and *The Island*.[86]

In Europe, the moral limitations on patentable subject matter, particularly those concerned with suffering or environmental impact, may limit the patenting of certain synthetic organisms. In light of the European Union's ban on human cloning, this would almost certainly include those derived from humans.

With regard to nonhuman synthetic organisms, as seen in the 2005 EPO opinion regarding the Harvard Oncomouse, moral concerns regarding the suffering of the synthetic organisms, or their threat to the environment, is likely to be weighed against the organisms' usefulness to humans and their medical benefit.[87]

In the European Union, the public seems less opposed to the creation of genetically modified organisms used in medical or industrial applications as it is opposed to those being used as food for human

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83. ETC Group, Backgrounder: J. Craig Venter Institute's Patent Application on World's First Human-Made Species 3 (June 7, 2007), http://www.etcgroup.org/upload/publication/pdf_file2/631.

84. European Patent Convention, *supra* note 48, rule 23d(d), *available at* http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/r23d.html.

85. *See* H.R. 2560, 110th Cong. (2007).

86. *See* Synopsis of *The Island*, http://www.imdb.com/title/tt0399201/synopsis (last visited Mar. 29, 2008); *see also* Plot Summary of *The 6th Day*, http://www.imdb.com/title/tt0216216/plotsummary (last visited Mar. 29, 2008).

87. *See* Case T315/03, Harvard/Transgenic Animal, [2005] E.P.O.R. 271, 321-24 (Technical Bd. App. 2004).

consumption.[88] Therefore, context-dependent deviation in patentability may emerge even within the European Patent Office.

And in Canada, higher-order organisms, whether made by completely synthetic means or through transgenic manipulation, will be unpatentable, as long as the Canadian Supreme Court's decision continues to stand that Canada's parliament did not intend the subject matter requirements of "manufacture" and "composition of matter" to include higher-order organisms.[89]

V. CONCLUSIONS

The creation of synthetic organisms offers the promise of tremendous technological advances and should generally be incentivized through the patent system. From the creation of cheaper biofuels and the degradation of toxic waste, to the cleansing of carbon dioxide and other pollutants from the atmosphere, synthetic organisms offer hope and possible solutions to myriad modern problems.

However, with this promising new realm of technology comes the possibility of unintended consequences such as the creation of deadly pathogens and further destruction of the environment. Forward-thinking studies, such as the Synbiosafe program, are valuable for examining the dangers as well as the benefits of synthetic organisms, educating the public, and can be helpful in outlining areas of synthetic biotechnology that should remain ineligible for patents.

Further, as synthetic biology technology progresses, we should remain aware that organisms, whether synthetic or natural, retain the capacity for suffering. With the newly acquired understanding of life at the most fundamental levels, it is important that we do not regress into previous Pascalian modes of regarding nonhuman organisms as simply machines to be owned, used up, and discarded. U.S. and European patentability laws, whether set forth legislatively or judicially, should therefore reflect a moral obligation not to incentivize the undue suffering of patented organisms.

There are possible consequences, however, for countries and their trading partners when a unilateral moral choice is made not to patent certain organisms. Extrapolating from past jurisprudence it is unlikely that any such restrictions on patenting synthetic organisms will first arise in the United States. This is especially supported when one considers the

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88. *See* Synbiosafe, Safety and Ethics of Synthetic Life (2007), http://www.synbiosafe.eu/uploads/pdf/Synbiosafe.pdf.

89. Harvard College v. Canada (Comm'r of Patents), [2002] 4 S.C.R. 45 (Can.).

broad language of *Chakrabarty* and the failure to enact a ban on human cloning in the United States compared with the controversy toward the Harvard Oncomouse in Europe, the enactment of rules 23(a) through (e) EPC, and the denial of the Oncomouse patent in Canada.

The consequences of a divergence in patentability may be profound even if the same synthetic organisms remained patentable domestically. Given the large volume of trade with the European Union and Canada, such restrictions would have strong disincentivizing effects on U.S. inventors who could no longer expect to exploit their patents globally. This divergence would be a loss for U.S. inventors, but a win for those seeking to limit the overall incentives for creating dangerous or vulnerable synthetic organisms.