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# Controlling Pandora's Box: The Need for Patent Protection in Transgenic Research

John J. Quick

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# CONTROLLING PANDORA'S BOX: THE NEED FOR PATENT PROTECTION IN TRANSGENIC RESEARCH

JOHN J. QUICK\*

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## I. INTRODUCTION

With the emergence of biotechnology and the ability to manipulate genetic material, the patenting of living organisms is becoming an area of increased interest.<sup>1</sup> The creation of the Human Genome Project has served to further intensify the debate over the patenting of living organisms.

This paper will serve as a guided tour through the present status of transgenic research, the laws, and proposed laws created to regulate it. Part B will provide a brief overview of biotechnology, transgenic research and the Human Genome Project. Part C of this paper will generally explore the

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<sup>1</sup> Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 399-400 (1988).

four current legal means of protecting genetically modified organisms. These means of protection include the Plant Patent Act, the Plant Variety Protection Act, the Utility Patent Act and trade secret law. Part D of this paper will provide a historical recounting of actions taken by the United States Patent and Trademark Office. Part E will discuss and rebut various arguments against transgenic research. Finally, Part F will propose an amendment to provide for specific patent protection for transgenic research.

## II. GENETIC RESEARCH

### A. A Brief Overview

In 1953, the discovery of DNA by J. D. Watson and Francis Crick created the fuel for the intellectual fire of transgenic research.<sup>2</sup> Watson and Crick's discovery of DNA's<sup>3</sup> presence in all living organisms led to numerous scientific advances.<sup>4</sup> The discovery of the double-helix enabled scientists to better understand individual gene characteristics and the results attributed to the expression of each gene.<sup>5</sup> It has also permitted scientists to genetically modify an organism through genetic engineering, which "allows for the recombination of genetic material of more than one organism."<sup>6</sup>

### B. Transgenic Research

Transgenic research involves modification to plants, animals and microorganisms.<sup>7</sup> Commonly known as transgenic testing,<sup>8</sup> this process

<sup>2</sup> Edmund J. Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551, 552 (1988-1989).

<sup>3</sup> For a more detailed discussion regarding DNA, see Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 846, 848-53 (2005).

<sup>4</sup> Jerzy Koopman, *The Patentability of Transgenic Animals in the United States of America and the European Union: A Proposal for Harmonization*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 103, 111-12 (2002).

<sup>5</sup> *Id.* at 106.

<sup>6</sup> *Id.* at 112.

<sup>7</sup> See generally John M. Moye, Recent Development, *The Court of Appeals of North Carolina's Narrow Approach to Trade Secrets Protection in North Carolina Farm Partnership v. Pig Improvement Company*, 83 N.C. L. REV. 1567, 1586 (2005); James F. Ewing, *Agricultural Biotechnology: Is the International Regulation of Transgenic Agricultural Plants for the Birds (and the Bees)?*, 25 SUFFOLK TRANSNAT'L L. REV. 617 (2002); Jon Owens, *The Future of the Animal Rights Movement: Environmental Conflict, Artificial Intelligence, and Beyond*, 33 ENVTL. L. REV. 10265 (2003); Sease, *supra* note 2; D.L. Uchtmann, *Starlinktm – A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159 (2002).

<sup>8</sup> Kevin W. O'Connor, *Patenting Animals and Other Living Things*, 65 S. CAL. L. REV. 597, 608 (1991).

enables scientists to implant human genes into an organism allowing scientists to test the reaction of that human gene without using human test subjects.<sup>9</sup>

There are two forms of transgenic creation.<sup>10</sup> The first, and at present, most common is that of microinjection.<sup>11</sup> The process of microinjection involves the extraction of a gene "from one organism using special bacterial enzymes capable of slicing a DNA molecule at the appropriate place."<sup>12</sup> Purified gene copies are then injected "into a fertilized single-cell egg of another species," which is then implanted into a female of the same species.<sup>13</sup> Each developing cell of the newly born animal will then develop to contain the implanted gene.<sup>14</sup>

The second form of transgenic creation involves embryo fusion.<sup>15</sup> This method is completed by combining the cells of two organisms and then implanting the newly fused cell into a surrogate mother, which is a species of one of the two cell types.<sup>16</sup> This method does not produce genetically identical offspring, instead producing offspring that will resemble one of the two combined organisms.<sup>17</sup>

There are three major areas in which transgenic research may exhibit commercial value.<sup>18</sup> First, transgenic research may help to further develop the agriculture industry by expediting the benefits derived from classic animal breeding.<sup>19</sup> Additionally, transgenic animals may be used to increase the productivity of common farm animals.<sup>20</sup> These improvements may include heightened resistance to disease, alterations to muscle mass or size and the creation of more protein-filled milk.<sup>21</sup>

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<sup>9</sup> Dresser, *supra* note 1, at 405-06.

<sup>10</sup> See Carolyn A. Schmotzer, Assessment of Murine Embryo Development Following Electroporation and Microinjection of a Green Fluorescent Protein DNA Construct (July 31, 2001) (unpublished M.S. thesis, Virginia Polytechnic Institute and State University), at <http://scholar.lib.vt.edu/theses/available/etd-08062001-122413/unrestricted/FinalThesisforETD.pdf>.

<sup>11</sup> Dresser, *supra* note 1, at 405.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 406.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 406-07.

<sup>18</sup> *Id.* at 407.

<sup>19</sup> *Id.*

<sup>20</sup> Koopman, *supra* note 4, at 115.

<sup>21</sup> Thomas Traian Moga, *Transgenic Animals as Intellectual Property (Or the Patented Mouse that Roared)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 511, 530-31 (1994).

Second, transgenic organisms can assist the advancement of biomedical research.<sup>22</sup> Most importantly, scientists may utilize transgenic animals as “a fundamental tool for studying human disease and its treatment.”<sup>23</sup> In fact, scientists are already using transgenic research in an attempt to cure human albinism by altering the embryos of albino mice to ensure that each altered embryo grows into a regularly-pigmented mouse.<sup>24</sup> Additionally, transgenic research may allow scientists to further expand the Human Genome database through studies of specific genes implanted in animals.<sup>25</sup> Such research could enable scientists to further study gene expression when attempting to treat hereditary diseases in humans.<sup>26</sup>

Third, transgenic animal research may have a positive effect upon the environment.<sup>27</sup> Through genetic alteration, scientists may be able to modify an organism’s internal functions so as to lessen the organism’s discharge<sup>28</sup> or enable it to break down potentially harmful material, thereby reducing the overall impact upon the environment.<sup>29</sup>

### C. *The Human Genome Project*

The constant desire of scientists to better understand the living world led to the United States Department of Energy and the National Institute of Health (“NIH”) establishing the Human Genome Project in 1990.<sup>30</sup> This coordinated federally-funded project began to “enhance the ability to gather and organize information that may predict a person’s future potential and disabilities.”<sup>31</sup> The key goal of the Human Genome Project is “to determine the sequence of the three billion chemical base pairs that make up the human DNA and to identify the approximately 35,000 genes in human DNA.”<sup>32</sup> Completion of this goal was originally scheduled for 2005,<sup>33</sup>

<sup>22</sup> Dresser, *supra* note 1, at 407.

<sup>23</sup> *Id.*

<sup>24</sup> Koopman, *supra* note 4, at 114.

<sup>25</sup> Elizabeth Joy Hecht, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1037 (1992).

<sup>26</sup> Dresser, *supra* note 1, at 408.

<sup>27</sup> *Id.* at 407.

<sup>28</sup> Koopman, *supra* note 4, at 116.

<sup>29</sup> *Id.* at 116-17.

<sup>30</sup> Jeremy A. Colby, *An Analysis of Genetic Discrimination Legislation Proposed by the 105th Congress*, 24 AM. J.L. & MED. 443, 445 (1998).

<sup>31</sup> Larry Gostin, *Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers*, 17 AM. J.L. & MED. 109, 110 (1991).

<sup>32</sup> Robert A. Curley, Jr. and Lisa M. Caperna, *The Brave New World is Here: Privacy Issues and the Human Genome Project*, 70 DEF. COUNS. J. 22, 23 (2003).

<sup>33</sup> Colby, *supra* note 30, at 445.

however, "rapid technological advances accelerated the completion date to 2003."<sup>34</sup> These 35,000 genes comprise forty-six strands of DNA<sup>35</sup> which make up each human cell<sup>36</sup> and are grouped into twenty-three pairs.<sup>37</sup>

The Human Genome Project was established to map each chromosome<sup>38</sup> in order to identify an area on the chromosome that indicates which trait the gene will express.<sup>39</sup> This map will allow scientists to detect altered genes that predispose<sup>40</sup> an individual to certain genetic diseases.<sup>41</sup> Once completed, this project will allow scientists from across the globe to conduct transgenic research and compare and contrast the reactions of each transgenically implanted human gene.<sup>42</sup>

### III. THE FOUR CURRENT MEANS OF PROTECTING GENETICALLY MODIFIED ORGANISMS

There are four main legal methods to protect genetically modified organisms.<sup>43</sup> These methods are: (1) the Plant Patent Act of 1930 ("PPA");<sup>44</sup> (2) the Plant Variety Protection Act of 1970 ("PVPA");<sup>45</sup> (3) the use of trade secret law;<sup>46</sup> and (4) the Utility Patent Act ("UPA").<sup>47</sup>

#### A. *The Plant Patent Act And The Plant Variety Protection Act*

As its name insinuates, the PPA protects only genetically-modified plant species.<sup>48</sup> Patent protection is extended only if the scientist can show that

<sup>34</sup> *About the Human Genome Project*, at [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/about.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml) (last visited March 2, 2007).

<sup>35</sup> Also known as chromosomes. See *supra* note 30, at 446.

<sup>36</sup> Curley & Caperna, *supra* note 32, at 23.

<sup>37</sup> Colby, *supra* note 30, at 446.

<sup>38</sup> The process of mapping is the assignment of genes to specific chromosomes. *Id.* at 447.

<sup>39</sup> *Id.*

<sup>40</sup> It is important to note that a predisposition to certain genetic diseases does not indicate a certainty of contracting that genetic disease. See Thomas F. Wieder, *Privacy Protection is Needed for DNA*, 2002 L. REV. MICH. ST. U. DET. C.L. 927, 931 (2002).

<sup>41</sup> Paul Steven Miller, *Is There a Pink Slip in my Genes? Genetic Discrimination in the Workplace*, 3 J. HEALTH CARE L. & POL'Y 225, 229 (2000).

<sup>42</sup> See generally Gostin, *supra* note 31.

<sup>43</sup> O'Connor, *supra* note 8, at 604-07.

<sup>44</sup> Pub. L. No. 71-245, 46 Stat. 376 (codified as amended at 35 U.S.C. § 161-164 (1988)).

<sup>45</sup> Pub. L. No. 91-577, 84 Stat. 1542 (codified as amended at 7 U.S.C. § 2321-2583 (1988)).

<sup>46</sup> See generally Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 379-380 (2002).

<sup>47</sup> 35 U.S.C. § 101 (2000), et seq.

<sup>48</sup> See John M. Czarnetzky, *Altering Nature's Blueprints for Profit: Patenting Multicellular Animals*, 74 VA. L. REV. 1327, 1341-42.

the plant is a "new and distinct asexually propagated variet[y] other than tuber propagated plants."<sup>49</sup> The PPA explicitly states that it does not apply to plants propagated through seed, as it was originally thought that seed was incapable of producing a truly similar type.<sup>50</sup>

Congress extended the protection of the PPA to include sexually-reproduced plants through its enactment of the PVPA.<sup>51</sup> Congress enacted this statute to provide financial incentive as a means to stimulate new development of sexually reproduced plants within the commercial sector.<sup>52</sup> The protection afforded under the PVPA, however, is not officially a patent.<sup>53</sup> Instead, plant variety certificates are issued by the United States' Department of Agriculture for any "novel variety of [a] sexually reproduced plant . . . ."<sup>54</sup>

The PVPA, however, does exempt two categories of people for certificate infringement.<sup>55</sup> First, the PVPA provides an exemption for farmers, whose primary occupation is the sale of homegrown crops.<sup>56</sup> This exemption allows a farmer to maintain a stockpile of seed for the use of growing crops on the farm.<sup>57</sup> Second, the PVPA also provides an exemption for researchers, allowing for the use of the certificated seed for the sole purpose of developing a new seed variety.<sup>58</sup>

The PPA and the PVPA provide much needed protection for both inventors and investors of genetic research, but this protection remains too limited in scope. PPA and PVPA protection affords only limited safeguards to a narrow group of living organisms. Moreover, the protection provided by each extends only to plants and does not protect genetic research involving other forms of living material. As a result, specific statutory protection of transgenic animals does not exist.

<sup>49</sup> O'Connor, *supra* note 8, at 604 (stating that since the enactment of the PPA, the United States' Patent and Trademark Office has issued over six thousand plant patents).

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 605.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* (Plant variety protection does not extend to a limited number of novel plant varieties, including fungi, bacteria or first generation hybrid).

<sup>55</sup> Pub. L. No. 91-577, 84 Stat. 1542 (codified, as amended, at 7 U.S.C. § 2544 (1988)).

<sup>56</sup> O'Connor, *supra* note 8, at 605.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.* (stating since the enactment of the PVPA, the United States' Department of Agriculture has issued 1,850 protection certificates while 260 applications remain pending).

## B. Trade Secret Law

The use of trade secret law provides a broader means of protection.<sup>59</sup> Trade secret law<sup>60</sup> is an attractive mode of protection since no eligibility requirements for protection exist.<sup>61</sup> Moreover, with a potentially limitless timeline, it offers permanent protection to the inventor.<sup>62</sup> Trade secret law views protectable subject matter through a functional definition.<sup>63</sup> A trade secret can include almost anything so long as the company maintains the subject matter as a secret, it is not commonly known by competitors, and it would provide the company with a competitive advantage.<sup>64</sup>

The creation of a trade secret rather than a patent may be desirable to a company because unlike patents, a trade secret does not require the publication of the subject matter within eighteen months of the application for patent protection.<sup>65</sup> Furthermore, the extent of patent protection appears to be under attack in at least one jurisdiction. The First Circuit Court of Appeals limited the Doctrine of Equivalence,<sup>66</sup> holding that by narrowing a claim to obtain a patent, prosecution estoppel serves as a bar to suit against every equivalent claim of that nature.<sup>67</sup>

The United States Supreme Court, however, has quashed this movement for the moment.<sup>68</sup> In so doing, the Court announced that while prosecution estoppel requires that claims be interpreted in light of underlying proceedings in the patent office during the application process,

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<sup>59</sup> Mark W. Lauroesch, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100, 107-09 (1988).

<sup>60</sup> It is important to note that trade secret law does not necessarily provide limitless protection. Courts in at least one state have held that under certain circumstances "trade secrets" may be subject to discovery under public records laws. See *Cubic Transp. Systems, Inc. v. Miami-Dade County*, 899 So. 2d 453 (Fla. 3d DCA 2005); *Sepro Corp. v. Fla. Dept. of Environ. Protection*, 839 So. 2d 781, 784 (Fla. 1st DCA 2003).

<sup>61</sup> Beckerman-Rodau, *supra* note 46, at 379-80.

<sup>62</sup> Lauroesch, *supra* note 59, at 107.

<sup>63</sup> Beckerman-Rodau, *supra* note 46, at 379.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 381.

<sup>66</sup> The Doctrine of Equivalence "prohibits a would-be infringer from making an 'insubstantial' modification to a product, method, etc., to avoid infringement of a patent claim." Scott M. Alter, *Festo and the Future of the Doctrine of Equivalence*, 735 PLI/PAT 45, 48 (2003).

<sup>67</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (1st Cir. 2000), *vacated*, *Festo Corp. v. Shoketsu Kinzo Kogyo Kabushiki Co.*, 535 U.S. 722 (2002)).

<sup>68</sup> See generally *Festo Corp.*, 535 U.S. 722 (2002).

a narrowing amendment made during patent prosecution does not bar all equivalents from suit.<sup>69</sup>

The use of trade secret protection would have far reaching consequences on the scientific community, as well as the population at large. If trade secret protection becomes the preferred means of transgenic research protection, there would be a strong incentive for scientists not to disclose their breakthroughs.<sup>70</sup> Moreover, a company would have to shift money that could be used for innovation and discovery to the protection of the trade secret.<sup>71</sup>

While this means of protection will maximize the profit potential of a researcher or company, it will consequently slow the exchange of information within the scientific community.<sup>72</sup> Furthermore, the use of trade secrets will create unnecessary waste within the scientific community by requiring that separate researchers expend otherwise unnecessary time and money in duplicating a particular trade secret.<sup>73</sup> Similarly, the existence of trade secrets will harm the public as a whole. Allowing one company to establish an indefinite monopoly on a scientific discovery effectively bars the vast majority of the population from access to the discovery.

### C. Utility Patents

The UPA provides that the United States Patent and Trademark Office (“PTO”) is to be the entity to oversee all patent applications.<sup>74</sup> Section 101 of the UPA provides a broad definition of patentable matter by explaining that “whoever invents or discovers any useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore . . . .”<sup>75</sup> The UPA, then, specifies three additional requirements before the PTO may issue a patent.<sup>76</sup>

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<sup>69</sup> *Id.* at 740-41.

<sup>70</sup> Lauroesch, *supra* note 59, at 108.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> 35 U.S.C. § 1-376 (2000).

<sup>75</sup> 35 U.S.C. § 101 (2000).

<sup>76</sup> See generally Czarnetzky, *supra* note 48, at 1334-35; Koopman, *supra* note 4, at 119-21. For an example of a living organism which meets these three requirements, see Milkyung Kim, *An Overview of the Regulation and Patentability of Human Cloning and Embryonic Stem Cell Research in the United States and Anti-Cloning Legislation in South Korea*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 645, 697-98 (2005).

First, the prospective patentable organism must "have some utility apart from research."<sup>77</sup> This prerequisite requires that the organism be a "new and useful . . . composition of matter . . ."<sup>78</sup> This portion of the statute was established to provide some minimal requirement for patent application.

The second prerequisite requires that the organism fulfill the novelty requirement as established under Section 102 of the UPA.<sup>79</sup> The UPA defines novel as something that does not already exist.<sup>80</sup> This requirement will not be met if the organism is both naturally occurring and considerably unaltered.<sup>81</sup> This prerequisite further requires that the organism meet three separate conditions: general utility, specific utility and beneficial utility.<sup>82</sup> General utility requires that the organism/invention be operable and capable of general use.<sup>83</sup> Specific utility mandates that the organism/invention be able to solve the problem it is designed to correct.<sup>84</sup> Lastly, the beneficial utility requires that the organism/invention, at a minimum, provide some overall societal benefit.<sup>85</sup>

The third UPA prerequisite requires that the organism fulfill a non-obvious requirement.<sup>86</sup> In order to successfully satisfy this requirement, the newly created organism must not have been open and obvious to anyone other than the inventor.<sup>87</sup> In establishing non-obviousness, courts take into account three factors.<sup>88</sup> Courts first consider the content and scope of any prior similar inventions.<sup>89</sup> Second, courts consider what differences exist, if any, between the organism/invention at issue and prior inventions.<sup>90</sup> Last, courts look to ensure that the inventor surpassed the level of ordinary skill existing in the area of invention.<sup>91</sup>

<sup>77</sup> Czarnetzky, *supra* note 48, at 1335.

<sup>78</sup> 35 U.S.C. § 101 (2000); *See Brenner v. Manson*, 383 U.S. 519, 528-31 (1966).

<sup>79</sup> 35 U.S.C. § 102 (2000).

<sup>80</sup> *Id.*

<sup>81</sup> PATENT AND TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 706.03(a) (2006).

<sup>82</sup> ROBERT PATRICK MERGES, PATENT LAW AND POLICY 189 (1982).

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> 35 U.S.C. § 103 (2000).

<sup>87</sup> *Id.*

<sup>88</sup> *See generally Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Custom Accessories Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 958 (Fed. Cir. 1986).

<sup>89</sup> *Graham*, 383 U.S. at 17; *Custom Accessories*, 807 F.2d at 958.

<sup>90</sup> *Graham*, 383 U.S. at 17; *Custom Accessories*, 807 F.2d at 958.

<sup>91</sup> *Graham*, 383 U.S. at 17; *Custom Accessories*, 807 F.2d at 958.

Patent protection's biggest drawback to investors is the twenty-year statutory length of the patent.<sup>92</sup> However, during the twenty-year period the researcher is granted an exclusive right to produce the patented organism.<sup>93</sup> While an investor may be scared off by the possibility of a return-on-investment limited to twenty years after the time application is filed, this period still allows a researcher to sell the use rights of the patent to any number of other researchers. Furthermore, this requirement allows for the full disclosure of the processes of creation. The exclusive ownership period benefits both the research community and public as a whole by enabling researchers to bypass the mistakes made in prior research and build upon what has already been established.

#### IV. ACTION BY THE PTO

In the past, the PTO rejected attempts to patent such innovations as headless shrimp on the grounds that the alterations were not sufficiently permanent.<sup>94</sup> Moreover, the PTO has previously stated that no living organism is eligible for patenting because the Product of Nature Doctrine preempts patentability.<sup>95</sup>

The first major case involving the granting of utility patents for living organisms occurred in *Diamond v. Chakrabarty*.<sup>96</sup> The Supreme Court in *Chakrabarty* found that since Congress enacted the UPA in such broad terms, § 101 must be read so as to extend patent protection to living organisms.<sup>97</sup> The Court further stated that until Congress specifically speaks to the subject, the Court will view the UPA as extending patent protection to living organisms.<sup>98</sup>

Another court held that the PTO further expanded the category of patentable matter when, in approving an application, it overrode an examiner's rejection of larger-than-normal oysters.<sup>99</sup> Relying on *Chakrabarty*, the PTO reasoned that since the PPA includes man-made organisms, the oysters at issue were non-naturally occurring.<sup>100</sup> In a statement, the PTO announced that all non-naturally occurring multi-

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<sup>92</sup> Beckerman-Rodau, *supra* note 46, at 383.

<sup>93</sup> *Id.* at 387.

<sup>94</sup> Koopman, *supra* note 4, at 124.

<sup>95</sup> *Id.* at 123.

<sup>96</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>97</sup> *Id.* at 309-10.

<sup>98</sup> *Id.* at 317-18.

<sup>99</sup> See *In re Allen*, 846 F.2d 77 (Fed. Cir. 1988).

<sup>100</sup> *Id.*

cellular, non-human organisms would be considered patentable under the UPA.<sup>101</sup> Since that statement, the PTO has issued only a handful of patents, covering specific animals, rather than classes or orders of animals.<sup>102</sup>

Most recently, in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*,<sup>103</sup> the United States Supreme Court stated that utility patents are a permissible means of protecting newly developed sexually-reproduced plants and plant seeds.<sup>104</sup> The Court found that in enacting both the PPA and the PVPA, Congress did not limit the UPA's broad scope.<sup>105</sup> The Court upheld its previous holding in *Chakrabarty* in finding that since the UPA was written in such broad terms, it was clearly Congress' intent to give the UPA a broad scope.<sup>106</sup> In so holding, the Court upheld the Appellate Court's ruling that the UPA permits the patenting of living organisms.<sup>107</sup> If this holding does not already explicitly allow for the granting of utility patents for transgenic animal research, it certainly opens the door for such a holding.<sup>108</sup> Taken in connection with the prior holdings, *J.E.M. AG Supply* appears to advance the new trend of the patenting of transgenic animals.<sup>109</sup>

## V. ARGUMENTS AGAINST THE PATENTING OF TRANSGENIC ANIMALS

Most of the arguments against the patenting of living organisms tend to focus on the moral and ethical issues involved. Viewing living organisms as products is the most difficult concept with which many people grapple.<sup>110</sup> Critics of the inclusion of living organisms as patentable matter argue that such inclusion degrades the value of life.<sup>111</sup> Critics further contend that

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<sup>101</sup> See James P. Daniel, *Of Mice and 'Manimal': The Patent & Trademark Office's Latest Stance Against Patent Protection for Human-Based Inventions*, 7 J. INTELL. PROP. L. 99, 116-18 (1999).

<sup>102</sup> See Koopman, *supra* note 4, at 131-32.

<sup>103</sup> 534 U.S. 124 (2001).

<sup>104</sup> *Id.* at 127.

<sup>105</sup> *Id.* at 145.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.* at 145-46.

<sup>108</sup> See generally *Velandar v. Garner*, 348 F.3d 1359 (Fed. Cir. 2003) (citing U.S. Patent No. 5,304,489 (filed Oct. 24 1990) and U.S. Patent No. 4,873,316 (filed Jun. 23, 1987) (denying patentability of a transgenic animal, but doing so pursuant to UPA analysis); see also U.S. Patent No. 6,987,211 (filed May 12, 1999) (granting patent for "Transgenic non-human mammals producing a cholinesterase in their milk"); see also U.S. Patent No. 6,953,874 (filed Feb. 5, 2001) (granting patent for "Transgenic animals having a modified glycoprotein V gene").

<sup>109</sup> See Bratislav Stankovic, *Patenting the Minotaur*, 12 RICH. J.L. & TECH. 5, at \*5 (2005) (explaining that the PTO will not grant patents for human-animal chimera creations).

<sup>110</sup> See Lauroesch, *supra* note 59, at 114-16.

<sup>111</sup> *Id.* at 114.

viewing life as a commodity can be seen as continuing the systematic submission of less powerful animals. This argument finds its support primarily in the antiquated "morality doctrine" which prevents the patenting of an invention "designed for an immoral use."<sup>112</sup> However, this morality argument fails to acknowledge the history of man's ownership of animals such as dogs, cows and sheep, and it necessarily fails.<sup>113</sup>

The second major criticism of patenting living organisms revolves around the treatment of the patented material during testing.<sup>114</sup> However, both federal and state laws prohibit the inhumane treatment of lab animals.<sup>115</sup> Furthermore, if the PTO were to eliminate patents for living organisms, the fear of inhumane lab treatment would not be cured.<sup>116</sup> However, should the PTO eradicate such patents, it would severely impair the societal benefits associated with laboratory research.<sup>117</sup>

Thirdly, critics project negative future effects for allowing for the patenting of living organisms. Many critics feel that by allowing the patenting of non-human animals, the next logical step will be to include genetically manufactured humans as patentable subject matter.<sup>118</sup> This fear, however, should remain unfounded, as it is unlikely that a court would refuse to extend the Thirteenth Amendment<sup>119</sup> to non-natural humans.<sup>120</sup>

## VI. A PROPOSED SOLUTION FOR PROTECTING TRANSGENIC RESEARCH

Transgenic research can allow scientists to better understand the workings of the human body and specific genes. As a result, Congress must enact a statute specifically protecting transgenic research. While trade secret protection may provide sufficient security to a corporate researcher, it does not advance the societal benefits associated with transgenic research. Congress should instead either enact a new statute protecting transgenic

<sup>112</sup> See Kim, *supra* note 76; see also *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (D. Mass. 1817); Stankovic, *supra* note 109, at \*36-44.

<sup>113</sup> See Kim, *supra* note 76; see also *Lowell*, 15 F. Cas. at 1019; Stankovic, *supra* note 109, at \*36-44.

<sup>114</sup> Hecht, *supra* note 25, at 1041.

<sup>115</sup> Lauroesch, *supra* note 59, at 117 (discussing the Animal Welfare Act and guidelines established by both the National Institute of Health and the American Association for Accreditation of Laboratory Animal Care).

<sup>116</sup> *Id.* at 118.

<sup>117</sup> See Moye, *supra* note 7, at 1587-88.

<sup>118</sup> Lauroesch, *supra* note 59, at 115.

<sup>119</sup> U.S. Const. amend. XIII (protecting human beings from being subject to exclusive property rights of another).

<sup>120</sup> Lauroesch, *supra* note 59, at 115.

research or amend the UPA so as to include transgenically produced animals within the class of patentable subject matter.

Congress proposed legislation similar to the PVPA, in attempting to create a farmers' exemption from protection.<sup>121</sup> This exemption would allow family farmers to reproduce the transgenic animals for the sole purpose of breeding within their own farm. The exemption, however, would not extend to reproduction with animals not presently owned by the farmer.<sup>122</sup>

This exemption unfortunately may be an invitation to misuse. To protect against such an outcome, this exemption needs to include a moratorium on the sales of all reproduced transgenic animals by farmers. Further, to ensure that the moratorium does not significantly harm the farmer, its effectiveness would need to be for only a limited period after birth. Otherwise, a farmer would be financially tied to the newborn animal. This moratorium would be enacted in an attempt to close the loophole created by the exemption. However, this loophole would not be closed unless a moratorium on all sales is also enacted. Moreover, this moratorium is not possible since it would severely damage most farmers. Since no clear exemption is possible, Congress should not enact one.

Explicit patent protection for transgenic research is required so as to keep the United States among the top countries in cutting edge research. Such protection will promote the flow of information between researchers and the publication of results. This will allow other researchers to duplicate the tests previously conducted and improve upon those tests. Furthermore, patent protection will provide researchers with adequate security and encourage investor contribution. While some critics complain that patent protection does not extend far enough, the alternatives would stifle research everywhere. The most obvious and effective solution to this dilemma is a Congressional amendment to the UPA which would include transgenically produced and/or modified animals.

## VII. CONCLUSION

Transgenic research, while in its infancy, promises to play an important role in the future. The United States, as a scientifically-advanced nation, must provide some protection to promote scientific innovation and

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<sup>121</sup> For a discussion of the proposed legislation, see Hecht, *supra* note 25, at 1066-68.

<sup>122</sup> Regardless, Congress has been slow to act on any of these proposed bills. See, e.g., Brief for the United States as Amicus Curiae Supporting the Respondents, at 17, *Duke Univ. v. Madey*, United States Supreme Court (No. 02-1007), available at <http://www.uspto.gov/web/offices/com/sol/ambriefs/Duke.pdf> (last visited March 2, 2007).

development in the area of transgenic research. Our current means of protection do not provide sufficient guidance for the future, and Congress' continued silence on the issue of patent protection for transgenic research forces the PTO and the courts to speak on its behalf. This should not be the accepted means of deciding what can and should fall within the definition of protected subject matter. Congress must speak so as to establish guidelines for protection in order to quell potential fears of researchers, investors and the public at large. Should Congress choose to remain silent, a flood of research and investment potential could shift from the United States to other parts of the world such as the European Union. In order to protect against this, Congress should amend the UPA to include transgenic research within the definition of patentable subject matter.