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## "... and on his farm he had a geep": Patenting Transgenic Animals

Barry S. Edwards

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**“... and on his farm he had a geep”<sup>1</sup>:  
Patenting Transgenic Animals**

*Barry S. Edwards\**

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1. A "geep" is a transgenic cross between a goat and a sheep. See Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 406 (1988); Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L. J. 443, 445-46 (1999).

## INTRODUCTION

Calling its task a narrow one of statutory interpretation<sup>2</sup> (interpreting 35 U.S.C. § 101—the patent statute), the Court in *Diamond v. Chakrabarty*<sup>3</sup> approved a patent application for a multi-cellular life form. Seven years later, the Patent and Trademark Office (PTO) declared that multi-cellular, non-human life forms are patentable subject matter.<sup>4</sup> Since then, many who believe that the Court and PTO's decisions could have unfortunate results have voiced their objections. They have noted the potential negative effects on family farms,<sup>5</sup> on the environment,<sup>6</sup> and on the animals themselves.<sup>7</sup> Nevertheless, since the *Chakrabarty* decision and the 1987 PTO ruling, scientists have genetically engineered (famously) a mouse with a human gene that makes the mouse more susceptible to breast cancer,<sup>8</sup> a "geep,"<sup>9</sup> and many more new animals.<sup>10</sup>

Controversy over such genetic modification of animals and plants has been growing considerably over the past decade, particularly in Europe and, increasingly, in the U.S. "In England," for example, "scarcely a day goes by without a headline questioning 'Frankenstein Food' or television images of protesters ripping up test plots of 'transgenic' plants."<sup>11</sup> As a result, "[t]he European Union, reacting to consumer fears and torn between differing opinions in its member states, has enacted a de facto moratorium preventing the import of

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2. See *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

3. *Id.*

4. Patent and Trademark Office Notice: Animals-Patentability, 1077 Official Gazette U.S. Pat. & Trademark Off. 24 (Apr. 21, 1987) [hereinafter PTO Notice].

5. See *infra* text accompanying notes 100-110.

6. See *infra* text accompanying notes 112, 141-162.

7. See *infra* text accompanying notes 113-115, 116-140.

8. U.S. Patent No. 4,736,866 (Apr. 12, 1988).

9. See *supra* note 1.

10. One author counts "eighty-five genetically-engineered mice, three rats, three rabbits, a sheep, a bird, a fish, a pig, a guinea pig, an abalone, and a cow." Magnani, *supra* note 1, at 444. Another author counts "106 mice, 9 rats, 9 rabbits, 8 sheep, 8 pigs, 7 cows, 7 goats, and one each of a nematode, bird, fish, guinea pig, abalone, canine, and turkey hen." Rochelle K. Seide & Janet M. MacLeod, *Drafting Claims for Biotechnological Inventions*, 585 PLI/Pat. 381, 388 n. 10 (1999).

11. Veronique Mistiaen and Isabelle Bucq, *Big Stakes Ride on Dispute over Crop Engineering*, PORTLAND OREGONIAN, September 20, 1999, at A7.

transgenic products for at least the next 18 months.”<sup>12</sup> Such concerns are significantly less in the U.S., but they appear to be on the rise. In November 1999, forty-eight Members of Congress joined several groups in urging the Food and Drug Administration (FDA) to require that foods with genetically modified components be labeled.<sup>13</sup> As a result of these expressions of concern, the FDA held several public comment meetings in November and December of 1999 and now requires that genetically modified foods be labeled if the foods represent a chance of a safety risk.<sup>14</sup> Thus far, however, it is up to the biotechnology company to flag such potential risks.<sup>15</sup> Yet, safety concerns only begin to address the myriad concerns to which transgenic foods give rise. Some vegetarians might object to the presence of animal genes in their food, and some Jews might be concerned that kosher foods with genes of non-kosher animals might enter their food supply in an unrecognizable way.

Awareness of the potential harms of genetically modified foods comes, in part, from two highly-publicized discoveries in 1999. Pioneer Hi-Bred, International asked a University of Nebraska scientist to test a variety of soybean seed into which a Brazil nut gene had been introduced (to increase the bean’s protein level).<sup>16</sup> The scientist discovered that the soybean caused an allergic reaction in people with Brazil nut allergies.<sup>17</sup> Similarly, scientists at Cornell University discovered that corn that had been genetically altered to produce an insecticide released pollen on nearby plants with the unexpected result of killing monarch butterfly larvae, potentially threatening the entire monarch butterfly population as well as threatening the plants and animals that rely on the monarchs.<sup>18</sup> Nor have

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12. *Id.*

13. See Rob Hotakainen, *Farmers in Crossfire of Fight over Labeling Genetically Altered Food*, MINNEAPOLIS STAR TRIBUNE, November 13, 1999, at A1.

14. See *FDA Announces Public Meetings on Bioengineered Foods* (visited Jan. 15, 2000) <<http://www.fda.gov/bbs/topics/NEWS/NEW00695.html>>.

15. See *id.*

16. See Paul Jacobs, *Protests May Mow down Trend to Alter Crops*, L.A. TIMES, October, 1999, at A1.

17. See *id.*

18. See Rick Weiss, *Biotech vs. “Bambi” of Insects? Gene-Altered Corn May Kill Monarchs*, THE WASHINGTON POST, May 20, 1999, at A3. While scientists disagree on the meaning of the studies of the effects of “Bt corn” on monarch butterflies, the latest study, conducted at Iowa State University, seems to confirm the earlier studies: it shows that this genetically-engineered corn does

transgenic animals, themselves, been free of alarming, unintended side effects. Some of these transgenic animals have been horribly unfortunate, such as the pig with a human growth gene that unexpectedly grew to be “excessively hairy, riddled with arthritis, and cross-eyed,” seldom even standing up.<sup>19</sup> The ability to create such animals comes with responsibilities.<sup>20</sup>

The purpose of this note is to raise the visibility of the patenting of transgenic animals and to encourage active control of a process that has proceeded thus far without specific direction. Part I surveys some of the arguments advanced by a wide variety of people affected by transgenic animal patenting.<sup>21</sup> Part II, discusses first whether animals should be patented, reviewing both the ethical implications of modifying animal genetic structures and the safety concerns of transgenic animals.<sup>22</sup> Part II, further, discusses potential solutions to these concerns, including that the PTO should revive the Moral Utility Requirement to ban or postpone patenting transgenic animals and that, simultaneously, Congress should act to enact a ban or a moratorium on such patents.<sup>23</sup> Specifically, this note argues that given the number of unknowns and the number of unintended consequences of genetic modification of animals—and the consequent public apprehension of these processes and products—Congress should pass legislation directing the PTO’s response to future applications for transgenic animal patents.<sup>24</sup> Congress should direct the PTO to discourage the commercial use of this technology—through a ban or a moratorium—until it is better understood.<sup>25</sup>

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threaten monarch butterfly populations. *See also* *Pollen from Altered Corn Can Kill Monarch Butterflies*, MINNEAPOLIS STAR TRIBUNE, Aug. 22, 2000, at A8.

19. Andrew Kimbrell, *The Patenting of Life and the Global Market in Body Parts*, in *THE CASE AGAINST THE GLOBAL ECONOMY: AND FOR A TURN TOWARD THE LOCAL* 131, 137 (Jerry Mander and Edward Goldsmith eds., 1996).

20. *See infra* text accompanying notes 113-115, 116-140, 136-161 for a discussion of the responsibility scientists and the rest of society owe to technology-created animals.

21. *See infra* Part I, BACKGROUND.

22. *See infra* Part II.A, ANALYSIS: SHOULD TRANSGENIC ANIMALS BE PATENTED?

23. *See infra* Part II.B, ANALYSIS: WHAT RESPONSES ARE APPROPRIATE?

24. *See infra* CONCLUSION.

25. *See id.*

## I. BACKGROUND

The U.S. Constitution reserves for the federal government the power to grant exclusive patents.<sup>26</sup> It states, “[t]he Congress shall have Power . . . 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. . . .”<sup>27</sup> For Congress, parlaying this Constitutional delegation of power to grant patents into legislation was an early priority. Thus, Congress passed The Patent Act in 1793.<sup>28</sup> In its first three sections,<sup>29</sup> the current patent statute identifies the three elements necessary for a patent. The first identifies the general purpose of the statute and articulates the requirement that the invention be “useful.”<sup>30</sup> The second explains the “novelty” requirement.<sup>31</sup> The third requires that the matter not be “obvious.”<sup>32</sup>

In the twentieth century, Congress began to modify patent laws to account for humanity’s increasing ability to alter and, even, create plant life. In 1930, Congress passed the Plant Patent Act (PPA), which allows for patents on newly-discovered or -invented, distinct, asexually-reproduced plants.<sup>33</sup> Congress later passed the Plant Variety Protection Act of 1970 (PVPA) which extends patent protection to those who develop new varieties of sexually-reproduced plants.<sup>34</sup> No specific legislation has yet been passed regarding patent protection for the

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26. U.S. CONST. art. I, § 8, cl. 8.

27. *Id.*

28. Act of April 10, 1790, ch. 7, 1 Stat. 109 (1790).

29. See 35 U.S.C. §§ 101-103.

30. See *id.* at § 101 (“Inventions patentable: 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.”).

31. See *id.* at § 102 (“A person shall be entitled to a patent unless—(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent . . .”).

32. See *id.* at § 103 (explaining that a patent shall be granted “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.”).

33. Plant Patent Act, Pub. L. No. 71-245, 46 Stat. 376 (1930) (current version at 35 U.S.C. § 161) (1988).

34. Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (current version at 7 U.S.C. §§ 2321-2582 (1994 & Supp II 1996)).

manufacture of animals, either through genetic engineering or through selective breeding.<sup>35</sup>

The courts and the PTO have—after lengthy debate<sup>36</sup>—determined that the patent statute allows for the patenting of animals, thus opening the floodgates to animal patents. In 1980, the Supreme Court held in *Diamond v. Chakrabarty* that “a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.”<sup>37</sup> *In re Merat* marked the United States Court of Customs and Patent Appeals’ (C.C.P.A.) first rejection of a claim to patent a living organism, in this case a dwarf chicken.<sup>38</sup> The PTO rejected the application for the chicken because, the Court ruled, it was not a “manufacture” but the product of selective breeding.<sup>39</sup> The C.C.P.A., however, granted a patent for a micro-organism used to produce an antibiotic in *In re Bergy*.<sup>40</sup>

The seminal *Chakrabarty* case involved Ananda M. Chakrabarty’s application to patent a “human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil.”<sup>41</sup> Chakrabarty wanted to obtain patents on three discoveries: (1) the method of producing the bacterium,<sup>42</sup> (2) “an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria,”<sup>43</sup> and (3) “the bacteria themselves.”<sup>44</sup> The patent examiner accepted the first two but rejected the claim to the bacteria themselves, reasoning that the micro-organisms were “products of nature” and that living matter is not patentable under 35 U.S.C. § 101.<sup>45</sup> The Patent Office Board of Appeals affirmed on the second rationale—that living matter is not

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35. See *infra* text accompanying notes 183-217 for a discussion of the legislation that has been proposed.

36. See *infra* text accompanying notes 36-72.

37. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

38. 519 F.2d 1390, 186 U.S.P.Q. (BNA) 471 (C.C.P.A. 1975).

39. See *id.* Ultimately, the C.C.P.A. rejected the patent as “not particularly point[ing] out or distinctly claim[ing] the subject matter of appellants’ invention.” *Id.* at 1396.

40. 596 F.2d 952 (C.C.P.A. 1979), *cert. dismissed*, 444 U.S. 1028 (1980), *aff’d* 447 U.S. 303 (1980).

41. Chakrabarty, “a microbiologist, filed a patent application, assigned to the General Electric Co.” 447 U.S. at 305.

42. *Id.*

43. *Id.* at 305-06.

44. *Id.*

45. See *id.* at 306.

patentable.<sup>46</sup> However, relying on its rationale in *In re Bergy*, the C.C.P.A. reversed.<sup>47</sup> After a remand<sup>48</sup> and a reaffirmation,<sup>49</sup> the Supreme Court granted certiorari<sup>50</sup> and affirmed,<sup>51</sup> giving Chakrabarty his patent not only on the processes and corollary products but on the micro-organisms, themselves.

The Court in *Chakrabarty* identified its task as “one of statutory interpretation.”<sup>52</sup> It was to consider the “narrow” question of “whether [Chakrabarty’s] micro-organism constitutes a ‘manufacture’ or ‘composition of matter’ within the meaning of [35 U.S.C. § 101].”<sup>53</sup>

Despite significant concerns expressed by the amicus briefs and expressly noted in the Court’s decision, the Court specifically rejected the challenge of addressing these concerns in issuing its ruling.<sup>54</sup> The amicus briefs, which included the statements of “[s]cientists, among them Nobel laureates,”<sup>55</sup> “point[] to a parade of horrors,” including “that genetic research may pose a serious threat to the human race, . . . spread pollution and disease, . . . [and] result in a loss of genetic diversity.”<sup>56</sup> The Court specifically deemed such concerns outside the scope of its review.<sup>57</sup> Chief Justice Burger wrote, “[i]t is argued that this Court should weigh these potential hazards in considering whether respondent’s invention is patentable subject matter under § 101. We

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46. *See id.*

47. In *In re Bergy*, the court stated, “[i]n short, we think the fact that microorganisms . . . are alive is a distinction without legal significance and that disposes of the board’s ground of rejection and the sole reason for refusal of a patent argued by the solicitor.” *In re Bergy* 563 F.2d 1031, 1038 (C.C.P.A. 1977).

48. *See Parker v. Bergy*, 438 U.S. 902 (1978).

49. *See Application of Bergy*, 596 F.2d 952 (C.C.P.A. 1979).

50. *See Parker v. Bergy*, 444 U.S. 924 (1979).

51. *See Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that the language of 35 U.S.C. § 101 “embraces [Chakrabarty’s] invention”).

52. *Id.* at 307.

53. *Id.* 35 U.S.C. § 101 states that, “[w]hoever 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” [emphasis added].

54. *See Chakrabarty*, 447 U.S. at 316-17. The Court reasoned that their decision would “not deter the scientific mind from probing” and, therefore, not affect whether research continued and that the Court was “without competence to entertain these arguments.” *Id.*

55. *Id.* at 316.

56. *Id.*

57. *See id.* at 316-17.



disagree.”<sup>58</sup> Thus the courts have not examined whether transgenic animals *ought* to be patentable but only whether they *are* patentable.

The *Chakrabarty* decision was relied on shortly thereafter to grant a patent to non-naturally occurring man-made multicellular plants<sup>59</sup> and then to support the grant of a patent to a genetically altered strain of oysters.<sup>60</sup> Four days after the oyster case was decided, the Patent and Trademark Office (“PTO”) issued a statement in the Official Gazette stating,

The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. s. 101.

The Board’s decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article. . . .<sup>61</sup>

The statement expressly excludes “human being[s]” from the description of patentable subject matter.<sup>62</sup> The first animal patent, the patent for the famous Harvard Onco-mouse, was published one year later.<sup>63</sup> The PTO has, since breaking this barrier, granted many transgenic animal patents.<sup>64</sup> In an effort to halt the grant of animal patents, several groups joined to file suit challenging the PTO’s procedure in making these decisions.<sup>65</sup> Their suit was dismissed for lack of standing.<sup>66</sup> The

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58. *Id.*

59. *Ex parte* Hibberd, 227 U.S.P.Q. 443 (Bd. Pat. App. & Int. 1985) (ruling that the principles of *Chakrabarty* could be extended to allow the patenting of genetically-engineered plants, seeds, and plant tissue).

60. *Ex parte* Allen, 2 U.S.P.Q. 2d 1425 (Bd. Pat. App. & Int. 1987) (denying the patent request on the alternative basis of “obviousness” but affirming a broad reading of the patentability of living organisms, generally), *aff’d* 846 F.2d 77 (Fed. Cir. 1988).

61. See PTO Notice, *supra* note 4.

62. Evidently, the PTO recognized and, therefore, noted that “[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.” *Id.* See also Magnani, *supra* note 1, at 448 (noting that the PTO appears implicitly to have been referring to the 13th Amendment).

63. U.S. Patent No. 4,736,866.

64. See *supra* note 10.

65. See *Animal Legal Defense Fund v. Quigg* 932 F.2d. 920 (Fed. Cir. 1991). The Animal Legal Defense Fund, et al. argued that the PTO violated section 553 of the Administrative Procedure Act (5 U.S.C. § 553 (2000)) by failing to provide notice and an opportunity for comments. See *id.* Moreover they contend that the PTO violated Section 706(c) (2) of the APA (5 U.S.C. § 706 (2000)) by acting in excess of statutory jurisdiction. See *id.*

66. *Id.*

grant of patents for genetically engineered plants and animals has proceeded steadily since.<sup>67</sup>

The *Chakrabarty* decision, subsequent PTO ruling, and consequent grants of patents for genetically-altered plants and animals have generated considerable controversy. The *Chakrabarty* Court was divided 5-4.<sup>68</sup> That division reflects a similarly-divided society.<sup>69</sup> Indeed, responding to such concern, two giant international food producers, the fast-food restaurant chain McDonalds and the snack food manufacturer Frito-Lay, have asked their suppliers not to supply them with potatoes grown from genetically-modified seed.<sup>70</sup> In his *Chakrabarty* dissent, Justice Brennan noted that in the PPA and PVPA, “Congress had addressed the general problem of patenting animate inventions and has chosen carefully limited language granting protection to some kinds of discoveries, but specifically excluding others.”<sup>71</sup> He stated that if Congress had considered plants and other “living organisms” patentable under 35 U.S.C. § 101, it would not have passed the PPA and PVPA.<sup>72</sup> Justice Brennan cautioned that the PTO’s decision to patent living organisms “uniquely implicates matters of public concern.”<sup>73</sup>

#### A. CLARIFYING THE PARAMETERS OF THE CURRENT LAW

The PTO’s announcement that living matter is patentable has led to several calls for clarification and modification. One author notes that, “[b]ecause of the requirement that the animal be ‘nonnaturally occurring,’ the consensus is that a patent would not be awarded to a particular breed of a species that was improved by classical breeding techniques,” thus

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67. See *supra* note 10.

68. 447 U.S. at 304.

69. See *infra* Part II.A, SHOULD TRANSGENIC ANIMALS BE PATENTED on the concerns of farmers, animal rights activists, the international community, and on legislation to regulate patenting of transgenic animals offered by over twenty-one different members of Congress. See *supra* text accompanying notes 5-7, 11-15. Also the fact that 48 Members of Congress recently called for labeling of genetically-modified food demonstrates considerable public concern over such products. See also Hotakainen, *supra* note 13 (stating that eighty-one percent of Americans support labeling genetically altered food, which implies, at least, a desire to know whether their food has been genetically altered).

70. *World News Tonight* (ABC television broadcast, Apr. 28, 2000).

71. 447 U.S. at 319 (Brennan, J., dissenting).

72. See *id.* at 320.

73. *Id.* at 322.

limiting patentability to genetically-engineered animals.<sup>74</sup>

While he interrogates what “nonnaturally occurring” might mean, others have wondered about the April 1987 PTO statement’s use of the term “non-human.”<sup>75</sup> Specifically, Jeremy Rifkin and Dr. Stuart Newman have asked whether “non-human” would apply to human-animal chimeras.<sup>76</sup> This debate has been stoked by the December 1997 patent application of Rifkin, an opponent of biotechnology, and Newman, a cellular biologist at New York Medical College.<sup>77</sup> The Rifkin-Newman patent application “covers the production of human-animal chimeras that could be up to 50% human.”<sup>78</sup> The purpose of the Rifkin-Newman patent application is to obstruct the patenting of human-animal chimeras either by receiving the patent, thereby preventing others from receiving such a patent and using it, or by raising enough public debate to effect a statutory restriction on the practice.<sup>79</sup> This development was anticipated shortly after the PTO’s policy statement.<sup>80</sup>

In addition to the moral and theological concerns regarding the ontological status of human-animal chimeras, a more subtle concern has attracted the attention of some: the devaluation of human life that would attend the patenting of a creature with even a few human genes. Professor Dresser summarizes animal-patenting opponents’ three most significant concerns about a process of creating non-human animals with human genes.<sup>81</sup> First, she notes a concern with “endanger[ing] the special value society gives to human life.”<sup>82</sup> Second, she reiterates the view that such processes would “cast[] doubt on our basic assumptions about the unique character of the human species,” including problematizing the cultural taboo

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74. Paul Blunt, Note, *Selective Breeding and the Patenting of Living Organisms*, 48 SYRACUSE L. REV. 1365, 1370 (1998).

75. *See id.*

76. A “chimera” is “[a]n organism, esp. a plant, with tissues from at least two genetically distinct parents.” WEBSTERS II NEW RIVERSIDE DICTIONARY 256 (1988). This definition’s emphasis on plant chimeras indicates that biotechnology advances are changing the word, itself.

77. *See generally* Magnani, *supra* note 1.

78. *Id.* at 443.

79. *See id.*

80. *See* Dresser, *supra* note 1, at 415-17.

81. *Id.*

82. *Id.* at 415.

against human/animal procreation,<sup>83</sup> and finally, she asks about “the moral and legal status we would confer on such hybrids.”<sup>84</sup> Dresser concludes that “the real questions involve the appropriate regulatory actions to take to avoid unacceptable intrusions on respect for life and other important human values.”<sup>85</sup>

Blunt finds the argument that animal patenting will lead to the devaluation of human life an “unsubstantiated hypothesis” based on a “questionable psychological assumption.”<sup>86</sup> James Chiapetta counters concerns such as Dresser’s by arguing that “the rationale and incentive for biotechnological innovation has been recognition of the value of human life,” as biotechnology eases human suffering.<sup>87</sup> It is not entirely clear that opponents in this debate are addressing each others’ concerns.<sup>88</sup> Many are simply calling for a public discussion and, if then deemed necessary, legislation.<sup>89</sup>

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83. *Id.* at 415-416.

84. *Id.* at 416.

85. *Id.* at 417.

86. Blunt, *supra* note 74, at 1379.

87. James R. Chiapetta D.V.M., Comment, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 WM. MITCHELL L. REV. 155, 181-82 (1994).

88. Blunt does not identify the “questionable psychological assumptions” nor what is questionable about them. See Blunt, *supra* note 74. Chiapetta is content to posit the non-sequitur that because biotechnology often eases human suffering, a devaluation of human life would not result from genetic engineering that placed human genes in non-human animals. See Chiapetta, *supra* note 87.

89. See, e.g., Magnani, *supra* note 1, at 460; Dresser, *supra* note 1, at 434-35; David Manspeizer, *The Cheshire Cat, The March Hare, and the Harvard Mouse: Animal Patents Open up a New Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417, 419 (1991); Michael E. Sellers, Case Note, *Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economic, Environmental, and Ethical Challenges Facing “Animal Patents,”* 47 ARK. L. REV. 269, 295 (1994); Carrie F. Walter, Note, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L. J. 1025, 1049 (1998); Elizabeth Joy Hecht, Note, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1048-50, 1074 (1992).

## B. INTERNATIONAL RECOGNITION OF PATENT RIGHTS IN TRANSGENIC LIFE

While laws might be restricted to discrete jurisdictions, science is not. Thus, one area of interest is the coincidence, or lack thereof, between U.S. law and law in other countries. Dresser pointed out in 1988 that “Bulgaria, Hungary, and Romania are the only other countries that currently provide some level of patent protection on animal ‘inventions.’”<sup>90</sup> Magnani points out that the European Community has prohibited “the patenting of ethically questionable practices.”<sup>91</sup> This fact is testified to by the fact that “. . . the European Parliament . . . voted to revoke a patent to Harvard University for a transgenic mouse, pending further examination of the ethical issues surrounding the patenting of animals.”<sup>92</sup> However, while the European Patent Convention seems unambiguous in denying patent rights to new plants and animals, in January of 2000 the European Patent Office lifted its moratorium on applications for such patents.<sup>93</sup> Thus, all of the European Union now offers patent protection for transgenic plants and animals. Nevertheless, as Former Senator Hatfield notes, according to the U.S. Office of Technology Assessment, “[t]he United States is virtually alone in the industrialized world in not having a commission to examine bioethics issues.”<sup>94</sup>

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90. Dresser, *supra* note 1, at 399, n.1. Dresser also explains that there is no such patent protection for transgenic life forms in Japan, Australia, and “several other countries,” while the status of such patents in thirteen European countries (governed by the European Patent Convention) “has not been definitively established.” The European Community once prohibited issuing patents for transgenic plants and animals under Article 53(b) of the European Patent Convention. Denise M. Kettelberger, *Biotech Patents Face Critical Decision in Europe* (visited Jan. 15, 2000) <<http://www.ljx.com/patents/p11biotech.html>>. It later reversed that interpretation of that article of the European Patent Convention. See *infra* text accompanying note 93.

91. Magnani, *supra* note 1, at 443.

92. *Animal Patent Moratorium Bill Reintroduced*, 5 NO. 5 J. PROPRIETARY RTS. 25 (1993).

93. European Patent Convention Art. 53 states that “European patents shall not be granted in respect of . . . plant or animal varieties or essentially biological processes for the production of plants or animals.” European Patent Convention Art. 53. See Quirin Schiermeier and David Dickinson, *Europe Lifts Patent Embargo on Transgenic Plants and Animals*, 403 NATURE 3 (Jan. 20, 2000) <[http://www.biotech-info.net/europe\\_lifts.html](http://www.biotech-info.net/europe_lifts.html)>.

94. Sen. Mark O. Hatfield, *From Microbe to Man*, 1 ANIMAL L. 5, 7 (1995).

## C. ECONOMIC IMPLICATIONS OF TRANSGENIC ANIMAL PATENTS

Trade and economics are deeply implicated by the patenting of transgenic life forms, both plants and animals. Michael Sellers explains that “[a]lthough the United States is still the leader in the commercial exploitation of biotechnology, proponents fear this lead could be lost without a system to support the patenting of genetically engineered animals.”<sup>95</sup> He expresses concern that the United States could lose its economic advantage in biotechnology to either Europe or to Japan.<sup>96</sup> On the other side of the economic coin, Elisabeth T. Jozwiak argues that the problems “lesser-developed countries” face with disease and starvation could be reduced if they had a better system of patent protection for transgenic animals.<sup>97</sup> She asserts that the United States should form bilateral agreements with such countries to promote the patent protection currently enjoyed in the U.S.<sup>98</sup> The rub is protecting economic interests afforded by patent protection while promoting the common good of which biotechnology might be capable.<sup>99</sup>

## D. PROTECTION FOR FARMERS: FARMERS’ EXEMPTION

Another oft-expressed concern is that large agribusinesses will own the patents to the most sought-after transgenic plants and animals, thus allowing them to freeze out the small family farm.<sup>100</sup> One possible solution to this problem is a “Farmers’ Exemption.” As a possible solution to the negative effects of such patent monopolies, The Transgenic Animal Patent Reform Act<sup>101</sup> stated, *inter alia*, that “[i]t shall not be an act of

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95. Sellers, *supra* note 89, at 286.

96. *See id.*

97. *See* Elisabeth T. Jozwiak, Comment, *Worms, Mice, Cows and Pigs: The Importance of Animal Patents in Developing Countries* 14 NW. J. INT’L L. & BUS. 620 (1994).

98. *See id.* at 640-41.

99. *See generally* David G. Scalise and Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT’L L. 83, 86 (1995) (advancing “alternatives for achieving an international sharing of technology while avoiding the deleterious effects upon the biotechnology industry of globally recognized farmers’ privilege”).

100. *See infra* text accompanying notes 201-202.

101. H.R. 4970, 100th Cong., 2nd Sess. (1988).

infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.”<sup>102</sup> The hearings that produced the proposed Act also considered narrow exceptions to patent protection focused on the family farm, prohibiting animal patents entirely, and setting royalty rates based on the number of generations a purchaser wished to purchase.<sup>103</sup> Such an exemption could parallel the Farmers’ Exemption for plant patents which exists in the PVPA.<sup>104</sup>

Making an argument for protection along the lines of a “Farmers’ Exemption” in *Animal Legal Defense Fund. v. Quigg* were farmers and farming organizations, who were among the many plaintiffs.<sup>105</sup> These farmers “assert[ed] economic injury from the [PTO] Commissioner’s allegedly erroneous interpretation of [35 U.S.C.] section 101.”<sup>106</sup> The court rejected this allegation, denying the farmers standing. The court stated that “the alleged economic injuries of individual farmers and farm organizations are not ‘fairly traceable’ to the allegedly erroneous interpretation of the statute by the Commissioner.”<sup>107</sup> There is, however, considerable debate about whether a “Farmers’ Exemption” would on the one hand effectively eliminate the incentive to research such transgenic life forms,<sup>108</sup> or would, on the other hand, “only minimally reduce[] the incentive effect of patent protection.”<sup>109</sup> Still others argue that not all farmers object to issuing animal patents, and some even opposed the Transgenic Animal Patent Reform Act because of its Farmers’ Exemption.<sup>110</sup>

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102. *Id.*

103. *See* Sellers, *supra* note 89, at 287-88 (1994).

104. 7 U.S.C. § 2543 (1982).

105. *See* *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 931-32 (Fed. Cir. 1991).

106. *Id.* at 931.

107. *Id.* at 936. *See* Hecht, *supra* note 89, at 1048-49.

108. *See* Dresser, *supra* note 1, at 433.

109. Manspeizer, *supra* note 89, at 451.

110. *See* Walter, *supra* note 89, at 1041-42.

## II. ANALYSIS

Like the man in the joke who, although lost and unsure where he is heading, insists that he is making good time, scientists continue to engineer transgenic animals, and the PTO routinely offers patents on these transgenic animals. Because of the competing interests of the corporations that benefit financially from patents on these animals, the public, which might be affected negatively by unintended consequences, and those who advocate on behalf of the animal populations themselves, Congress should step forward and direct the PTO which is currently granting animal patents in an *ad hoc* manner.

### A. SHOULD TRANSGENIC ANIMALS BE PATENTED?

#### 1. The Rights of the Animals

Other concerns emerged in calls for a more carefully-studied approach to the rights of the animals that might be affected.<sup>111</sup> Among the concerns more commonly expressed are that genetically-engineered animals could damage or destroy native species by over population, over consumption, habitat destruction, or simply interbreeding so that no “natural” examples of a species remain.<sup>112</sup> Others are concerned that animal patenting will cause increased animal suffering.<sup>113</sup> Among the plaintiffs in *Animal Legal Defense Fund v. Quigg* were not only farm organizations, but also groups concerned with animal rights, *per se*.<sup>114</sup> The 9th Circuit dismissed the suit for lack of standing. Invoking a newly-entertained legal theory, some have also questioned whether humans’ property rights over animals are such that they allow humans to alter animals’ genetic structures.<sup>115</sup>

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111. See Dresser, *supra* note 1, at 422-24.

112. See *infra* text accompanying notes 142-162.

113. See Chiapetta, *supra* note 87, at 182-84; *infra* text accompanying notes 120-139. *But see* Manspeizer, *supra* note 89, at 441 (dismissing such concerns as having no “factual basis”).

114. Other plaintiffs included the American Society for the Prevention of Cruelty to Animals, The Marin Humane Society, the Association of Veterinarians for Animal Rights, People for the Ethical Treatment of Animals, farm organizations, and individual farmers. See *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 931-32 (Fed. Cir. 1991).

115. See *infra* text accompanying notes 116-140.



## 2. Should Animals Be Patentable “Things”?

The status of animals as mere property has become an increasingly common subject of debate in the legal world.<sup>116</sup> The legal community tends to think of property rights as legal relations between people and things.<sup>117</sup> Thus, several people and entities might have a property interest in a particular parcel of real property.<sup>118</sup> While the common law tradition considers animals as property in just the same way as other objects, contemporary statutory law has changed our relationship to animals as objects of property in many meaningful ways.<sup>119</sup> Every state now has a statute criminalizing cruelty to animals.<sup>120</sup> These statutes vary considerably, some considering animal cruelty a felony while some consider it a misdemeanor, and all but three containing one or more exemptions (typically for farming, research, and veterinary practices).<sup>121</sup> Nevertheless, each of these statutes limits property rights in animals by limiting the range of dominion people have over animals.<sup>122</sup>

In addition to these pervasive state statutes, are several federal statutes, of which “the Animal Welfare Act is the broadest.”<sup>123</sup> The Animal Welfare Act of 1970<sup>124</sup> affects how

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116. See, e.g., GARY L. FRANCIONE, ANIMALS, PROPERTY, AND THE LAW (1995); STEVEN M. WISE, RATTLING THE CAGE: TOWARD LEGAL RIGHTS FOR ANIMALS (2000); Gary L. Francione, *Animals as Property*, 2 ANIMAL L. 1 (1996); Thomas G. Kelch, *Toward a Non Property Status for Animals*, 6 N.Y.U. ENVTL. L. J. 531 (1998); Steven M. Wise, *How Non-human Animals Were Trapped in a Nonexistent Universe*, 1 ANIMAL L. 15 (1995); Steven M. Wise, *The Legal Thinghood of Non-Human Animals*, 23 ENVTL AFF. 471 (1996).

117. See BLACK'S LAW DICTIONARY 1216 (6th ed. 1990) (defining “property” as “[i]n the strict legal sense, an aggregate of rights which are guaranteed and protected by the government”).

118. One person might, for example, own a present possessory interest while another owns a future interest while yet another might possess a very limited property interest in the same land in the form of an easement or other servitude.

119. See Kelch, *supra* note 116, at 533-40 (discussing the historical common law definition of animals as property).

120. See Pamela D. Frasch et al., *State Animal Anti-Cruelty Statutes: An Overview*, 5 ANIMAL L. 69 (1999).

121. See *id.*

122. See *id.* (surveying the provisions of all fifty states' animal cruelty statutes).

123. See Kelch, *supra* note 116, at 542.

124. 7 U.S.C. §§ 2131-59 (1994) (requiring the “humane treatment” of animals in a wide variety of circumstances implicating interstate commerce).

people can legally treat a wide range of animals. The Humane Methods of Slaughter Act of 1978<sup>125</sup> and the Twenty Eight Hour Law<sup>126</sup> limit the property rights farmers have in their livestock. Other federal statutes limit the property rights people have vis-à-vis various types of animals. For example, the Antarctic Science, Tourism, and Conservation Act of 1996,<sup>127</sup> the Bald and Golden Eagle Protection Act,<sup>128</sup> the Endangered Species Act of 1973,<sup>129</sup> the Fur Seal Act of 1966,<sup>130</sup> and the Marine Mammal Protection Act of 1972<sup>131</sup> all limit peoples' property interest in wild animals.<sup>132</sup> Implicit in this lengthy list of statutes is a pervasive, on-going belief that humans' dominion over animals has limits, that we do not consider ourselves free to subject animals to cruelties and other forms of abuse simply as we wish. These myriad statutes imply something of a consensus, in fact, less of a dominion over animals than of a stewardship over them, a stewardship that we appear regularly to interpret as requiring that we protect animals from abuse and extinction.

Even research facilities, so often held separate because of their medical activities, now must maintain at least one “institutional animal care and use committee” (“IACUC”).<sup>133</sup> These state and federal statutes affect our relationships to pets,

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125. 7 U.S.C. §§ 1901-06 (1994) (stating that “the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods”).

126. 46 U.S.C. §§ 3901-02 (1994) (“prescrib[ing] standards for space, ventilation, fittings, food and water supply, and other requirements the Secretary of Agriculture considers necessary for the safe and proper transportation and humane treatment of . . . animals”).

127. 16 U.S.C. §§ 2401-13 (1994).

128. 16 U.S.C. § 668 (1994).

129. 16 U.S.C. §§ 1531-44 (1994).

130. 16 U.S.C. §§ 1151-75 (1994).

131. 16 U.S.C. § 1361 (1982).

132. See Kelch, *supra* note 116, at 543-79 (citing these laws and arguing that the status of animals as property should be changed via the common law). See also Appellants' Opening Brief at 29-30, *Animal Legal Defense Fund* (“ALDF”) 932 F.2d at 920 (No. 90-1364) (citing many of these state and federal statutes and arguing that such statutes establish that animals are not “things”). ALDF thus argued that the PTO's interpretation of Congress' saying that the patent statutes allow for patenting “anything under the sun made by man” should not include animals. *Chakrabarty*, 447 U.S. at 303 (1980). The court did not address this argument as the case was not decided on the merits. See *ALDF*, 932 F.2d at 939 (holding that ALDF did not have standing to challenge the PTO's ruling in 1077 Official Gazette U.S. Pat. & Trademark Off. 24 (Apr. 21, 1987)).

133. Language requiring IACUCs was amended onto the Animal Welfare Act in 1985. See 7 U.S.C. § 2143.

farm animals, wild animals, and research animals as property. They, to a greater or lesser degree, affect the limits of our property rights in animals, problematizing a world view in which animals are thought of as property in just the same way as inanimate objects are. In the language of Professor Francione, these statutes identify animals' "non-tradable interests," that is, interests that are not subject to possession by others.<sup>134</sup> Several lawyers have successfully challenged assumed property rights in animals, arguing that contrary to being property subject to fee simple possession by others, animals retain rights independent of their owners'.<sup>135</sup>

Furthermore, there is reason for concern over how much transgenic research animals might suffer. Some of these animals are created to suffer.<sup>136</sup> Others suffer as a result of unanticipated consequences.<sup>137</sup> The Animal Welfare Act ("AWA"), which was passed to protect, *inter alia*, research animals, allows tremendous abuses of such animals to occur.<sup>138</sup> Animals created to suffer for the entertainment purposes of people, animals created for the purpose of their freakish appearance or their size (big or small) or their unusual abilities, could forseeably endure lifetimes of suffering with no real protection.<sup>139</sup> These concerns are unique to beings that feel

134. See Francione, *Animals as Property*, *supra* note 116, at v (arguing that these statutes do not recognize enough non-tradable interests in animals).

135. See, e.g., William Glaberson, *Legal Pioneers Seek to Raise the Lowly Status of Animals*, N.Y. TIMES, Aug. 18, 1999, at A1 (citing several recent victories in protecting the limited property status of animals).

136. See *supra* note 63. The Harvard Mouse, for example, was designed to be susceptible to and, presumably, die of, cancer. This intentional design raises the question of whether humans have the right to create an animal specifically to die of a painful disease.

137. See, e.g., *supra* text accompanying note 19.

138. See Francione, ANIMALS, PROPERTY, AND THE LAW *supra* note 116, at 211. Professor Francione explains the reason that the AWA is an ineffective tool for relieving animal suffering at the hands of researchers:

Before being assigned enforcement of the AWA, the USDA dealt primarily with the production, treatment, and slaughter of food animals. USDA has never enjoyed a reputation as an organization interested in the humane treatment of animals as a general matter. Indeed, in one case, a court struck down a USDA regulation, holding that the regulation 'does not reflect the views of an agency which gave serious consideration to the prevention of cruelty to animals.' In another case, a court held that the USDA declined 'to consider the benefit to animals as worthy of serious consideration as it decides how best to carry out its mandate' [footnotes omitted].

*Id.*

139. Pamela D. Frasch et al., *supra* note 120, at 69. The only protection

pain, and, therefore, concerns that transgenic animals, as opposed to transgenic plants, generate.

Under the contemporary legal paradigm of assumed stewardship over the natural world, and over animals in particular, regulation preserving the natural animal gene pool seems both reasonable and prudent. As the animal cruelty and other animal-protection statutes exemplify, there has always been a place in American law for doing not only what is practical but also for doing what is good.<sup>140</sup> Engaging in cautious circumspection before extending our dominion over animals to the point of altering their genetic code, even if for the purpose of “improving” them, is a just such a case when it would behoove us to consider not only what is possible, even practical, but also what is good.

### 3. Are Transgenic Animals Safe?

In addition to the questions raised by the potential abuse of transgenic animals, a second category of concern surrounds the questions about whether transgenic animals are safe for people and the natural environment. Cautionary tales about the dangers of altering the natural universe permeate the Western mythos. Some of these stories tell of human hubris while others relate the unintended results of carelessness. Ranging from classical mythology (Dedalus and Pygmalion), to Romantic nineteenth century literature (*Frankenstein*), to popular cinema (*Godzilla*), cautionary tales regarding the dangers of altering the natural universe are a persistent subgenre in the Western tradition. Whether they are grounded, then, in our primordial fears or in rational grasp of metaphysics and science, concerns about genetic engineering abound.

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animal property has against abuse are state animal cruelty statutes. These statutes are famously under-enforced. Professor Pamela Frasch explains that

... some prosecutors are less likely to charge or prosecute animal cruelty compared to other violent crimes, except in the most extreme cases. This apparent reluctance to prosecute stems from many factors, including: real or perceived limited resources; inexperienced staff; incomplete or botched investigations; pressure from the community to focus on other crimes; and personal or political bias against taking animal abuse seriously as a violent crime.

*Id.*

140. See, e.g., Frasch et al., *supra* note 120.

Many of these concerns arise out of the agricultural community. While, it has been argued that some people merely fear the loss of the traditional family farm out of some idealistic or Luddite sensibility,<sup>141</sup> some fears are based squarely in science or economics. Some worry whether transgenic animals could pollute natural gene pools, biodiversity, and ecosystems.<sup>142</sup> Elisabeth Jozwiak asserts that such transgenic animals could not survive in the wild “since the transgenic animals that are produced in the laboratory are acclimated to the sterile laboratory environment.”<sup>143</sup> Jozwiak, however, merely supports this assertion by reference to the gene transference procedure as described by David Manspeizer.<sup>144</sup> However, while the gene insertion is a laboratory process, the “cattle, pigs, sheep, fish, goats, and fowl” thus created<sup>145</sup> do not live in sterile laboratories. They live outdoors subject to the vicissitudes of weather, fence-wrecking accidents, sabotage, theft, and other phenomena which threaten the security of farm animals. And, while some proposed legislation would proscribe the release of genetically-altered animals into the wild,<sup>146</sup> legislative consensus means little to a “geep.”<sup>147</sup>

Non-native species of plant and animal regularly invade environments causing great harm. Manspeizer cites the example of the gypsy moth which, artificially introduced to the United States, has “defoliated an estimated ten million acres.”<sup>148</sup> Professor Dresser cites the damage caused by introducing the non-native kudzu vine into the United States as another example of the harm that can be caused by the release of non-native species into the wild.<sup>149</sup> The gypsy moth

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141. Professor Jim Chen critiques opposition to developments of technology and scale in agribusiness as rooted in “bucolic illusions” arising from “Little Bo Peep” and “Little House on the Prairie.” Jim Chen, *The Agroecological Opium of the Masses*, CHOICES, Fourth Quarter 1995, at 19, 21.

142. See, e.g., Kimbrell, *supra* note 19, at 138-39; Dresser, *supra* note 1, at 412; 138 CONG. REC. E1118 (daily ed. Apr. 28, 1992) (statement of Rep. Cardin); Muir & Howard, *infra* note 155.

143. Jozwiak, *supra* note 97, at 630.

144. See *id.* at 621.

145. See Manspeizer, *supra* note 89, at 424.

146. See, e.g., S. 1291, 102nd Cong. § 105(a)(2) (1991); H.R. 4989, 102nd Cong. § 105(a)(2) (1991) (forbidding “the entering of genetically engineered animals into the open environment beyond appropriately confined research or commercial settings”).

147. See Dresser, *supra* note 1.

148. Manspeizer, *supra* note 89, at 432.

149. See Dresser, *supra* note 1, at 411-12. The non-native kudzu vine has

and kudzu vine were non-native species that were *intentionally* introduced into the U.S. ecosystem, and they, nevertheless, have caused great damage. What damage might be caused by species that are not only “non-native” but also “non-natural” and which might be introduced into the wild *unintentionally* and without controls? Zebra mussels were unintentionally introduced into American lakes in the 1980s.<sup>150</sup> In less than twenty years, they have significantly changed the ecology of some American lakes and rivers, threatening several species of native animals.<sup>151</sup> In addition to consuming food resources native fish and mussel species require and depleting oxygen levels in the waters they inhabit, these accidentally-introduced mussels also clog power station pipes and damage boats.<sup>152</sup>

Several articles have recently expressed concern over transgenic salmon escaping into the wild and, possibly, endangering native populations through over-consumption or over population.<sup>153</sup> Such salmon are typically raised in “net pens” in the sea, which are often rent by waves or predators, allowing thousands of fish to escape.<sup>154</sup> Evidence of the dangers escaped transgenic animals could cause to the environment was recently supplied by two Purdue University scientists who modeled the release of transgenic fish into a wild environment and concluded that “introduction of genetically modified organisms into natural populations could result in ecological hazards, such as species extinction.”<sup>155</sup> Professors Muir and Howard inserted human growth hormone genes into medaka (a type of small fish) to study “the ecological consequences of transgene release into natural populations.”<sup>156</sup> Specifically, they noted “increased male mating success but reduced

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wreaked havoc throughout the Southeastern U. S., growing uncontrollably and devastating crops, since it was introduced to control soil erosion.

150. See Tom Meersman, *Zebra-Mussel Threat Grows in St. Croix*, MINNEAPOLIS STAR TRIBUNE, Aug. 24, 2000, at A1.

151. See *id.*

152. See *id.*

153. See Carol Kaesuk Yoon, *Altered Salmon Lead the Way to the Dinner Plate, but Rules Lag*, N.Y. TIMES, May 1, 2000, at A1. See also Sharon Schmickle, *Professor Acknowledges Worries About Genetically Altered Fish*, MINNEAPOLIS STAR TRIBUNE (Minneapolis), July 24, 2000, at B1.

154. See Yoon, *supra* note 144, at A20.

155. William M. Muir & Richard D. Howard, *Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis*, 96 PROC. NAT'L ACAD. SCI. 13853, 13853 (2000).

156. *Id.*

offspring viability.”<sup>157</sup> They discovered that the transgenic fish had a four-fold mating advantage<sup>158</sup> which spread the transgene in a manner which could be disastrous for the native species: “[w]e refer to this type of extinction as the ‘Trojan gene effect,’ because the mating advantage provides a mechanism for the transgene to enter and spread in a population, and the viability reduction [of the offspring] eventually results in population extinction.”<sup>159</sup>

One proponent of genetically-modified organisms criticizes assertions regarding the potential environmental threats of genetically-engineered animals.<sup>160</sup> He states,

Jeremy Rifkin compares the risks of biotechnology with those of the petrochemical industry and concludes that the risks from rDNA technology are greater. . . . It is hard to understand how Mr. Rifkin can make this assertion in light of dioxin, nuclear waste, oil spills, agent orange, PCBs, and the myriad of other chemical poisons with which we have covered the earth [sic] [citation omitted].<sup>161</sup>

How this critique of Rifkin argues *against* caution in tampering with the Earth is a curious bit of reasoning, indeed. Whether the unforeseeable results of introducing transgenic animal life are greater than, less than, or just the same as the results of the “myriad of . . . chemical poisons with which we have covered the [E]arth” or greater than, less than, or just the same as the invasions of non-native plant and animal species, this argument in favor of patenting transgenic animals sounds a loud cautionary note *against* doing just that. It would be wise to acknowledge Representative Cardin’s simple warning: “[w]e must remember biological pollution cannot be recalled.”<sup>162</sup>

Circumspection is required before we proceed willy-nilly with the creation of transgenic life, and the U.S. patent system, with the guidance of Congress, is in a position to direct the PTO so that it decides whether and when to grant patents for transgenic animals in a manner consistent with the several competing public policy concerns implicated by this technology.

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157. *Id.*

158. *See id.*

159. *Id.* at 13855.

160. Manspeizer, *supra* note 89, at 455 n. 99.

161. *Id.*

162. 138 CONG. REC. E1118 (daily ed. Apr. 28, 1992) (statement of Rep. Cardin).

## B. WHAT RESPONSES ARE APPROPRIATE?

### 1. PTO: The Moral Utility Requirement

Patent law is flexible enough to recognize and adapt to changing social values. As the brief survey of statutes limiting people's property rights in animals reveals,<sup>163</sup> these statutes are new, all having become part of our legal code within the second half of the twentieth century. Patent law can adapt to limit genetic manipulation of animals as well.

Some have argued that the PTO, itself, might employ the “moral utility requirement” of the patent law to deny the Rifkin-Newman patent application for a human-animal chimera.<sup>164</sup> The moral utility requirement is a common law doctrine tracing its lineage from *Lowell v. Lewis*,<sup>165</sup> in which Justice Story explained that “[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral.”<sup>166</sup> As examples of “mischievous or immoral” inventions, Justice Story cites “a new invention to poison people, or to promote debauchery, or to facilitate private assassination.”<sup>167</sup> While the word “moral” was at one time read into the “utility” element of 35 U.S.C. § 101 with the effect of denying patents to “gambling devices and other inventions historically frowned upon by society at large,”<sup>168</sup> such interpretations of the “utility” requirement have largely been abandoned.<sup>169</sup>

Nevertheless, there is some indication that the moral utility requirement might reemerge. In 1991, the Federal Circuit quoted Justice Story's “sound morals” language in

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163. See *supra* text accompanying notes 120-132.

164. See Magnani, *supra* note 1, at 451-54.

165. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (D. Mass.1817) (No. 8568) (defining “useful” as being in contradistinction to frivolous and mischievous rather than a superior invention).

166. *Id.*

167. *Id.*

168. Magnani, *supra* note 1, at 451-54. (citing DONALD S. CHISUM, CHISUM ON PATENTS § 4.03 (1998)).

169. See *id.* at 454.



defining the word “utility” in *Tol-o-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft*.<sup>170</sup> Furthermore, as recently as 1998, the PTO cited both *Lowell* and *Tol-o-Matic* in a “Media Advisory” specifically addressing the possibility of rejecting transgenic patents on moral grounds.<sup>171</sup> Importantly, the PTO, in this case, was addressing the patenting of a “human/non-human chimera,” not a pure transgenic animal, *per se*.<sup>172</sup> However, the PTO does not define how many human genes an animal must have to qualify as a “human/non-human chimera,” and many animals are patented with at least one human gene.<sup>173</sup> Furthermore, the PTO speaks of the morality requirement in broad terms. In stating why it might consider a “human/non-human chimera” not patentable, the PTO Media Advisory states that such an application “would fail to meet the public policy and morality aspects of the utility requirement.”<sup>174</sup> The PTO, thus, breathes life into both “public policy” and “morality” as grounds for considering patents.<sup>175</sup> It does not refer to these elements of the “utility requirement” as specifically limited to human/non-human chimeras.<sup>176</sup> It cites these elements as a regular feature of patent law.<sup>177</sup>

Denying patent protection for the sake of public policy or morality is neither archaic nor beyond the scope of reason. Indeed, in *Chakrabarty* Chief Justice Burger emphasized that the Court was not judging whether multi-cellular animals *should* be patented but merely whether the language of 35 U.S.C. § 101 included such animals.<sup>178</sup> He invited Congress “to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering” if Congress wished to exclude “living things” from patent protection.<sup>179</sup> And Chief Justice Burger cited as an example of a federal statute denying patent protection to an invention that contravenes the public good 42

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170. 945 F.2d 1546, 1553 (Fed. Cir. 1991), *abrogated on other grounds by* *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1991).

171. *See Facts on Patenting Life Forms Having a Relationship to Humans*, Media Advisory, 98-6, (visited Aug. 28, 2000) <<http://www.uspto.gov/web/offices/com/speeches/98-06.htm>> [hereinafter *Facts*].

172. *Id.*

173. The Harvard Mouse, for example, has a human gene.

174. *Facts*, *supra* note 171.

175. *Id.*

176. *See id.*

177. *See id.*

178. 447 U.S. at 318.

179. *Id.*

U.S.C. § 2181(a), which “exempt[s] from patent protection inventions ‘useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.’”<sup>180</sup> Similarly 35 U.S.C. § 287(c) exempts from liability for patent infringement any “medical practitioner” who performs a “medical activity,” thus freeing medical practices for their beneficial uses.<sup>181</sup>

## 2. Congress: Proposed Legislative Responses

Congress has, indeed, taken some steps to take up Chief Justice Burger’s challenge. Whether or not the PTO moves to postpone or proscribe transgenic animal patents based on the Moral Utility Requirement, Congress can and should revive these efforts. Immediately after the April 1987 PTO ruling that “nonnaturally occurring non-human multicellular organisms, including animals, [are] patentable subject matter within the scope of 35 U.S.C. s. 101,”<sup>182</sup> Representative Robert W. Kastenmeier (D. Wisc.) encouraged the PTO to impose an eight-month moratorium on issuing such patents.<sup>183</sup> The PTO agreed,<sup>184</sup> however it issued the patent for the Harvard Mouse shortly after the moratorium expired.<sup>185</sup> Representative Kastenmeier then ushered the Transgenic Animal Patent Reform Act (H.R. 4970) through the House of Representatives; however, the bill never became law.<sup>186</sup>

The several above-mentioned concerns over the patenting of transgenic animals have reached Congress, resulting in a flurry of proposed legislation. Since Rep. Kastenmeier’s bill many others have been introduced. Former Senator Mark Hatfield, the author of several bills intended to restrict transgenic animal patents,<sup>187</sup> has expressed concern that “the

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180. 42 U.S.C. § 2181(a).

181. 35 U.S.C. § 287(c).

182. *See supra* note 4.

183. *See* Edmund J. Sease, *From Microbe to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551, 565 n. 85 (1988-1989).

184. *See id.*

185. *See supra* note 8.

186. *See id.*

187. *See, e.g.*, S. 1291 102nd Cong. (1991) (imposing a five-year moratorium on the granting of patents on invertebrate or vertebrate animals to provide Congress time to examine issues raised by such patents); S. 387, 103rd Cong. (1993) (imposing a two-year moratorium on patenting certain human tissues and animal organisms to provide Congress time to examine issues raised by

most difficult biomedical ethical issues of our time . . . [have] linger[ed] with little guidance or dialogue.”<sup>188</sup> Hatfield argues that “Congress *may* act to significantly restrict or alter the Patent and Trademark Office policy of patenting animals. . . ;”<sup>189</sup> therefore, he argues, “Congress—as the elected representatives of the people—*must* play a role in making these important decisions” (emphasis added).<sup>190</sup> Senator Hatfield “introduced legislation to place a moratorium on allowing the [PTO] to issue patents on living organisms” in every session of Congress between 1987 and 1995.<sup>191</sup> However, despite frequent calls for Congressional oversight,<sup>192</sup> the PTO, as Senator Hatfield puts it, continues to decide the nuances of the current law’s applicability “aided only by centuries old patent law.”<sup>193</sup> Senator Hatfield’s “Life Patenting Moratorium Act of 1993” called for a two-year moratorium during which no “genetically engineered animal shall be considered patentable subject matter.”<sup>194</sup> As his reasons for slowing the progress of patenting transgenic life, Senator Hatfield noted that “[t]he rapid advances in biotechnology and biomedical research capabilities are creating a wide range of ethical, legal, economic, environmental, international and social issues, including concerns about the patenting of life forms, eugenics, genetic discrimination, and conflicts of interest for biomedical researchers. . . .”<sup>195</sup>

A sample of the bills introduced in Congress as a result of the transgenic animal patent boom include the “Transgenic Animal Patent Reform Act,”<sup>196</sup> the “Transgenic Animal Regulatory Reform Act,”<sup>197</sup> the “Transgenic Animal Patent Improvement Act,”<sup>198</sup> and the “Life Patenting Moratorium Act

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such patents).

188. Hatfield, *supra* note 94, at 5.

189. S. 387, 103rd Cong. § 2(6) (1993).

190. Hatfield, *supra* note 94, at 5.

191. Hatfield, *supra* note 94, at 6. Absent committee reports, there is little documentary evidence to explain why each of these several bills did not emerge from their committees to be debated on the floor.

192. See Dresser, *supra* note 1, at n. 2; Manspeizer, *supra* note 89, at 419 n.17.

193. Hatfield, *supra* note 94, at 6.

194. S. 387, 103rd Cong. (1993) § 3.

195. *Id.* § 2.

196. H.R. 1556, 101st Cong. (1989).

197. H.R. 1557, 101st Cong. (1989).

198. H.R. 5598, 101st Cong. (1990).

of 1993.”<sup>199</sup> These bills have been sponsored or co-sponsored by twenty-one different members of the House and the Senate.<sup>200</sup> While these Members of Congress are united in their opposition to or concern about patenting transgenic animal life, their reasons, and, therefore, their proposed solutions, vary widely.

Benjamin Cardin has been among the most outspoken Members of Congress on the subject of patenting transgenic animals, expressing several different concerns. On the subject of corporate consolidation of the means of agribusiness, he has predicted that “[i]n years to come there could be increasing competition for corporate control and ownership of the gene pool of animal species.”<sup>201</sup> Reflecting the concerns some small farmers have about this phenomenon, Rep. Cardin continued,

The most immediate economic effect of this policy could be felt in agriculture, where the major chemical[,] biotechnology, and pharmaceutical companies could conceivably position themselves to take over animal husbandry. The Patent Office has confirmed farmers will have to pay patent fees every time they breed a patented animal or sell part of their herds which contain such patented animals. This will also be true for researchers using patented laboratory animals. The economic consequences of animal patenting on small farmers and research institutions need to be carefully examined.<sup>202</sup>

Congressman Cardin has also expressed concern that genetically engineered animals could destroy native species either directly (by breeding with the natural animals, thereby, permanently altering their gene pool) or indirectly (through behavior such as displacing native species from their habitat, over population, or over consumption).<sup>203</sup> As a result, his bill (identical to one offered in the Senate by Senator Hatfield) calls for a five-year moratorium on the patenting of transgenic

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199. S. 387, 103rd Cong. (1993).

200. Senator Hatfield, Representatives Benjamin Cardin (D-MD), Robert Kastenmeier (D-WI), Robert Roe (D-NJ), Mike Synar (D-OK), John Bryant (R-TX), George Sangmeister (D-IL), Marilyn Lloyd (D-TN), Steve Schiff (R-NM), Rick Boucher (D-VA), Carlos Moorhead (R-CA), Mel Levine (D-CA), Dan Glickman (D-KS), James Sensenbrenner (R-WI), Robert Matsui (D-CA), James Bates (D-CA), Helen Bentley (R-MD), Brian Bilbray (D-NV), Cardis Collins (D-IL), Bill Lipinski (D-IL), and Dale Kildee (D-MI).

201. 138 CONG. REC. E1118 (daily ed. Apr. 28, 1992) (statement of Rep. Cardin).

202. *Id.*

203. *See id.*

animals.<sup>204</sup>

Other bills have approached the subject of restraining the growth of transgenic animal patents differently. Representative Kastenmeier advocates regulation of the technology rather than retardation of it. His "Transgenic Animal Regulatory Reform Act" called for establishing a "Biotechnology Science Coordinating Committee" comprising members of relevant administrative agencies.<sup>205</sup> This committee would "serve as a coordinating forum for addressing scientific problems, sharing information, and developing consensus with respect to methods for evaluating potential risks to human health and the environment which are or may be caused by genetically-engineered animals."<sup>206</sup> This committee would foster consensus and would promote "consisten[t]" and "good" laboratory and manufacturing practices.<sup>207</sup> Representative Kastenmeier's bill would also "protect[] . . . agricultural resources" by issuing temporary, renewable permits, without which "no person may use a genetically-engineered animal in an agricultural activity."<sup>208</sup> While Rep. Kastenmeier's Biotechnology Science Coordinating Committee never saw the light of day, President Clinton authorized a National Bioethics Advisory Commission, the function of which is to, *inter alia*, advise government agencies on the ethics of *human* genetic research.<sup>209</sup>

Yet another group of bills proffered in response to the flourishing animal patent industry attempted to address the concerns small farmers have voiced about being pushed out of farming by big agribusiness companies with monopolies on animal patents. The common solution to that concern is to grant a "farmers' exemption" to patent infringement.<sup>210</sup> The "Transgenic Animal Patent Reform Act," for example, states that "[i]t shall not be an infringement for a person whose

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204. See H.R. 4989, 102nd Cong. (1992) § 2(b) ("During the 5-year period beginning on the date of the enactment of this section, no invertebrate or vertebrate animal, including any genetically engineered animal, shall be considered patentable subject matter under [Title 35].").

205. See H.R. 1557, 101st Cong. (1989) § 101.

206. *Id.*

207. *See id.*

208. *Id.* § 202.

209. See Exec. Order No. 12,975, 60 Fed. Reg. 52063 (1995).

210. While Rep. Cardin also recognized the potential threat to farmers of an agribusiness monopoly or oligopoly controlling animal genes he did not include a farmers' exemption in H.R. 4989, 102nd Cong. (1992).

occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.”<sup>211</sup> While this statute, however, expressly forbade selling “the germ cells, semen, or embryos of a patented transgenic farm animal,” the “Transgenic Animal Patent Improvement Act,” introduced eighteen months later, exempted dissemination of the animals if reproduced through conventional means. It stated that “[i]t shall not be an act of infringement for a person to . . . use or sell the reproductive material, including germ cells, sperm, eggs, or embryos, of [a patented transgenic farm animal] in the farming operation.”<sup>212</sup> This modified legislation would have given farmers even greater access to such animals than the previous bills’ farmers’ exemptions would have.<sup>213</sup> In addition to a “farmers’ exemption,” several of the bills that have been presented to Congress also have an exemption for biomedical research.<sup>214</sup>

While the number of bills to regulate the patenting of transgenic animals has dropped off in recent years, the upsurge in public awareness and concern over genetic modification of both plants and animals<sup>215</sup> indicates that Congress should reconsider the issue afresh. That such bills have not succeeded in the past should not discourage Members of Congress from reintroducing some of the old bills or writing new bills aimed at restricting the PTO’s patent grants for transgenic animals. That the bills did not succeed does not necessarily signal the death of the issue. Public awareness of the issue is growing, and the U.S. Congress is rife with examples of legislation which was proposed several times, sometimes lying dormant for decades before becoming law. For example, voting rights of women were proposed at the very founding of the country, but were only realized in 1920. The line-item veto was proposed during the Nixon administration, lay dormant for decades, and became law during the Clinton administration. In

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211. H.R. 1556, 101st Cong. (1989) § 2.

212. H.R. 5598, 101st Cong. (1990) § 202. Rep. Kastenmeier was the sole (H.R. 1556) or primary (H.R. 5598) sponsor of both bills. Another difference in the similar bills is that H.R. 5598, part of a larger, general patent reform act, extended the exemption for use of patented transgenic farm animals to “a person” rather than “a person whose occupation is farming” as had H.R. 1556.

213. See Manspeizer, *supra* note 89, at 450-51 (discussing the proposed farmers’ exemptions and their potential effects on research).

214. See, e.g., H.R. 1557 101st Cong. (1989) § 202(a).

215. See *supra* text accompanying notes 11-19.

*Chakrabarty*, Chief Justice Burger noted that given the language of the patent statute, as a matter of statutory interpretation, the Court could only decide the case one way, and he challenged Congress to amend the patent statute.<sup>216</sup> Several Members of Congress rose to that challenge, despite the relative paucity of public knowledge of or interest in the issue. Now that the public is aware of the issues surrounding the patenting of transgenic animals, as well as plants, Congress would have a greater chance of passing such legislation and should try again.<sup>217</sup>

## CONCLUSION

As the realities of science surpass what only recently passed for science fiction,<sup>218</sup> Congress should reconsider legislation regulating the issuing of patents for transgenic animals. Among the questions that should be faced directly, rather than answered by Congress' lack of action, is what animals are patentable. If most agree that oil-eating microbes are appropriately patentable but human-animal chimeras ("geople"?) are not, where is that line to be drawn? What are appropriate uses for transgenic animals? As long as doing so is profitable, business will find new uses for transgenic animals. It is easy to imagine transgenic domestic dogs and cats which could breed with natural dogs and cats, spreading unforeseen genetic defects through pet breeds. Transgenic nuisance animals (crows and squirrels, for example) could be created to destroy native populations (through over-consumption of resources or territory), leading to a chain-reaction effect on ecosystems that require these or other animals. Freakish animals could be created for entertainment purposes without adequate attention given to the animal's potential to suffer. Indeed, one man has inserted a jellyfish gene into a domestic rabbit to create a glow-in-the-dark rabbit, which he considers a work of art.<sup>219</sup>

It is too late to put the technological genie back into the bottle. We have and always will have the technology to

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216. *See supra* text accompanying notes 179-181.

217. *See supra* text accompanying notes 11-19 and 69-70.

218. The science fiction film *SPACE TRUCKERS* includes pigs that have been genetically-engineered to be square, for ease of stacking. (Lions Gate Films 1997).

219. *World News Tonight* (ABC television broadcast, Sept. 18, 2000).

genetically manipulate non-human and human animals. However, this process must be controlled before greater or lesser harm is caused to humans, to the environment, or to the animals, themselves. Congress must pass, and the President must sign, legislation to create a supervisory committee to determine the advisability and ethics of allowing patents on whatever genetically-manipulated animal is profitable.

Otherwise, before we can teach our children “Old Macdonald,” we will first have to ask, “What sound does a geep make?”



