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## Hindering The Progress Of Science: The Use Of The Patent System To Regulate Research On Genetically Altered Animals

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# HINDERING THE PROGRESS OF SCIENCE: THE USE OF THE PATENT SYSTEM TO REGULATE RESEARCH ON GENETICALLY ALTERED ANIMALS

## I. Introduction

On April 17, 1987, the United States Patent and Trademark Office (PTO) announced<sup>1</sup> that the PTO would begin accepting patent applications on new forms of animal life created by genetic engineering.<sup>2</sup> The PTO's new patenting policy initiated a ground swell of controversy involving legal,<sup>3</sup> economic,<sup>4</sup> environmental<sup>5</sup> and eth-

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1. See *U.S. to Grant Patents on Animals*, Wash. Post, Apr. 18, 1987, at A24, col. 1 [hereinafter *Patents on Animals*]. The new patent policy was set forth in an April 7, 1987, memorandum by Patent and Trademark Office Commissioner Donald Quigg. See *id.* The announcement was prompted by the patent office appellate board's ruling, four days earlier, in *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (B.P.A.I. 1987). *Id.*

2. Genetic engineering refers to genetic manipulation technologies, such as the recombinant deoxyribonucleic acid (DNA) technique. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986).

Cells of every living organism contain chromosomes. Each chromosome comprises tens of thousands of genes strung next to each other in a chain. Genes are made up of DNA, the genetic material determining the structure and biochemistry of all living organisms. The DNA sequences found in genes determine which amino acids and proteins are produced by cells which, in turn, produce the particular characteristics of the entire organism. See generally OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 33-36 (1984) [hereinafter OTA STUDY]; W. HEXTER & H. YOST, THE SCIENCE OF GENETICS 285-321 (1976); Talbot, *Introduction to Recombinant DNA Research, Development and the Evolution of the NIH Guidelines, and Proposed Legislation*, 12 U. TOL. L. REV. 804, 804-14 (1981) [hereinafter Talbot].

A genetic engineer can isolate a specific gene from an organism and insert that gene into the chromosome of another organism, altering its genetic code for a particular characteristic. The specific gene is not added to a mature organism, but to a single-cell fertilized egg. The egg divides into millions of cells resulting in a mature organism. Each cell of the new organism contains the specific gene that was added to the original egg. See *Patents and the Constitution: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 3 (1987) (statement of T. Wagner, Director of the Edison Animal Biotechnology Center at Ohio University, June 11, 1987) (these hearings were in response to the PTO's decision allowing animal patents) [hereinafter *Hearings: Patents*].

3. See *infra* notes 161-81 and accompanying text.

4. See *infra* notes 182-91 and accompanying text.

5. See *infra* notes 192-99 and accompanying text.

ical issues.<sup>6</sup> Although patents had previously been granted for genetically altered bacteria,<sup>7</sup> this marked the first time that patents could be granted for animals genetically altered by man.<sup>8</sup> Then, on April 12, 1988, less than one year after the PTO's announcement, the world's first animal patent was issued for a genetically altered mouse.<sup>9</sup>

In deciding to allow the patenting of genetically altered animals, the PTO relied on the Supreme Court's recent decision in *Diamond v. Chakrabarty*,<sup>10</sup> in which the Court determined that patentable subject matter included "anything under the sun that is made by man."<sup>11</sup> *Chakrabarty*'s broad interpretation of patentable subject matter led to a tremendous increase in the number of companies doing research in the field of genetic engineering.<sup>12</sup> With the promise of patents to protect their investments,<sup>13</sup> researchers began inventing genetically altered bacteria,<sup>14</sup> which yielded a variety of bene-

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6. See *infra* notes 200-04 and accompanying text.

7. Recently obtained patents for genetically altered bacteria include U.S. Pat. No. 4,362,816 (1982) (process for creating new microorganisms that produce insulin, assigned to Upjohn Co.); U.S. Pat. No. 4,350,769 (1982) (microorganisms that produce thickening agent for aqueous systems, assigned to Merck & Co., Inc.); U.S. Pat. No. 4,259,444 (1981) (microorganisms that can digest crude oil, assigned to General Electric Co.).

8. See *New Animal Forms Will Be Patented*, N.Y. Times, Apr. 17, 1987, at A20, col. 1 [hereinafter *New Animal Forms*].

9. See *Mouse Patent, a First, Issued to Harvard*, N.Y. Times, Apr. 13, 1988, at A1, col. 5 (U.S. Pat. No. 4,736,866 for "transgenic nonhuman mammals") [hereinafter *Mouse Patent*]; *Some Fear a Future of Animal Patents*, Boston Globe, Apr. 13, 1988, at 10, col. 3 ("the U.S. government this week crossed a Rubicon") [hereinafter *Future of Animal Patents*]; see also *A Mouse That Roared*, TIME, Apr. 25, 1988, at 83 (first animal patent causes storm in Congress). For a discussion of the new patent, see *infra* note 129 and accompanying text.

10. 447 U.S. 303 (1980); see "Animals-Patentability," Memorandum of Donald Quigg, Commissioner of the Patent and Trademark Office, Apr. 7, 1987 (available at *Fordham Urban Law Journal* office) [hereinafter PTO Memorandum].

11. *Chakrabarty*, 447 U.S. at 309 (quoting Committee Reports accompanying Patent Act of 1952, S. REP. NO. 1979, 82d Cong., 2d Sess. 5, reprinted in 1952 U.S. CODE CONG. & ADMIN. NEWS 2394, 2399).

12. See Gore & Owens, *The Challenge of Biotechnology*, 3 YALE L. & POL'Y REV. 336, 339 (1985) [hereinafter *Gore*]; M. KENNEY, *BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* 190-91 (1986). In 1987, some four hundred firms, representing an aggregate investment of over one billion dollars, participated in the biotechnology industry. See *Science Debates Using Tools to Redesign Life*, N.Y. Times, June 8, 1987, at A17, col. 1 [hereinafter *Redesign Life*].

13. The Patent and Trademark Office Commissioner's notice of July 29, 1980, heralded the decision to apply *Chakrabarty* to patent applications for microorganisms. 997 OFF. GAZ. PAT. OFFICE 24 (Aug. 24, 1980).

14. Since 1980, the PTO has issued almost 200 patents on genetically altered bacteria. See *New Animal Forms*, *supra* note 8, at A20, col. 2; see also Hutz, *Patent*

fits.<sup>15</sup> For example, genetically altered microorganisms have been utilized in cleaning up toxic waste and oil spills,<sup>16</sup> protecting crops from frost,<sup>17</sup> creating new beneficial drugs,<sup>18</sup> enhancing food production<sup>19</sup> and furnishing a more efficient means to produce chemicals.<sup>20</sup> Technology regarding genetically altered animals, it is believed, promises even greater advances in scientific knowledge.<sup>21</sup>

A coalition of animal rights activists,<sup>22</sup> farm lobbyists,<sup>23</sup> and environmental<sup>24</sup> and religious groups,<sup>25</sup> however, believe that the potential benefits of genetically altered animals are overshadowed by the potential dangers of this new technology.<sup>26</sup> The coalition

*Protection for Living Organisms*, 5 DEL. LAW. 30, 30 (1986) [hereinafter Hutz]; Gore, *supra* note 12, at 339.

15. See Hutz, *supra* note 14, at 30. See generally OTA STUDY, *supra* note 2, at 119-257; Karny, *Regulation of Genetic Engineering: Less Concern about Frankensteins But Time For Action on Commercial Production*, 12 U. TOL. L. REV. 815 (1981).

16. Chakrabarty concerned the patentability of oil-eating microorganisms. 447 U.S. at 305; see also OTA STUDY, *supra* note 2, at 217-25 (use of genetically altered microorganisms for pollution control).

17. See Recombinant DNA Research; Actions Under Guidelines, 48 Fed. Reg. 24,549 (1983) (release of strains of *Pseudomonas syringae* and *Erwinia herbicola*, bacteria sprayed on crops to prevent freezing); OTA STUDY, *supra* note 2, at 184 (genetic material causing initiation of ice crystals was removed).

18. See OTA STUDY, *supra* note 2, at 119 (pharmaceutical industry is leader in applications of new genetic technologies).

19. See *id.* at 183-84 (microorganisms produce insecticides and aid in disease suppression to increase food production); SUBCOMM. ON INVESTIGATION AND OVERSIGHT OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 95TH CONG., 2D SESS., THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 14 (Comm. Print 1984) (statement of R. Hardy, Director of Life Sciences Research at Du Pont) (six billion people will inhabit the earth by the year 2000).

20. See OTA STUDY, *supra* note 2, at 5, 195 (use of genetically altered bacteria replaces traditional methods of chemical production).

21. See *Hearings: Patents*, *supra* note 2, at 4 (statement of M. Ostrach, Senior Vice-President and General Counsel, Cetus Corp., Aug. 21, 1987); *Mouse Patent*, *supra* note 9, at A1, col. 5 (genetically altered mouse presents scientists with more efficient means for testing new drugs and therapies to treat cancer). See generally OTA STUDY, *supra* note 2, at 119-257. For the purpose of this Note, an animal is a multicellular organism that is not a plant or bacterium.

22. See *infra* notes 136-38 and accompanying text.

23. See *infra* notes 134-35 and accompanying text.

24. See *infra* notes 139-41 and accompanying text.

25. See *infra* notes 142-44 and accompanying text.

26. See *Concern Over Genetics Prompts a New Coalition of Critics*, N.Y. Times, June 9, 1987, at C1, col. 3 (promise and risk of genetic engineering) [hereinafter *New Coalition*]; *Religious Groups Join Animal Patent Battle*, 237 SCIENCE 480, 480 (1987) (quoting A. Brouwer, General Secretary of the National Council of Churches) ("[t]he gift of life from God, in all its forms and species, should not be regarded solely as if it were a chemical product, subject to genetic alteration and patentable for economic benefit") [hereinafter *Religious Groups Join*].

alleges that by patenting genetically altered animals, the animal kingdom will be reduced to a commercial commodity<sup>27</sup> with genetically altered human beings next in line for ownership.<sup>28</sup>

On the other hand, many groups support the patenting of genetically altered animals.<sup>29</sup> Pharmaceutical firms, biotechnology companies and many researchers believe that they must protect their investments and move forward in an internationally competitive field.<sup>30</sup>

The controversy surrounding the patenting of genetically altered animals<sup>31</sup> led to the introduction of a bill in Congress that would impose a two-year moratorium on the issuance of such patents.<sup>32</sup> Specifically, the moratorium pertains to patents that list animals produced by artificial genetic manipulations as the patents' subject matter.<sup>33</sup>

This Note considers whether animal inventions should be protected by the PTO and discusses the ramifications of a congressionally imposed moratorium on the issuance of animal patents. Part II of the Note discusses the purpose of the patent system and analyzes case law concerning patents on living organisms. Part III examines the controversy surrounding the patenting of genetically altered animals. Part IV examines the implications of patenting genetically altered animals and contains a discussion of the PTO's role in issuing an ethically controversial patent. Finally, the Note concludes that the PTO was correct in determining that genetically altered animals are patentable subject matter.

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27. See *Biotechnology's New Strain of Strife*, INSIGHT, Aug. 31, 1987, at 56 (statement of J. Rifkin, President, Foundation on Economic Trends) [hereinafter *Strain of Strife*].

28. See *New Coalition*, *supra* note 26, at C8, col. 1 (remarks of G. Annas, Professor of Health Law at the Boston University School of Public Health) ("[Genetic engineering] is a slippery slope. Where do we draw the line?").

29. See *infra* notes 145-54 and accompanying text.

30. See *Hearings: Patents*, *supra* note 2, at 5-7 (statement of W. Duffey on behalf of Intellectual Property Owners, Inc. and Industrial Biotechnology Association, July 22, 1987); *id.* at 2 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987).

31. See *infra* notes 130-60 and accompanying text.

32. 133 CONG. REC. H7206 (daily ed. Aug. 5, 1987) (statement of Rep. Rose); see *New Bill Seeks 2-Year Delay For Any Patents for Animals*, N.Y. Times, Aug. 6, 1987, at A18, col. 1 [hereinafter *New Bill*].

33. H.R. 3119, 100th Cong., 1st Sess. (1987) (introduced by Rep. Rose); see *New Bill*, *supra* note 32, at A18, col. 1 (same). This is the first time in the 197-year history of the patent system that legislation has been proposed to block a policy that the PTO has already put into effect. *Id.*

## II. Background

For almost 200 years the United States patent system has encouraged inventors to invest in new, high-risk technology by offering temporary protection from invention thieves.<sup>34</sup> This encouragement continued in the technological field of genetic engineering by affording new bacterium inventions patent protection.<sup>35</sup> When genetic engineers focused their innovative skills on animals,<sup>36</sup> the PTO continued to encourage research by protecting the scientists' new inventions.<sup>37</sup>

### A. The Patent System

Congress created the patent system in 1790 as the legal instrument to promote innovation in the technological sciences.<sup>38</sup> The Constitution authorizes Congress "to promote the [p]rogress of [s]cience and the useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries"<sup>39</sup> and "[to] make all [l]aws which shall be necessary and proper for carrying into [e]xecution the foregoing [p]owers."<sup>40</sup> Thomas Jefferson, who was instrumental in drafting this provision, felt that ingenuity should be liberally encouraged<sup>41</sup> and, accordingly, one should receive a patent for inventing or discovering any useful art,<sup>42</sup> manufac-

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34. See 1 A. WALKER, WALKER ON PATENTS § 1:9, at 57 (E. Lipscomb 3d ed. 1984) (the first Patent Act was enacted in 1790) [hereinafter WALKER]. A patent allows an inventor to exclude all others from making, using or selling his or her invention for seventeen years. 35 U.S.C. § 154 (1982).

35. See *supra* notes 13-14 and accompanying text.

36. See Talbot, *supra* note 2, at 806 (higher organisms are next class to be explored).

37. See PTO Memorandum, *supra* note 10, at 1 (PTO considers animals to be patentable subject matter); see also OTA STUDY, *supra* note 2, at 400-01 (promotion of genetic engineering through patents).

38. See 1 WALKER, *supra* note 34, § 1:9, at 57-58 (Thomas Jefferson spoke highly of First Patent Act of 1790).

39. U.S. CONST. art. I, § 8, cl. 8.

40. *Id.* § 8, cl. 18.

41. See 1 WALKER, *supra* note 34, § 1:9, at 58, § 2:1, at 72.

42. "Art" is included in the definition of process. See 35 U.S.C. § 100(b) (1982); 1 WALKER, *supra* note 34, § 2:4, at 103. In *Cochrane v. Deener*, 94 U.S. 780 (1876), the Supreme Court defined a process as "[a] mode of treatment of certain materials to produce a given result . . . . The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence." *Id.* at 788. It should be noted that the process or method itself is patentable subject matter and the claim need not

ture,<sup>43</sup> machine,<sup>44</sup> device or any improvement thereof not before known or used.<sup>45</sup> The current Patent Act,<sup>46</sup> which was enacted in 1952,<sup>47</sup> preserves these basic, liberal requirements.<sup>48</sup>

When filing a patent application with the PTO, an applicant must set forth a statement satisfying certain requirements of the Patent Act.<sup>49</sup> Section 101 of the Patent Act<sup>50</sup> provides the first requirement for patentability: "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."<sup>51</sup> This first requirement contains three separate and distinct elements:<sup>52</sup> novelty,<sup>53</sup> utility<sup>54</sup> and patentable subject matter.<sup>55</sup> While section 101 states that the invention must be new, section 102<sup>56</sup> deals exclusively with the issue of novelty.<sup>57</sup> Consequently, one does not have to show novelty of invention to satisfy the section 101 requirement of patentability.<sup>58</sup> The novelty element of section 101 focuses on whether the invention presents a new patentable subject matter,<sup>59</sup> as opposed to the section 102 requirement which seeks a comparison with prior inventions to determine

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involve a structure or end product. *See* *Dennison Mfg. Co. v. Ben Clements & Sons, Inc.*, 467 F. Supp. 391, 405 (S.D.N.Y. 1979).

43. *See infra* note 70 and accompanying text.

44. *See infra* note 69 and accompanying text.

45. *See* *Maloney-Crawford Tank Corp. v. Sauder Tank Co.*, 465 F.2d 1356, 1365 (10th Cir. 1972). An improvement is some variance, simplification or addition that is new and different from existing machines, processes or manufactures. *See* 1 WALKER, *supra* note 34, § 2:10, at 148.

46. 35 U.S.C. §§ 100-376 (1982) (Patent Act of 1952).

47. *Id.*

48. *See* *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980); *In re Bergy*, 596 F.2d 952, 973-74 (C.C.P.A. 1979), *dismissed as moot sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

49. *See* 35 U.S.C. § 112 (1982) (specification of new invention).

50. *Id.* § 101.

51. *Id.* "The first door which must be opened on the difficult path to patentability is § 101." *Bergy*, 596 F.2d at 960.

52. *See Bergy*, 596 F.2d at 960.

53. *See infra* note 73 and accompanying text.

54. *See infra* notes 62-66 and accompanying text.

55. *See infra* notes 67-71 and accompanying text.

56. 35 U.S.C. § 102 (1982) (patentability conditions for novelty and loss of right to patent).

57. *See Bergy*, 596 F.2d at 961.

58. *See In re Waldbaum*, 457 F.2d 997, 1002-03 (C.C.P.A. 1972) (court discusses "new" uses under patent statutes).

59. *See* *Diamond v. Diehr*, 450 U.S. 175, 188-91 (1981) (the novelty of an invention is examined in § 102 and not in § 101).

if the invention is actually "new."<sup>60</sup> The two remaining elements, utility and subject matter, must also be satisfied under section 101.<sup>61</sup>

The utility element of section 101 requires that the invention: (1) have a known purpose that is either apparent from the description of the invention in the patent application or, if not apparent, is specifically recited in the application;<sup>62</sup> and (2) operate to perform its intended purpose or function.<sup>63</sup> This second aspect of the utility element, operability, requires that patent application statements regarding the performance of the invention for its intended purpose be "believable on its face to persons skilled in the art in view of contemporary knowledge."<sup>64</sup> The inventor must submit "adequate proof"<sup>65</sup> of the invention's operability through affidavits of experts, test results or a model of the invention.<sup>66</sup>

The subject matter element of section 101 requires that the invention fit into one of four categories: a process, a machine, a manufacture or a composition of matter.<sup>67</sup> The term "process" is defined in section 100(b) as a "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."<sup>68</sup> A "machine" is defined as any mechanical contrivance designed to perform some function.<sup>69</sup> The term "manufacture" means the production of articles from raw materials produced by changing the raw materials into new forms, giving them new qualities, properties or combinations.<sup>70</sup> A "composition

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60. See *id.*; see also *Waldbaum*, 457 F.2d at 1002-03; 1 WALKER, *supra* note 34, § 4:4, at 269-70. An invention is not novel if before it was invented it was "known or used by others in this country, or patented or described in a printed publication in this or a foreign country . . ." 35 U.S.C. § 102(a) (1982).

61. See *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979), *dismissed as moot sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

62. See 1 WALKER, *supra* note 34, § 5:4, at 490-91 (comprehensive definition of "useful" is difficult to convey).

63. See *id.*

64. See *Hearings: Patents*, *supra* note 2, at 3 (statement of R. Tegtmeyer, Assistant Commissioner of PTO, June 11, 1987).

65. See 1 WALKER, *supra* note 34, § 5:17, at 558-59 (admissibility of utility requires any competent evidence).

66. See *Hearings: Patents*, *supra* note 2, at 3-4 (statement of R. Tegtmeyer, Assistant Commissioner of PTO, June 11, 1987).

67. 35 U.S.C. § 101 (1982); see also *Parker v. Flook*, 437 U.S. 584, 584-96 (1978) (holding computerized method of updating alarm limits outside four categories of § 101 subject matter).

68. 35 U.S.C. § 100(b) (1982); see also 1 WALKER, *supra* note 34, § 2:4, at 102-03; *Cochrane v. Deener*, 94 U.S. 780, 788 (1877) ("[a] process is a mode of treatment of certain materials to produce a given result").

69. See 1 WALKER, *supra* note 34, § 2:7, at 134-35.

70. See *id.* § 2:8, at 139 (the term "manufacture" does not include processes, machines and compositions of matter).



of matter” is construed to mean all composite articles, whether they are the result of gases, fluids or powders, or mechanical mixtures.<sup>71</sup>

After satisfying the elements of section 101, the inventor must meet the “novelty” and “nonobvious” requirements of section 102 and 103, respectively.<sup>72</sup> “Novelty” means that a patent can only be obtained if the identical subject matter did not exist in a prior art.<sup>73</sup> “Nonobviousness” means that a patent can only be obtained if differences exist between the invention and the prior art to the extent that one skilled in the relevant art, at the time the invention was made, would not conclude that the invention as a whole is equivalent to the prior art.<sup>74</sup>

Finally, the patent applicant must comply with the disclosure and claiming requirements of section 112.<sup>75</sup> Section 112 requires that the patent application describe the invention in such a manner that one skilled in the relevant art can make and use the invention without the exercise of independent inventive skills.<sup>76</sup> Furthermore, the patent application, in one or more claims, must set forth particularly and distinctly the subject matter of the invention.<sup>77</sup>

## B. Patentability of Living Organisms

### 1. *Pre-Chakrabarty Treatment of Living Organisms*

The PTO has been issuing patents on living matter for more than a century.<sup>78</sup> For example, in 1873, the PTO issued patent

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71. See *id.* § 2:9, at 143-44; see also *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (Supreme Court’s definition of “composition of matter” is consistent with its common usage).

72. 35 U.S.C. §§ 102-103 (1982); see *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979), *dismissed as moot sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980) (§ 102 and § 103 are the second and third doors that must be opened to obtain a patent).

73. See 35 U.S.C. § 102 (1982); see also 1 WALKER, *supra* note 34, § 4:1, at 258-59.

74. 35 U.S.C. § 103 (1982). For a discussion of “nonobviousness” and § 103, see *Graham v. John Deere Co.*, 383 U.S. 1, 12-19 (1966).

75. See 35 U.S.C. § 112 (1982). See generally 3 WALKER, *supra* note 34, § 10:1, at 182-87.

76. See 35 U.S.C. § 112 (1982).

77. See *id.*

78. See *In re Bergy*, 596 F.2d 952, 985 (C.C.P.A. 1979), *dismissed as moot sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980); I. COOPER, *BIOTECHNOLOGY AND THE LAW* § 2.02, at 2-5 (1982) [hereinafter COOPER]; Hutz, *supra* note 14, at 34 .n.3.

141,072 to Louis Pasteur for his invention of a pure culture of yeast.<sup>79</sup> Since 1873, several patents involving living organisms were issued by the PTO<sup>80</sup> which recognized that living organism inventions were a result of human ingenuity and research, and hence, fully protected by the patent statutes.<sup>81</sup>

The PTO's practice of issuing patents on living "processes" was first challenged in *Guaranty Trust Co. v. Union Solvents Corp.*,<sup>82</sup> a patent infringement case.<sup>83</sup> In *Guaranty Trust Co.*, the infringer attacked the validity of a patent issued for a bacteriological process used in making acetone and alcohol,<sup>84</sup> alleging that a "life process of a living organism" does not constitute patentable subject matter.<sup>85</sup> The court rejected this argument and held that life processes were patentable subject matter.<sup>86</sup> The appellate court affirmed the decision because it was persuaded "that the invention disclosed in the patent created a new and important commercial enterprise [which should be protected against infringement] . . . ."<sup>87</sup>

The patenting of a living "process," however, was not without restrictions. The PTO would not issue a patent on a naturally occurring process, a "handiwork of nature."<sup>88</sup> Even when the process used an organism that expressed traits not typically exhibited in nature, if the traits were a natural property of the organism, the process that used the organism could not be patented.<sup>89</sup> Furthermore, merely because a non-natural living process was found to be patentable, the microorganism used in that living process was

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79. See COOPER, *supra* note 78, at 2-5 to -6; Biggart, *Patentability in the United States of Microorganisms, Processes Utilizing Microorganisms, Products Produced by Microorganisms and Microorganism Mutational and Genetic Modification Techniques*, 22 IDEA 113, 114 (1981) [hereinafter Biggart].

80. See, e.g., COOPER, *supra* note 78, at 2-6 & n.14 (list of patents issued by the PTO on living organisms); Biggart, *supra* note 79, at 114-15 (patents of living matter issued before *Chakrabarty*).

81. See *Ex parte Prescott*, 19 U.S.P.Q. 178, 180-81 (P.B.A. 1932). *But see* *Funk Bros. Seed Co. v. Kala Inoculant Co.*, 333 U.S. 127 (1948). In *Funk Bros.*, which considered a claim to a mixture of bacteria, the Supreme Court invalidated the relevant patent for want of invention because the mixture was a natural phenomenon. *Id.* at 131-32. Although the organisms expressed traits not exhibited in nature, these were natural properties of the organisms whose discovery failed to warrant the issuance of a patent. *Id.* at 130-31.

82. 54 F.2d 400 (D. Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932).

83. *Id.* at 401.

84. *Id.*

85. *Id.* at 410.

86. *Id.*

87. *Guaranty Trust Co.*, 61 F.2d at 1041.

88. *Funk Bros. Seed Co. v. Kala Inoculant Co.*, 333 U.S. 127, 130-31 (1948).

89. *Id.*

not necessarily patentable.<sup>90</sup> Indeed, prior to 1980, the lowest form of an organism, a bacterium, was not patentable subject matter under section 101.<sup>91</sup>

One of the earliest cases discussing whether animals were patentable subject matter under section 101 was *In re Merat*.<sup>92</sup> In that case, the inventor sought to patent a dwarf chicken which was produced by a controlled breeding method,<sup>93</sup> not by genetic implantation of a dwarfism gene. The PTO refused to grant the patent, holding that a thing occurring in nature that was produced by controlled propagation is not a "manufacture" and, therefore, not patentable under section 101.<sup>94</sup>

In affirming the PTO's decision in *In re Merat*, the Board of Patent Appeals (BPA)<sup>95</sup> agreed that the subject matter requirement of section 101 was not satisfied.<sup>96</sup> The United States Court of Customs and Patent Appeals (CCPA), however, failed to address whether the dwarf chicken met the requirement of section 101 because the court affirmed the PTO's decision on other grounds.<sup>97</sup>

In 1979, the CCPA reached a decision on whether non-naturally occurring microorganisms are patentable subject matter under sec-

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90. See Comment, Bergy, Flook and Microorganisms as Patentable Products, 29 CATH. U.L. REV. 485, 490-91 (1980) (discussing *In re Mancy*, 499 F.2d 1289 (C.C.P.A. 1974)).

91. See 997 OFF. GAZ. PAT. OFFICE 24 (Aug. 24, 1980) (previously suspended microorganism patent applications are now being examined); Hutz, *supra* note 14, at 33 (before 1980 PTO refused to allow bacteria patents). Bacteria, however, did become patentable as a result of the *Chakrabarty* decision. See *supra* note 10 and accompanying text.

92. 519 F.2d 1390 (C.C.P.A. 1975).

93. *Id.* at 1391.

94. *Id.* at 1393.

95. In 1984, the BPA and the Board of Patent Interferences (BPI) were combined into the Board of Appeals and Interferences. See 4 WALKER, *supra* note 34, § 12:56, at 242 n.18.

After a rejection of a patent application by a patent examiner, the applicant may appeal to the Board of Patent Appeals and Interferences (BPAI). If the BPAI's decision is adverse, the patent applicant may appeal to the Court of Appeals for the Federal Circuit (CAFC), which was created in 1982 by joining the Court of Claims and the Court of Customs and Patent Appeals (CCPA). The CAFC's decision cannot be appealed but it may be reviewed by the United States Supreme Court. See *id.* §§ 12:55-56, at 240-43, § 12:58, at 279-80.

96. See *In re Merat*, 519 F.2d 1390, 1393 (C.C.P.A. 1975).

97. See *id.* at 1394. The CCPA rejected the patent for failing to distinctly claim the subject matter as required by 35 U.S.C. § 112 (1982). *Id.*

tion 101.<sup>98</sup> In *In re Bergy*<sup>99</sup> and its companion case, *In re Chakrabarty*,<sup>100</sup> the court held that non-naturally occurring microorganisms were within the patentable subject matter requirement of section 101.<sup>101</sup> The court further stated that no patent application should be rejected on the sole ground that the application involves a living organism.<sup>102</sup> The court concluded:

We see no sound reason to refuse patent protection to the microorganisms themselves, or to pure microorganism cultures, . . . when they are new and unobvious. In fact, we see no *legally* significant difference between active chemicals which are classified as "dead" and organisms used for their *chemical* reactions which take place because they are "alive". . . . We think the purposes underlying the patent system require us to include microorganisms and cultures within the terms "manufacture" and "composition of matter" in [section] 101.<sup>103</sup>

The court stated that the role of the judiciary did not include imposing non-congressional limitations and restrictions on the patent laws.<sup>104</sup>

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98. See *Bergy*, 596 F.2d at 973. The patent applied for in *Bergy* was for a biologically pure culture of the microorganism *Streptomyces vellosus* that produces the antibiotic lincomycin. See *id.* at 967.

99. 596 F.2d 952 (C.C.P.A. 1979), *dismissed as moot sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

100. 596 F.2d 952 (C.C.P.A. 1979), *aff'd sub nom.* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

101. *Bergy*, 596 F.2d at 987. The CCPA reversed the decision of the Board of Patent Appeals in both *In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977) [hereinafter *Bergy I*], *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978), *aff'd on rehearing*, *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *dismissed as moot sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980), and *In re Chakrabarty*, 571 F.2d 40 (C.C.P.A. 1978) [hereinafter *Chakrabarty I*], *aff'd on rehearing sub nom.* *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *aff'd sub nom.* Diamond v. Chakrabarty, 447 U.S. 303 (1980), holding that the invention claims defined subject matter within § 101. See *Bergy I*, 563 F.2d at 1036; *Chakrabarty I*, 571 F.2d at 43.

The Supreme Court vacated the CCPA's judgment in *Bergy I* and remanded it to the CCPA for further consideration in light of Parker v. Flook, 437 U.S. 584 (1978). Flook sought to patent a method for correcting the value of alarm limits during catalytic conversion of hydrocarbons. This method involved using a novel mathematical formula Flook had discovered. See *id.* at 585-86.

After the remand of *Bergy I*, the CCPA vacated its decision in *Chakrabarty I* and because of the similarity of the cases the CCPA reheard *Bergy I* and *Chakrabarty I* together. See *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *dismissed as moot sub nom.* Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

102. *Bergy*, 596 F.2d at 975.

103. *Id.* (emphasis in original).

104. *Id.* at 987 (court's statement is based on United States v. Dubilier Condenser Corp., 289 U.S. 178, 199 (1933)).

## 2. *The Chakrabarty Court's Treatment of Living Organisms*

In 1980, the Supreme Court agreed to hear *Diamond v. Chakrabarty*.<sup>105</sup> The Court affirmed the CCPA's determination that a live, human-made microorganism is patentable subject matter under section 101.<sup>106</sup>

After reviewing the legislative history of section 101, the Supreme Court held that Congress intended the section to be construed broadly.<sup>107</sup> Patentable subject matter was to "include anything under the sun that is made by man."<sup>108</sup> The Court then stated that Congress, when determining the patentability of inventions, focused not on the distinction "between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."<sup>109</sup>

The specific organisms with which the Court was concerned were genetically engineered bacteria not found in nature.<sup>110</sup> The bacteria, capable of breaking down multiple components of crude oil, were invented to aid in fighting oil spills on large bodies of water.<sup>111</sup> Because these organisms were genetically altered by man and could not be found in nature, the Court held that the bacteria were patentable subject matter under section 101.<sup>112</sup>

## 3. *Post-Chakrabarty Treatment of Living Organisms*

With *Chakrabarty* in hand and with the tacit consent of Congress, the PTO began to issue patents on genetically altered microorganisms.<sup>113</sup> Experts predicted that it was only a matter of time before

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105. 447 U.S. 303 (1980). Although writ was granted to both *Bergy* and *Chakrabarty*, *Bergy* was dismissed as moot. 444 U.S. 1028 (1980).

106. *Id.* at 309-10.

107. *Id.* at 308-09.

108. *See supra* note 11 and accompanying text.

109. 447 U.S. at 313.

110. *See id.* at 305.

111. *See id.* In *Chakrabarty's* patent applications, in addition to claiming a *process* using a new organism, he claimed a new form of the bacterial *genus Pseudomonas* capable of digesting crude oil. *See Chakrabarty I*, 571 F.2d at 41-42.

112. *See Chakrabarty*, 447 U.S. at 309-10.

113. Almost two hundred patents have been granted on genetically altered bacteria since the *Chakrabarty* decision. *See supra* notes 7, 15 and accompanying text. Many new biotechnology companies emerged in reliance on this apparent stamp of approval by the government. *See Pinon, Recombinant DNA: Controversy and Promise, A Scientist's Overview*, in FROM RESEARCH TO REVOLUTION 8 (R. Bohrer ed. 1987); Gore, *supra* note 12, at 339. In 1987 almost four hundred companies were seeking to develop products based on genetic engineering technology. *See Redesign Life, supra* note 12, at A17, col. 1.

applicants would assert that higher life-form inventions were within the scope of section 101's patentable subject matter.<sup>114</sup>

In 1984, the PTO received a patent application requesting patents on both the method of inducing polyploidy<sup>115</sup> in oysters and the resulting polyploid oyster.<sup>116</sup> The patent examiner for the PTO approved the claim for the *method* of inducing polyploidy.<sup>117</sup> The patent examiner, however, rejected the patent claim for the polyploid oyster, concluding that an inventor's oyster is not patentable subject matter under section 101.<sup>118</sup> The examiner found that the polyploid oyster was a living entity that is "controlled by the laws of nature and not a manufacture by man that is patentable."<sup>119</sup>

In *Ex parte Allen*, the Board of Patent Appeals and Interferences (BPAI), the appellate review board for the PTO, reversed the patent examiner's section 101 rejection of the claim.<sup>120</sup> The BPAI based its reversal on *Chakrabarty's* determination that section 101 included non-natural human-made life forms.<sup>121</sup> The BPAI used the *Chakrabarty* test for determining whether an invention is patentable under section 101<sup>122</sup>—if a human-made invention cannot be found in nature, the invention is patentable subject matter.<sup>123</sup> *Ex parte Allen* thus upheld, for the first time, the patenting of higher life organisms by the PTO.<sup>124</sup>

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114. See COOPER, *supra* note 78, § 6.02, at 6-3 to -8; see also OTA STUDY, *supra* note 2, at 386 (patentable subject matter determined on case-by-case basis).

115. A polyploid organism is an organism with more than two sets of chromosomes; humans have two sets and are diploid. See W. KEETON, *ELEMENTS OF BIOLOGICAL SCIENCE* 528 (1972).

116. *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (B.P.A.I. 1987). Polyploidy in oysters causes sterility, increasing the oysters' size, and making them edible year-round. See *id.* at 1428.

117. *Id.* at 1425-26 (claims 1 and 9 involved the method of producing polyploid oysters and were patentable).

118. *Id.* (claims 8, 12, 13 & 14 involved the actual polyploid oyster and were rejected).

119. *Id.* at 1426. The oyster was also rejected under § 103 for being obvious to one of ordinary skill in the art. *Id.* at 1427.

120. *Id.* at 1426-27.

121. *Id.*

122. See *id.*

123. See *id.* at 1427 (citing *Chakrabarty*, 447 U.S. at 313).

124. See *Patents on Animals*, *supra* note 1, at A24, col. 1. The BPAI, however, affirmed the examiner's rejection of the patent claim based on the obviousness of the invention under § 103. Consequently, a patent was not issued for this oyster. See *Allen*, 2 U.S.P.Q.2d at 1427. The court stated that "[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *Id.*

### III. The Controversy Surrounding the Patentability of Animals

#### A. The PTO Announcement Concerning Animal Patentability

Based on the BPAI's decision in *Ex parte Allen*, the Assistant Secretary and Commissioner of Patents and Trademark announced on April 17, 1987, that the "Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. [section] 101."<sup>125</sup> The Commissioner explicitly stated that any claim that human life is patentable under section 101 would be rejected because the grant of a property right in a human being would be prohibited by the Constitution.<sup>126</sup> The thirteenth amendment forbids involuntary servitude, and therefore a person cannot own another human being.<sup>127</sup>

The PTO's new policy to allow the patenting of animals was implemented on April 12, 1988, when the PTO issued its first animal patent.<sup>128</sup> The patent was for a genetically altered mouse invented at Harvard Medical School. The Harvard researchers invented a mouse that is prone to develop cancer, enabling researchers to learn more about the disease.<sup>129</sup>

#### B. The Response to a Controversial Decision

##### 1. A Coalition of Critics

The PTO's decision to review patents on animals triggered a storm of controversy.<sup>130</sup> A coalition in opposition to the use of

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125. PTO Memorandum, *supra* note 10, at 1; *see supra* note 1 and accompanying text.

126. PTO Memorandum, *supra* note 10, at 1.

127. *See* U.S. CONST. amend. XIII, § 1. *But see* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 70-71 (1987).

128. *See supra* note 9 and accompanying text.

129. *See Future of Animal Patents, supra* note 9, at 10, col. 1. The scientists who invented the mouse were Dr. P. Leder, Chairman of Harvard Medical School's Department of Genetics, and Dr. T. Stewart, a scientist at Genentech Inc. in San Francisco. *Id.* A gene that causes cancer in many mammals, including humans, was isolated by the two researchers. This gene was then injected into a fertilized mouse egg that developed into the patented mouse. *See Mouse Patent, supra* note 9, at A1, col. 5. "Because half the females develop cancer, the altered breed serves as a more effective model for studying how genes contribute to the development of cancer, particularly breast cancer." *Id.* (statement of P. Leder).

130. *See New Coalition, supra* note 26, at C1, col. 3; *Strain of Strife, supra* note 27, at 56.

genetic engineering in altering the genes of animals<sup>131</sup> quickly began lobbying Congress to narrow the patent law and exclude animals from patentable subject matter.<sup>132</sup> The coalition has alleged that such patents will wipe out small farmers who cannot afford genetically altered livestock, encourage animal experimentation, and "lead to a Brave New World in which people [will] hold patents on other people."<sup>133</sup>

Several farm organizations are concerned with the possibility that animal patents will accelerate the decline of the small, family-owned farm.<sup>134</sup> In short, the organizations assert that a few large corporations, which have the assets to invest in genetically altered animals, will push the small farmer out of business.<sup>135</sup>

Animal rights groups contend that the patenting of genetically altered livestock will "[unleash] the potential for uncontrollable and unjustified animal suffering."<sup>136</sup> These groups believe that the patenting of animals will result in the elimination of less desirable breeds leading ultimately to a loss of genetic diversity within a species.<sup>137</sup> They further assert that the loss of certain beneficial genes will shrink the available gene pool and cause an increase in epidemics.<sup>138</sup>

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131. See *New Coalition*, *supra* note 26, at C1, col. 3. The coalition includes many diverse organizations: the Humane Society of the United States, the National Federation of Churches, the National Wildlife Federation, the Foundation on Economic Trends, and the National Farmers Union. See *Organizations and Individuals Supporting Legislation to Halt the Patenting of Animals* (Nov. 19, 1987) (information received from the Foundation on Economic Trends) (available at *Fordham Urban Law Journal* office).

132. See *Religious Groups Join*, *supra* note 26, at 480; see also *Hearings: Patents*, *supra* note 2, at 2 (statement of J. Hoyt, President of the Humane Society of the United States, June 11, 1987).

133. See *Should Man Make Beast?*, *NEWSWEEK*, May 4, 1987, at 72 [hereinafter *Man Make Beast*].

134. See *Hearings: Patents*, *supra* note 2, at 3-4 (statement of D. Schwarze on behalf of the Wisconsin Family Farm Defense Fund, Inc., Aug. 21, 1987); *id.* at 3 (statement of S. Huber on behalf of the Farmers Union Milk Marketing Cooperative and the Wisconsin Farmers Union, Aug. 21, 1987); *id.* at 2 (statement of A. Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation, July 22, 1987).

135. See *id.* at 1-2 (statement of T. Saunders on behalf of the Wisconsin Farm Alliance, Aug. 21, 1987); *id.* at 1 (statement of J. Rifkin, President, Foundation on Economic Trends, Nov. 5, 1987).

136. See *Hearings: Patents*, *supra* note 2, at 4 (statement of J. Hoyt, President of the Humane Society of the United States, June 11, 1987).

137. See *id.* at 5.

138. See *id.* at 3 (statement of S. Huber on behalf of the Farmers Union Milk Marketing Cooperative and the Wisconsin Farmers Union, Aug. 21, 1987); *id.* at 2



The National Wildlife Federation (NWF) is concerned with the patenting of genetically altered animals that are intended to be released into the wild.<sup>139</sup> The NWF claims that the release of genetically altered animals, such as fish developed for fish stocking, may have a serious impact on existing wildlife.<sup>140</sup> Similarly, environmentalists contend that, because genetically altered animal technology is still in its infancy, little is known about the potential effect of genetically altered animals on the environment.<sup>141</sup>

The patenting of genetically altered animals is also causing alarm in America's religious community.<sup>142</sup> The National Council of Churches (NCC) firmly supports a moratorium on the issuance of genetically altered animal patents.<sup>143</sup> The NCC contends that genetic engineering is advancing so rapidly that society has not had time to consider the ethical and moral questions raised by such technology.<sup>144</sup>

## 2. *A Coalition of Supporters*

Among those supporting the PTO's decision are pharmaceutical firms, biotechnology companies and researchers.<sup>145</sup> The proponents believe that patents will be critical to the success of companies working with high-risk technology.<sup>146</sup> Patents are believed to be the proper tools for turning laboratory experimentation into useful products that will benefit society.<sup>147</sup> Indeed, these groups maintain

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(statement of A. Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation, July 22, 1987); see also *OTA STUDY*, *supra* note 2, at 494.

139. See *Hearings: Patents*, *supra* note 2, at 4 (statement of M. Mellon, Manager of the Biotechnology Project of the National Wildlife Federation, Nov. 5, 1987).

140. See *id.*

141. See *id.*

142. See *Religious Groups Join*, *supra* note 26, at 480.

143. See *id.*; see also *Hearings: Patents*, *supra* note 2, at 4 (statement of Rev. W. Granberg-Michaelson on behalf of the National Council of Churches, Nov. 5, 1987).

144. See *Hearings: Patents*, *supra* note 2, at 4 (statement of Rev. W. Granberg-Michaelson on behalf of the National Council of Churches, Nov. 5, 1987). The General Secretary for the NCC has stated that "[o]ur culture's stance toward the gifts of God's creation, and our respect for all life, call for thoughtful reflection and judgment on these matters by churches and religious institutions . . ." *Id.* at app. (statement of religious leaders against animal patenting, endorsed by twenty-four religious organizations).

145. See *Strain of Strife*, *supra* note 27, at 56.

146. See *Hearings: Patents*, *supra* note 2, at 19 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987).

147. See *id.* at 18; see also *id.* at 1 (statement of R. Adler, intellectual property attorney, July 22, 1987).

that the prohibition or delay of patents on genetically altered animals could seriously delay new life-saving medicines and prevent major agricultural innovations.<sup>148</sup>

The American Farm Bureau Federation (AFBF), the largest general farm organization in the United States, is in favor of patenting genetically altered animals.<sup>149</sup> The AFBF believes that the role of genetic engineering in animal production will cause a reduction in farm costs and expand the utilization of farm products.<sup>150</sup> The AFBF supports the PTO's announcement because it claims that denying patents would deliberately delay genetically altered animal technology merely to calm unproven fears.<sup>151</sup>

Finally, proponents argue that animal patents will help society cope with the attendant problems of a continuing increase in the world population. Specifically, those in favor of animal patents point to the need for food suppliers to produce more food in the next forty years than they have since the beginning of modern agriculture,<sup>152</sup> and the need to discover cures for complex diseases which continue to threaten human life.<sup>153</sup> Indeed, the Supreme Court

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148. See *Hearings: Patents*, *supra* note 2, at 3 (statement of A. Smith, Vice-President of Integrated Genetics Inc., Nov. 5, 1987); *id.* at 20 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987). "I don't really understand the concern . . . . If I could understand it perhaps I could argue against it. There's some blind, gut feeling that somehow it ain't right. But to me it isn't right to stand by while thousands of American women die of cancer." *Future of Animal Patents*, *supra* note 9, at 10, col. 5 (statement of P. Leder, Chairman of the Department of Genetics at Harvard Medical School) (discussing concerns of animal patent opponents).

149. See *Hearings: Patents*, *supra* note 2, at 13 (statement of A. Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation, July 22, 1987); *Strain of Strife*, *supra* note 27, at 57.

150. See *Hearings: Patents*, *supra* note 2, at 1 (statement of A. Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation, July 22, 1987). The use of genetic engineering in animal husbandry allows farmers to achieve the uniform quality of product that was once confined to manufacturers. See *Cloning Offers Factory Precision to the Farm*, N.Y. Times, Feb. 17, 1988, at A1, col. 3.

151. *Hearings: Patents*, *supra* note 2, at 1 (statement of A. Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation, July 22, 1987).

152. See *id.* at 2 (statement of W. Brill, Vice-President of Research and Development, Agracetus Co., Aug. 21, 1987) (U.S. government must help agriculture in meeting food production challenges); *id.* at 1 (statement of R. Adler, intellectual property attorney, July 22, 1987) (world population of almost five billion projected to double within fifty years).

153. See *id.* at 3 (statement of A. Smith, Vice-President of Integrated Genetics Inc., Nov. 5, 1987) (moratorium on patents will hinder beneficial health care developments); *id.* at 7-8 (statement of T. Wagner, Director of the Edison Animal

in *Chakrabarty* stated that the issuance of patents to foster productive efforts by inventors "will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."<sup>154</sup>

### 3. Congressional Action

As a result of the controversy caused by the PTO's announcement, a bill was introduced in Congress on August 5, 1987, that would impose a two-year moratorium on the issuance of patents for genetically altered animals.<sup>155</sup> The introduction of this bill marked the first time in the history of the patent system that legislation was introduced to pre-empt a patenting decision by the PTO.<sup>156</sup> The bill would amend Chapter 10, title 35, of the United States Code,<sup>157</sup> by adding the following section:

[Section] 105. Patents on animals

During the two-year period beginning on the date of enactment of this section, vertebrate or invertebrate animals, modified, altered, or in any way changed through genetic engineering technology shall not be considered matter within the confines of patentability and shall not be patentable within the meaning of section 101 or section 102 or any other provision of this title and no such patent shall be granted. Any patent previously granted for any such animal is hereby revoked.<sup>158</sup>

The author of the bill believes that Congress cannot allow an issue as important as animal patenting to be decided by the Appeals Board of the PTO because it is solely within the province of Congress to establish new patent policy.<sup>159</sup> The author further maintains that "the long term economic, ethical, environmental and governmental consequences [of patenting genetically altered animals] . . . are extraordinary, complex and alarming."<sup>160</sup>

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Biotechnology Center at Ohio University, June 11, 1987) (discussing use of genetically altered animals as disease models to test drugs).

154. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1973)).

155. See *supra* note 32 and accompanying text.

156. See *New Bill*, *supra* note 32, at A18, col. 1.

157. H.R. 3119, 100th Cong., 1st Sess. (1987). Congress believes that "such monumental decisions about the fate of animal life should not be left solely to the Patent and Trademark Office." *Id.* at 1(4).

158. *Id.* at 2.

159. See *Hearings: Patents*, *supra* note 2, at 4 (statement of Rep. Rose, July 22, 1987).

160. *Id.* at 1.

#### IV. The Ramifications of Patenting New Forms of Animal Life

##### A. Should Genetically Altered Animals be Patentable?

The arguments against awarding animal patents stem from fears concerning the potential consequences of genetic engineering, rather than the patenting process itself.<sup>161</sup> Yet, if patent protection is denied, research in genetic engineering will continue:<sup>162</sup> "A patent does not confer the right to do something which could otherwise not be done."<sup>163</sup>

Genetically altered animals should not be excluded from patent protection because of ethical or economic reasons.<sup>164</sup> The patent system was designed to promote research and invention,<sup>165</sup> regardless of ethical or economic considerations.<sup>166</sup> Congress intended patentable subject matter to encompass "anything under the sun that is made by man."<sup>167</sup> The Supreme Court confirmed Congress' intent in *Chakrabarty*.<sup>168</sup> Since that decision, no legal argument has been advanced that would justify a change in the broad interpretation of the Patent Act.<sup>169</sup> Despite the passage of more than eight years, Congress has refrained from withdrawing patent coverage from inventions involving living man-made subject matter.<sup>170</sup> Congress'

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161. See *Hearings: Patents, supra* note 2, at 2 (statement of R. Merges, Julius Silver Fellow in Law, Science and Technology, Columbia Law School, July 22, 1987).

162. See *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980); see also *Hearings: Patents, supra* note 2, at 11 (statement of R. Tegmeyer, Assistant Commissioner of PTO, June 11, 1987); *id.* at 8 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987). The denial of patents on living organisms "will not deter the scientific mind from probing into the unknown anymore than Canute could command the tides." *Chakrabarty*, 447 U.S. at 317.

163. See *Hearings: Patents, supra* note 2, at 8 (statement of W. Duffey on behalf of Intellectual Property Owners, Inc. and Industrial Biotechnology Association, July 22, 1987).

164. See *id.*; *id.* at 7 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987); *Man Make Beast, supra* note 133, at 72.

165. See *supra* notes 38-48 and accompanying text.

166. See *supra* note 164 and accompanying text.

167. *Chakrabarty*, 447 U.S. at 309 (quoting Committee Reports accompanying Patent Act of 1952, S. REP. NO. 1979, 82d Cong., 2d Sess. 5, reprinted in 1952 U.S. CODE CONG. & ADMIN. NEWS 2394, 2399).

168. See *Chakrabarty*, 447 U.S. at 308-09 ("Congress plainly contemplated that the patent laws would be given wide scope").

169. See *infra* note 171 and accompanying text.

170. See *id.*

silence could be interpreted as legislative approval of the *Chakrabarty* decision.<sup>171</sup>

Congress' sudden interest in the ramifications of *Chakrabarty*, *i.e.*, the patenting of multi-celled (animals) as opposed to single-celled (bacteria) organisms, is unwarranted.<sup>172</sup> The proposed congressional moratorium is also the result of fears regarding the advancement of genetic engineering.<sup>173</sup> A moratorium on patenting animals, however, does not directly and sufficiently address these concerns.<sup>174</sup> It is true that research is promoted by the granting of patents.<sup>175</sup> In *Chakrabarty*, the Court conceded that whether living organisms "are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives."<sup>176</sup> Nevertheless, the inventor will not stop researching merely because his or her labors will not generate economic reward.<sup>177</sup>

If Congress is truly concerned that deleterious effects may result from genetic research, it should regulate such research.<sup>178</sup> Through regulation, Congress could restrict research in areas of genetic engineering deemed unsafe.<sup>179</sup> Like a patent moratorium, regulation

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171. See *Hearings: Patents*, *supra* note 2, at 3-4 (statement of M. Ostrach, Senior Vice-President and General Counsel, Cetus Corp., Aug. 21, 1987). Legislative approval may not be the only interpretation of Congress' silence, other interpretations may include—an unwillingness to be politically accountable, a lack of attention concerning this issue or a failure to recognize the significance of this issue.

172. See *id.* at 3 ("objections to animal patenting echo the arguments that have accompanied genetic engineering since its inception and have been refuted by the experience of the last 15 years"); *id.* at 21 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987) (to delay animal patents would be "unprecedented and certainly would be a drastic overreaction").

173. See *Hearings: Patents*, *supra* note 2, at 20-21 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987) (risks from genetic engineering are no greater than risks from traditional breeding techniques); see also *New Bill*, *supra* note 32, at A18, col. 1; *New Coalition*, *supra* note 26, at C1, cols. 3-4; *Strain of Strife*, *supra* note 27, at 56.

174. See *Hearings: Patents*, *supra* note 2, at 2-5 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987) (concerns about technological risks should be addressed by regulation not a patent moratorium).

175. See *supra* note 13-15 and accompanying text.

176. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

177. See *supra* note 162 and accompanying text.

178. See *Hearings: Patents*, *supra* note 2, at 7 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987); *id.* at 2, 8 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987).

179. See *id.* at 1 (statement of A. Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation, July 22, 1987).

would result in limiting economic and scientific gains;<sup>180</sup> however, regulation would also prevent the harm that the patent moratorium was drafted to prevent.<sup>181</sup>

## **B. The Economic, Environmental and Moral Implications of Genetically Altered Animals**

### *1. Economic Issues*

The major economic concern for proponents of a patent moratorium is the loss of the small, family-owned farm. The small farmer believes he is unable to compete with large corporations in the food market because he does not have the assets to purchase products of expensive although efficient genetic engineering technology.<sup>182</sup> Although this is a real concern for the small farmer, opponents of a moratorium believe that changing patent laws may not be the most realistic way of remedying this situation.<sup>183</sup> Congress can help small farmers by implementing programs that allow them to purchase the products of genetic engineering at an affordable price,<sup>184</sup> or by controlling the growth of their competitors (large corporations) through antitrust laws.<sup>185</sup>

The risk of losing small farms because of patents on genetically altered animals must be balanced against the societal benefits that result from promoting genetic engineering.<sup>186</sup> The population of the world is continuing to grow and expand,<sup>187</sup> causing a decrease in

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180. See OTA STUDY, *supra* note 2, at 355 ("restrictions . . . may delay or prevent important products from reaching the market").

181. The regulatory system is the proper forum to address issues of technological risks to society. See *Hearings: Patents*, *supra* note 2, at 2-5 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987). For a discussion of potential harms, see *infra* notes 182-203 and accompanying text.

182. See *supra* notes 134-35 and accompanying text.

183. See *Hearings: Patents*, *supra* note 2, at 8 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987); *id.* at 4 (statement of M. Ostrach, Senior Vice-President and General Counsel, Cetus Corp., Aug. 21, 1987).

184. See *id.* at 8 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987).

185. See *id.* at 2 (statement of A. Sorenson, Assistant Director, Natural & Environmental Resources Division, American Farm Bureau Federation, July 22, 1987).

186. See *generally id.* at 4-5 (statement of M. Ostrach, Senior Vice-President and General Counsel, Cetus Corp., Aug. 21, 1987).

187. See *id.* at 1 (statement of R. Adler, intellectual property attorney, July 22, 1987).

farmland and an increase in food demand.<sup>188</sup> The increased productivity of food suppliers has paralleled society's increased knowledge in science and technology.<sup>189</sup> It is believed that genetically altered animals will play an important role in the agricultural field.<sup>190</sup> A moratorium on patents will slow down scientific advancement in this new technology.<sup>191</sup>

## 2. *Environmental Issues*

The risks that a genetically altered animal presents to the environment depend upon the probability of the animal transferring its altered genes to other organisms in the environment.<sup>192</sup> These risks are similar in magnitude to the risks of introducing an unmodified organism into the environment.<sup>193</sup> The assessment of risks should be based on the *nature* of the organism that is introduced, as well as on whether the organism was genetically altered—unaltered animals can theoretically be as dangerous as genetically altered animals.<sup>194</sup>

The size and complexity of the organism are important factors used in determining potential risk to the environment.<sup>195</sup> Livestock are easily accounted for and physically confined because of their size and visibility. In nature, genetic material from livestock can only be transmitted during intraspecies reproduction, which limits the possible spread of synthetic genes.<sup>196</sup> As a result, genetically

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188. See J. BELDEN, *DIRT RICH, DIRT POOR* 6, 72-73 (1986) (three million acres of farmland are lost each year).

189. See G. PETERS & R. LARKIN, *POPULATION GEOGRAPHY* 223, 226 (1983) (patterns of urbanization); E. HIGBEE, *FARMS AND FARMERS IN AN URBAN AGE* 8-10 (1963) (same).

190. See *Hearings: Patents*, *supra* note 2, at 4 (statement of W. Duffey on behalf of Intellectual Property Owners, Inc. and Industrial Biotechnology Association, July 22, 1987) (enormous potential of biotechnology); *id.* at 15 (statement of R. Adler, intellectual property attorney, July 22, 1987) (animal patent protection "is imperative if the world is to feed its malnourished but ever expanding masses"); *id.* at 2 (statement of W. Brill, Vice-President of Research and Development, Agracetus Co., Aug. 21, 1987) ("[g]enetic engineering is going to change agriculture, worldwide").

191. See *id.* at 8 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987).

192. See *Hearings: Patents*, *supra* note 2, at 9 (statement of T. Wagner, Director of the Edison Animal Biotechnology Center at Ohio University, June 11, 1987).

193. See *id.* at 7 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987).

194. See *id.* The nature of the organism includes the organism's physical size, ecological niche and complexity.

195. See *id.* at 9 (statement of T. Wagner, Director of the Edison Animal Biotechnology Center at Ohio University, June 11, 1987).

196. See *id.*

altered large animals should have little impact on the environment.<sup>197</sup> On the other hand, the introduction of fish or oysters into the environment may have a serious impact on the native wildlife, due to the difficulty of controlling their reproduction and physical migration.<sup>198</sup> All told, appropriate government regulation could minimize or eliminate any risks caused by the introduction of genetically altered organisms into the environment.<sup>199</sup>

### 3. *Moral or Ethical Issues*

A recent government survey, based on a sampling that reflects the total United States population, reveals that sixty-eight percent of the American public (eighty-one percent of college graduates) believe that it is not morally wrong to alter animals genetically.<sup>200</sup> Indeed, eighty-two percent of the population support continued research into genetic engineering.<sup>201</sup>

Supporters of an animal patent moratorium believe there "must be ethical constraints to protect the sanctity and dignity of life."<sup>202</sup> Opponents of a patent moratorium believe ethics and morality should not dictate the operation of the PTO.<sup>203</sup> Furthermore, they believe that even if ethics and morality were a consideration in patent approval, patent laws promoting genetic engineering would still be supported by a majority of the United States population.<sup>204</sup>

### C. The Role of the Patent and Trademark Office

The patent system should not be used as an instrument to regulate the genetic engineering industry.<sup>205</sup> The goal of the patent system

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197. *See id.*

198. *See id.* at 4 (statement of M. Mellon, Manager of the Biotechnology Project of the National Wildlife Federation, Nov. 5, 1987).

199. *See id.* at 8-9 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987).

200. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., *NEW DEVELOPMENTS IN BIOTECHNOLOGY: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY 57-58* (1987) (survey was based on 1,273 telephone interviews) [hereinafter *PUBLIC PERCEPTION*]; *see Public of 2 Minds on Genetic Shifts*, N.Y. Times, May 31, 1987, at A21, col. 1 (most people feel benefits outweigh the risks).

201. *See PUBLIC PERCEPTION*, *supra* note 200, at 83. Americans do not hold different views about the morality of genetic techniques of animal manipulation versus classical breeding techniques. The moral objection is based on whether animals are manipulated by any technique. *Id.* at 59.

202. *See Hearings: Patents*, *supra* note 2, at 7 (statement of J. Hoyt, President of the Humane Society of the United States, June 11, 1987).

203. *See supra* notes 164-66 and accompanying text.

204. *See supra* notes 200-01 and accompanying text.

205. *See Hearings: Patents*, *supra* note 2, at 2 (statement of G. Karny, intellectual



is to help promote technological advancement by granting inventors property rights in their inventions.<sup>206</sup>

The issues raised by patenting genetically altered animals should be addressed by a regulatory agency.<sup>207</sup> The regulation of new technology has a different goal than patenting. Regulatory agencies focus on the dangers a new product may pose to the public; moreover, if the risks are unacceptable or greater than a product's benefits, a regulatory agency will prohibit or restrict the product's release.<sup>208</sup> The patent office simply has no place in addressing these safety and ethical issues.<sup>209</sup>

## V. Conclusion

The debate surrounding genetically altered animals will continue throughout future decades; however, the patent system is not the proper forum for such a debate. The PTO's proper role is to determine legal, not ethical issues. The injection of ethics and morality into the legal process of patent determination will cause uncertainty in business and scientific communities resulting in economic loss.

For the most part, the scientific community has concluded that the risks posed by genetically altering animals are no greater than the risks posed by traditional breeding techniques. Nevertheless, many people have concerns about genetically altered animals and the technology used to produce them. The current regulatory system provides the necessary oversight to respond to these concerns. In fact, administrative agencies can provide adequate regulation over this field without the need for new legislation.

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property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987); *id.* at 7 (statement of N. Seay, Professor of Patent Law at the University of Wisconsin Law School, Aug. 21, 1987).

206. See *Hearings: Patents*, *supra* note 2, at 2 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987); *id.* at 1 (statement of R. Adler, intellectual property attorney, July 22, 1987).

207. See *id.* at 2. For a discussion of the federal regulation of biotechnology, see *Hearings: Patents*, *supra* note 2, at app. (statement of R. Godown, President of the Industrial Biotechnology Association, Aug. 21, 1987).

208. See *Hearings: Patents*, *supra* note 2, at 2-4 (statement of G. Karny, intellectual property attorney, editor of *Biotechnology Law Report*, Nov. 5, 1987).

209. See *id.* at 8 (statement of W. Duffey on behalf of Intellectual Property Owners, Inc. and Industrial Biotechnology Association, July 22, 1987); *id.* at 6 (statement of A. Smith, Vice-President of Integrated Genetics, Nov. 5, 1987); *id.* at 2-3 (statement of R. Merges, Julius Silver Fellow in Law, Science and Technology, Columbia Law School, July 22, 1987); *Religious Groups Join*, *supra* note 26, at 480.

The legislation that is currently being proposed, *i.e.*, a moratorium on animal patents, does not adequately address the problems sought to be solved by the proponents of the moratorium. Moreover, a moratorium on patents is unprecedented; Congress has never before proposed legislation for the purpose of interfering with a PTO policy decision. Congress should either require greater regulation in the field of genetic engineering or allow inventors to obtain animal patents.

The PTO correctly determined that genetically altered animals are patentable subject matter under section 101; accordingly, there is no reason to prohibit, delay or revoke patents on genetically altered animals.

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