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# **Worms, Mice, Cows, and Pigs: The Importance of Animal Patents in Developing Countries**

by

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# **Worms, Mice, Cows and Pigs: The Importance of Animal Patents in Developing Countries**

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## I. INTRODUCTION

Transgenic animals play a large role in several critical industries: the pharmaceutical industry, the agricultural industry, farming, and medical research. As these biotechnology-oriented industries have grown, the United States and other industrialized nations have realized the importance of patent protection for genetically-engineered animals. Unfortunately, lesser-developed countries (LDCs), which can benefit the most from such industries, do not provide adequate patent protection for transgenic animals, even though patent protection for transgenic animals could ultimately lead to reduction in starvation and disease, two of the biggest problems facing many LDCs. The United States should pursue bilateral negotiations with developing countries in the area of animal patents to secure patent protection for transgenic animals. Because of their flexibility, bilateral agreements offer a better short-term solution than multilateral agreements.

This comment first describes the methods for creating transgenic animals and the importance of these animals. Second, this article outlines the current state of animal patents in industrialized countries and the various controversies those countries have faced during the development of their current policies. Third, this article explains and refutes the arguments advanced by developing countries to support their lack of adequate patent protection for transgenic animals. Finally, this article shows that the best short-term solution to align the views of the industrialized countries with those of the various developing countries are bilateral agreements rather than multilateral agreements.

## II. BIOTECHNOLOGY RELATING TO ANIMALS

### A. What are Patentable Animals?

Patentable animals are the result of recombinant DNA technology, commonly known as genetic engineering. DNA (deoxyribonucleic acid) is the essential molecule in living creatures, containing the information required to make cells grow into living creatures in the necessary manner.<sup>1</sup> DNA is made up of smaller units known as genes. Genes are the building blocks which contain certain characteristics an organism will have. Genes may be spliced and combined in different ways. Recombinant DNA (rDNA) technology involves this splicing and manipulation of genes.<sup>2</sup>

In addition to rDNA techniques, the slow and unpredictable traditional breeding technique is sometimes used to create animals with certain specified traits. In that traditional process, the breeder selects the animals to mate based on the specific physical traits that the breeder wishes the offspring to acquire, such as a certain color or weight.<sup>3</sup> The breeder chooses the animals to be bred based on manifest physical traits, rather than on particular genetic characteristics.<sup>4</sup> Therefore, the results are unpredictable, because one responsible gene is not identified and transferred by itself. Rather, a characteristic trait of an animal is chosen, and while the parent has the correct gene, the egg or sperm might not contain that gene, because the desired gene has not been isolated from other genetic material that might be selected instead.<sup>5</sup> The traditional methods also require that the breeding material be that of a closely related species, or different strains within a species, rather than two very different species.<sup>6</sup> Absent this factor, the animals could not breed successfully.

In contrast with classical breeding techniques, genetic engineering involves the alteration of animals through the addition of DNA from another species of animal or from a human.<sup>7</sup> The most common procedure is called microinjection, which involves several steps.<sup>8</sup>

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<sup>1</sup> Elizabeth Joy Hecht, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1026 (1992).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* at 1027.

<sup>5</sup> *Id.* at 1028 n. 21. The term 'selected' here means the random sampling that occurs when one item is chosen out of many.

<sup>6</sup> *Id.* at 1028 n. 22.

<sup>7</sup> *Id.* at 1027.

<sup>8</sup> Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 405 (1988).

First, a desired gene is isolated from the original species. Then the gene is microinjected through a glass tube into a fertilized embryo of the donee species while it is still at the single-cell stage.<sup>9</sup> The egg is then implanted into the female of the donee species, where the egg gestates until the resultant transgenic animal is born.<sup>10</sup> The embryo is injected at the single-cell stage, so as that single cell divides and multiplies, all cells in the resulting animal will contain the foreign gene. Therefore, the alien gene may be passed on to offspring, because the foreign gene will be part of the sperm or egg cells also.<sup>11</sup>

As a result of genetic engineering, breeders and scientists can more easily produce transgenic animals with specific desirable qualities. Examples of genetically engineered animals include: chickens immune to certain diseases, cows that provide more milk, pigs that produce low cholesterol meat, and mice or cows that produce medically-useful chemicals.<sup>12</sup>

#### B. What are the Benefits of Transgenic Animals?

Genetically-engineered animals are used in the agricultural pharmaceuticals, and biomedical research industries. These industries all incur high research and development costs, because large investments of time and money are required before a product is fully developed.<sup>13</sup> The only practical way to recoup investment is through patent protection.<sup>14</sup> Patent protection grants a monopoly to the original inventor for seventeen years, during which time nobody else may make, use or sell the patented invention.<sup>15</sup> During that time, the inventors may recoup their investment through royalties. While other forms of protection are available, they are not as reliable. For example, trade secret protection only protects an invention that has not become publicly known and does not prevent others from creating the same invention.<sup>16</sup> Thus, an inventor who relies on trade secrets risks the chance that somebody else will create a similar invention and be able to take some of the market share away from the original inventor.

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<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> Dorothy Nelkin, *Living Inventions: Animal Patenting in the United States and Europe*, 4 STAN. L. & POL'Y REV. 203, 203-04 (1993).

<sup>13</sup> Louis A. Schapiro, *The Role of Intellectual Property Protection and International Competitiveness*, 58 ANTITRUST 569, 572 (1989).

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

<sup>15</sup> Dresser, *supra* note 8, at 402.

<sup>16</sup> Hecht, *supra* note 1, at 1065 n. 251.

In the agricultural area, genetic engineers can create healthier livestock animals which produce greater quantities of food, since certain transgenic animals can grow faster with lower nutritional needs.<sup>17</sup> As the expected demand for worldwide food production increases, especially in developing countries, the need for such highly productive animals becomes compelling.<sup>18</sup> Critics complain that some of these animals have health problems. For example, some cows that are injected with a genetically-engineered hormone to produce larger amounts of milk suffer from inflamed udders, decreased immune function and reduced reproductive capacity.<sup>19</sup> However, according to scientists, these problems occur only at very high dose levels, and will not occur at the normal lower dose levels.<sup>20</sup>

In the pharmaceuticals industry, genetically-engineered animals serve several purposes. First, many animal proteins are used as vaccines to treat illnesses. These proteins may be more easily available through transgenic animals. Genes containing the protein may be inserted into the fertilized egg of a host species.<sup>21</sup> As a result, the milk from the transgenic animal will contain that protein, which may then be extracted from the milk and used as a pharmaceutical. For instance, in Japan, silkworms produce a vaccine for hepatitis.<sup>22</sup> LDCs could benefit greatly from improved pharmaceutical production capability. Second, pharmaceuticals companies use transgenic animals that are prone to certain diseases to test various drugs in order to determine their effectiveness.

Transgenic animals are also used for biomedical research. Using transgenic animals, scientists are studying how cells operate. Also, scientists are learning about human diseases, and treatments for illnesses such as Alzheimer's disease, cancer and AIDS.<sup>23</sup> For instance, the Harvard Mouse, patented in the United States, is designed to be more prone to cancer, allowing scientists to study cancer and possible methods of treatment.<sup>24</sup>

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<sup>17</sup> Dresser, *supra* note 8, at 407.

<sup>18</sup> Dresser, *supra* note 8, at 407.

<sup>19</sup> John Beiswenger, Note, *Moving Beyond Risk In Assessing Technological Artifacts: The Case of Recombinant Bovine Somatotropin*, 16 VT. L. REV. 667, 682-83 (1992).

<sup>20</sup> *Id.* at 684.

<sup>21</sup> See Nelkin, *supra* note 12, at 194.

<sup>22</sup> See Nelkin, *supra* note 12, at 194.

<sup>23</sup> See Hecht, *supra* note 1, at 1038.

<sup>24</sup> See Hecht, *supra* note 1, at 1035 n. 81. U.S. Patent Number 4,736,866. Researchers from Harvard isolated the gene that causes cancer in humans. Once isolated, the researchers injected that gene into a fertilized mouse egg that developed into the Harvard mouse. This resulted in more efficient laboratory testing of suspected carcinogens than was previously possible with or-

### III. PATENTING OF TRANSGENIC ANIMALS IN DEVELOPED COUNTRIES

#### A. The Current State of Animal Patents

In developed countries, the primary purposes behind patent laws are to encourage investment in research and development, and to promote scientific innovation.<sup>25</sup> Incentives include monopoly power and royalties.<sup>26</sup> For animal patents in particular, an additional goal is to promote research and development in understanding and combating disease.<sup>27</sup> Also, issuance of animal patents will promote industry-wide disclosure of important biotechnology research developments.<sup>28</sup> The developed countries that allow animal patents include the United States, the nations of the European Community, Australia and Japan.

In the United States, patents are granted for inventions that are useful,<sup>29</sup> novel<sup>30</sup> and non-obvious.<sup>31</sup> Additionally, a patent application must be written such that it will enable a person skilled in the relevant field to make and use the invention.<sup>32</sup> However, it was a long time before living organisms were patented. The patent statute was not construed to allow protection for living organisms until fairly recently. Although the United States now readily grants animal patents that meet the criteria of the patent statute, the first animal patents faced much skepticism from the American public and the Patent & Trademark Office (PTO). The first United States patent granted for a living organism was for a type of bacteria that breaks down components in crude oil.<sup>33</sup> After the PTO denied the patent, the United States Supreme Court granted certiorari. In *Chakrabarty*, the Supreme Court held that genetically engineered microorganisms were

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dinary mice. Harvard mice are useful because modified genes make them susceptible to carcinogens at levels comparable to those which might cause cancer in humans, thereby eliminating the need for extreme overdoses required to cause comparable results in unmodified animals.

<sup>25</sup> David Manspeizer, Comment, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a Whole New Wonderland*, 43 RUTGERS L. REV. 417, 422 (1991).

<sup>26</sup> A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE L.J. 831, 834 (1987).

<sup>27</sup> JUDITH CURRY, THE PATENTABILITY OF GENETICALLY ENGINEERED PLANTS AND ANIMALS IN THE U.S. AND EUROPE: A COMPARATIVE STUDY (1987); Michael B. Landau, *Multicellular Vertebrate Mammals as Patentable Subject Matter Under 35 U.S.C. § 101: Promotion of Science or and Open Invitation for Abuse?*, 97 DICK. L. REV. 203, 216-17 (1993).

<sup>28</sup> Hecht, *supra* note 1, at 1039.

<sup>29</sup> 35 U.S.C. § 101 (1988).

<sup>30</sup> 35 U.S.C. § 102 (1988).

<sup>31</sup> 35 U.S.C. § 103 (1988).

<sup>32</sup> 35 U.S.C. § 112 (1988).

<sup>33</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

patentable subject matter within the meaning of § 101.<sup>34</sup> The Court relied on evidence that Congress intended the patent statute to be construed broadly, including “anything under the sun that is made by man.”<sup>35</sup> Later, adhering to the *Chakrabarty* decision, the PTO decided that the patent statute would be extended to multicellular organisms.<sup>36</sup> A patent was issued for sterile oysters which were edible throughout the entire year.<sup>37</sup> Finally, the first animal patent was granted in the United States in 1988 for a mouse developed by several researchers from Harvard.<sup>38</sup> The “Harvard Mouse” was an animal designed to be prone to cancer by microinjection of cancer genes into the embryos of mice.<sup>39</sup> Since the “Harvard Mouse,” other strains of transgenic mice have been patented in the United States. For example, Ohio University patented a virus-resistant mouse that produces interferon, a useful treatment for disease.<sup>40</sup> GenPharm, a pharmaceutical company, has patented a strain of mice that does not have a fully-operating immune system.<sup>41</sup> Harvard has received another patent for a type of mouse whose males develop an enlarged prostate gland, enabling scientists to study the same common problem among human males.<sup>42</sup>

Europe has also granted patents for transgenic animals. Article 52(1) of the European Patent Convention (EPC) defines patentable subject matter as “inventions which are susceptible of industrial application, which are new, and which involve an inventive step.”<sup>43</sup> This definition is limited by Article 53(a) which contains a provision denying patents on inventions that are offensive to public morality.<sup>44</sup> Article 53(b) also lists specific exclusions to patentable inventions, including plant and animals varieties.<sup>45</sup> Initially, the Examining Division of the European Patent Office (EPO) interpreted these provisions to exclude the Harvard Mouse patent.<sup>46</sup> However, in 1991 the

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<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> Ex Parte Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (PTO Bd. Pat. App. & Int. 1987).

<sup>37</sup> *Id.* at 1428.

<sup>38</sup> Hecht, *supra* note 1, at 1035.

<sup>39</sup> Hecht, *supra* note 1, at 1035.

<sup>40</sup> *Dawn Of Age Of ‘Designer’ Lab Animals*, Daily News Telegraph, Dec. 31, 1992, available in WESTLAW, INT-NEWS-C Database.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> European Patent Convention, Article 52(1) (1980).

<sup>44</sup> European Patent Convention, Article 53(a) (1980).

<sup>45</sup> European Patent Convention, Article 53(b) (1980).

<sup>46</sup> Cynthia M. Ho, *Building A Better Mousetrap: Patenting Biotechnology in the European Community*, 3 DUKE J. COMP. & INT’L L. 173, 178 (1992).

Technical Board of Appeals of the European Patent Office reversed that decision, stating that Article 53(b) does not exclude animal patents per se.<sup>47</sup> Furthermore, the Board stated that for this particular patent, the contributions to human benefit outweighed any potential drawbacks.<sup>48</sup> Thus, the patent did not violate the ethical concerns of Article 53(a).<sup>49</sup> The Board also determined that animal patents in the European Community will be examined on a case by case basis, meaning that future patents for transgenic animal may or may not be granted in Europe.<sup>50</sup> This shows that Europe is still skeptical about granting patents for transgenic animals.

The Commission of the European Community has generally supported animal patents.<sup>51</sup> In fact, the European Community 1988 Council Directive states that all products of biotechnology, including genetically engineered animals and plants, are the result of microbiological processes and are patentable.<sup>52</sup> Yet, there have been proposals to amend this Directive. The proposals include a definition of biological material, and a provision denying patent protection to any transgenic animals which are likely to inflict suffering upon animals without any benefit to humans or animals.<sup>53</sup> Nevertheless, even if the EPO<sup>54</sup> grants a patent, certain legislation within individual member nations may restrict the use of the patent through regulation. For example, Denmark, Germany and the United Kingdom have legislation for biotechnology regulation.<sup>55</sup> In April, 1991, the Economic Community published a policy paper aimed at preventing such legislation because it prevents the "free flow" of biotechnological inventions.<sup>56</sup> But the response to the paper has been inconsistent throughout the European Community, and no developments are likely in the near future.<sup>57</sup>

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<sup>47</sup> Margaret J. Lane, *Patenting Life: Responses of Patent Offices in the U.S. and Abroad*, 32 JURIMETRICS J. 89, 99 (1991).

<sup>48</sup> *Id.* at 99-100.

<sup>49</sup> Ho, *supra* note 46, at 178.

<sup>50</sup> Lane, *supra* note 47, at 100.

<sup>51</sup> The member states include Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, and the United Kingdom.

<sup>52</sup> Lane, *supra* note 47, at 98.

<sup>53</sup> *EC Amends Biotech Directive*, 5 No. 4 J. PROPRIETARY RTS. 36 (1993).

<sup>54</sup> The EPO is the European counterpart to the PTO in the United States. The EPO is the office that examines patent applications and determines whether or not to grant a patent for a particular invention. The patent is then granted for all member states of the European Community, subject to regulation by the individual member states.

<sup>55</sup> Ho, *supra* note 46, at 179 n.38.

<sup>56</sup> Alan S. Gutterman, *International Intellectual Property: A Summary of Recent Developments and Issues for the Coming Decade*, 8 SANTA CLARA COMP. & HIGH TECH L.J. 335, 356-57 (1992) [hereinafter *Gutterman*].

<sup>57</sup> *Id.* at 357.



Australia also grants patent protection for transgenic animals. The Patents Act of 1990 defines patentable inventions as those that are useful, novel, and inventive, but the statute explicitly exempts human beings from patentability.<sup>58</sup> One example of patent protection for a transgenic animal is a patent for a genetically-engineered pig. That pig was injected with pig growth hormone, resulting in faster growth and leaner meat than normal pigs. Such an animal could be brought into the market faster with less food required per unit weight of the pig.<sup>59</sup>

Under the Japanese Patent Law, patents are granted to the first person to file for a patent, as long as the invention is novel, "industrially useful," inventive and properly disclosed.<sup>60</sup> Like Europe, Japan regards anything contrary to public morality as unpatentable.<sup>61</sup> Yet, Japan allows animals to be patented, and historically, the Japanese people have been very receptive to the extensive application of biotechnology to life.<sup>62</sup> This greater acceptance of biotechnology is quite different than the skepticism encountered in the United States and Europe.<sup>63</sup> Accordingly, Article 2 of the Japanese Patent Law, which defines an invention, includes microorganisms and "novel and distinct plant and animal varieties and species."<sup>64</sup> The first animal patent was filed in 1977 by the inventor of a rat designed to be born with hereditary cataracts.<sup>65</sup>

## B. Opposition to Animal Patenting

Most of the developed countries initially hesitated to grant patent protection for transgenic animals. Those countries encountered protests from animal rights activists, farmers, religious groups and environmentalists.

Animal rights activists argue that animal patents cause animals unnecessary suffering. They claim that inventors purposely cause ani-

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<sup>58</sup> Patents Act 1990, ch. 2, sec. 18 (Australia).

<sup>59</sup> *Australia Patent For Genetically Engineered Pig*, Australia and New Zealand Reuters Economic News, Apr. 1, 1993, available in WESTLAW, INT-NEWS-C Database.

<sup>60</sup> Takashi Ishida, *Helpful Hints to Effective Japanese Patent Protection*, in GLOBAL INTELLECTUAL PROPERTY SERIES: PRACTICAL STRATEGIES—PATENT, at 93, 95 (PLI Patents, Copyrights, Trademarks and Literary Property Course Handbook Series No. 319, 1991).

<sup>61</sup> Patent Law, ch. 3, art. 32 (Japan).

<sup>62</sup> Brian C. Cunningham & Joyce C. Chow, *The Biotechnology Industry in Japan: A Framework for Entry*, 4 No. 7 J. PROPRIETARY RTS. 13 (1992).

<sup>63</sup> *Id.*

<sup>64</sup> Ishida, *supra* note 60, at 97.

<sup>65</sup> Ishida, *supra* note 60, at 110 App. 3.

imals to be susceptible to diseases.<sup>66</sup> However, since the resulting animals are more responsive to experimental treatments, fewer animals are necessary for testing. Thus, the number of animals that suffer is actually reduced.<sup>67</sup> Moreover, it is at least arguable that the use of animals for testing purposes is justified, because our society determined long ago that it is acceptable to sacrifice the welfare of animals in order to obtain benefits for human beings.<sup>68</sup>

Smaller scale farmers fear that the use of transgenic animals will result in their being “squeezed” out of business.<sup>69</sup> They feel that they will be forced to pay more for patented livestock because of royalty and license fees paid to biotechnology companies.<sup>70</sup> Smaller scale farmers worry that these higher costs, plus the increased productivity per animal, will force them out of business. Moreover, farmers fear that biotechnology companies will control the market, and the farmers will become dependent on these companies.<sup>71</sup> Nevertheless, most of the livestock resulting from genetic engineering will actually help farmers. Diseases in farm animals cause many animals to die prematurely or produce infected meat. As a result, farm yields only reach sixty-five to seventy percent of their potential.<sup>72</sup> Since many transgenic animals are designed to be resistant to disease, these animals will help reduce the disease problem and increase farm productivity.<sup>73</sup> For example, a type of transgenic chicken has been injected with genes to protect the chickens against a common disease, avian leukosis.<sup>74</sup> This illness costs the poultry industry up to one hundred million dollars a year.<sup>75</sup> These costs will be greatly reduced as a result of this transgenic chicken. Congress has responded to the farmers’ arguments by proposing a farmers’ exemption.<sup>76</sup> Under such an exemption, it is not an act of infringement for a farmer to reproduce a patented transgenic animal through normal breeding, to use such an animal in farming operations, or to sell such an animal or its off-

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<sup>66</sup> Manspeizer, *supra* note 25, at 442.

<sup>67</sup> Lane, *supra* note 47, at 95.

<sup>68</sup> Hecht, *supra* note 1, at 1056.

<sup>69</sup> Hecht, *supra* note 1, at 1042.

<sup>70</sup> Hecht, *supra* note 1, at 1042.

<sup>71</sup> Presumably, this is a bigger concern for smaller scale farmers. Large farmers have a larger financial base, so that the payment of royalties will not have such a detrimental impact.

<sup>72</sup> Manspeizer, *supra* note 25, at 430.

<sup>73</sup> Manspeizer, *supra* note 25, at 430.

<sup>74</sup> Manspeizer, *supra* note 25, at 430.

<sup>75</sup> Manspeizer, *supra* note 25, at 430.

<sup>76</sup> Hecht, *supra* note 1, at 1066.

spring.<sup>77</sup> This exemption represents a reasonable compromise between the interests of the smaller scale farmers and the interests of the transgenic animal inventors.

Religious groups feel that transgenic animals are a means of "playing God".<sup>78</sup> These groups feel that respect for God is threatened, the value of human life is reduced, and the desire for profits has taken over more traditional values. They believe humans will essentially become commodities.<sup>79</sup> Nevertheless, these groups overlook the fact that humans are not patentable subject matter in any country, and scientists are unable to produce creatures with large portions of human cells. Furthermore, these concerns do not relate to the patent law. These arguments are against the existence of research itself.<sup>80</sup> Moreover, these groups ignore the fact that many of the animals used in research have been used and owned by humans for centuries.<sup>81</sup> Animal patent protection will not change this practice. Finally, on the other side of the argument, many religious and ethical scholars believe that humans have a moral obligation to pursue activities that can relieve or avoid undue suffering.<sup>82</sup> Gene manipulation is an activity that can ease human suffering tremendously, by allowing scientists to learn about disease and the mechanisms for treating disease, and by allowing enhanced food production to relieve starvation. The benefits of patents, particularly on transgenic animals, are in the areas which can greatly benefit humankind, including health care and farming.<sup>83</sup>

Finally, environmentalists are concerned that biodiversity will be disrupted by the mutations created by genetic engineering, and eventually, native species will be driven to extinction.<sup>84</sup> This argument has no basis. Species do not exist in nature as discrete creatures but as "reproductive communities".<sup>85</sup> Thus, there is no true biodiversity to be disrupted. Moreover, the animals in question are made up of thousands of genes; therefore, manipulating an insignificant number of genes will not destroy anything essential to the identity of a spe-

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<sup>77</sup> Manspeizer, *supra* note 25, at 450. However, the germ cells, sperm or embryo of the patented transgenic animal, may not be sold without permission from the patent owner.

<sup>78</sup> Dresser, *supra* note 8, at 411.

<sup>79</sup> Dresser, *supra* note 8, at 416.

<sup>80</sup> Manspeizer, *supra* note 25, at 436-37.

<sup>81</sup> Dresser, *supra* note 8, at 413.

<sup>82</sup> Manspeizer, *supra* note 25, at 438-39.

<sup>83</sup> Lane, *supra* note 47, at 96.

<sup>84</sup> Manspeizer, *supra* note 25, at 436-37.

<sup>85</sup> Kevin W. O'Connor, *Patenting Animals And Other Living Things*, 65 S. CAL. L. REV. 597, 610 (1991).

cies.<sup>86</sup> Also, environmentalists fear the potential harmful effects of widespread pollution and disease if genetically engineered creatures are released into the environment.<sup>87</sup> Yet, engineered animals are not released into nature so there will be little, if any, introduction of the altered genes into the natural gene pool. The likelihood that genetic material would be transferred between a transgenic animal and a normal animal is extremely slight.<sup>88</sup> Besides, even if the animals are released, they would not be likely to survive in the wild, since the transgenic animals that are produced in the laboratory are acclimated to the sterile laboratory environment.<sup>89</sup>

The majority of developed countries have come to realize that these arguments are not strong enough to overcome the benefits of animal patents. Nevertheless, many of these developed countries have taken the arguments into account by enacting morality clauses.

#### IV. PATENTING TRANSGENIC ANIMALS IN DEVELOPING COUNTRIES

Unfortunately, the LDCs do not grant adequate patent protection for transgenic animals. Historically, the scenario in lesser-developed countries with goods patented elsewhere has been as follows. A local entity pirates an invention developed in an industrialized country. "Copycats" can be sold at lower prices, since the pirates incur no research and development costs.<sup>90</sup> These pirates steal the profits from the developed country that originally created the product. At a first glance, the fact that the LDCs obtain the technology at a low cost might seem good. However, as described below, piracy can actually have detrimental effects on the LDCs, and can operate against the best interests of the LDCs.

##### A. Reasons for Denial of Patents

Developing countries are reluctant to enforce patent protection in general. Yet, even in countries where progress has been made to expand patent protection, patents may still be denied for animals.

Generally, developing countries have denied patents for several reasons. First, LDCs feel that their own domestic industries will be

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<sup>86</sup> Manspeizer, *supra* note 25, at 437.

<sup>87</sup> Manspeizer, *supra* note 25, at 432.

<sup>88</sup> Manspeizer, *supra* note 25, at 432.

<sup>89</sup> Manspeizer, *supra* note 25, at 424.

<sup>90</sup> Schapiro, *supra* note 13, at 570.

promoted by restricting patents.<sup>91</sup> Since granting a patent is like granting a monopoly, LDCs feel that their local businesses would not be able to compete. Second, LDCs want to guarantee low costs and availability of patented products to their citizens.<sup>92</sup> In granting the patent monopoly, the LDCs fear that the resulting price of patented technology would be artificially high. Third, LDCs want to allow domestic industries greater access to foreign technology.<sup>93</sup> They think this goal can be achieved only if domestic producers do not have to pay high royalties for the technology. Finally, there are basic cultural attitudes behind denial of intellectual property rights.<sup>94</sup> LDCs feel that knowledge is something to be used for public benefit. This goes against the view of industrialized nations that knowledge is a private capital good.<sup>95</sup>

Developing countries generally use several methods to restrict patent protection. First, LDCs restrict the subject matter of patentable inventions.<sup>96</sup> For instance, India and Argentina do not allow pharmaceutical products to be patented.<sup>97</sup> Second, LDCs have short patent terms.<sup>98</sup> Often, by the time an inventor from a developed country has received patent protection, the term is nearly expired. Third, LDCs have early lapse requirements.<sup>99</sup> That is, if a patented invention is not used in that country within a specified time period, the patent is automatically terminated, even though the patent term has not yet expired. Finally, LDCs often require compulsory licensing.<sup>100</sup> This restriction allows third parties to obtain licenses to use or sell a patented invention at very low royalty rates without the consent of the patent holder.

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<sup>91</sup> Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 122 n.224 (1993).

<sup>92</sup> *Id.* at 123. For example, LDCs view certain products such as pharmaceuticals to be essential to mankind, and such products should be available to their citizens at a lower cost. The monopoly rights of patent protection would only serve to increase the costs of those products.

<sup>93</sup> Adam L. Streltzer, *U.S. Biotechnology Intellectual Property Rights as an Obstacle To The UNCED Convention On Biological Diversity: It Just Doesn't Matter*, 6 TRANSNAT'L 271, 282 (1993).

<sup>94</sup> Gutterman, *supra* note 91, at 122.

<sup>95</sup> Gutterman, *supra* note 91, at 122.

<sup>96</sup> Gutterman, *supra* note 91, at 114.

<sup>97</sup> Gutterman, *supra* note 91, at 122.

<sup>98</sup> Gutterman, *supra* note 91, at 93.

<sup>99</sup> Gutterman, *supra* note 91, at 114.

<sup>100</sup> Gutterman, *supra* note 91, at 94.

## B. Benefits to Developing Countries of Patent Protection in General

Developing countries can benefit from strong patent protection. In fact, denial of patent protection actually leads to the detrimental results which the LDCs fear.

First, patent protection promotes the availability of an invention in that country.<sup>101</sup> Inventors from developed countries will not be afraid of piracy, and therefore will be more willing to make their invention available in the developing country. If a developing country denies patent protection for a certain invention created in an industrialized nation, the inventor will be reluctant to market the product in the developing country for fear of losing profits to pirates. As a result, without patent protection, the availability of the product is reduced.<sup>102</sup> Developing countries might still get things through the black market or counterfeiters, but this avenue is much more difficult than simply procuring license agreements or paying royalties.

Second, patents may promote the amount of foreign investment in an LDC, which would lead to increased development.<sup>103</sup> As the biotechnology industry is highly speculative and involves enormous research costs, substantial expectations of profits are necessary to convince investors to put their money at risk in a biotechnology entity. Without large returns, most investors will not have the incentive to become involved.<sup>104</sup> Such profit-earning capacity cannot exist in an environment that fosters piracy and counterfeiting, because pirates and counterfeiters steal profits from potential investors.<sup>105</sup> "Top-of-the-line" technology will not be brought into an LDC by other countries if it is not going to receive protection.<sup>106</sup>

Third, patents may promote the local knowledge base, leading to a better foundation for growth of domestic industries.<sup>107</sup> For instance, with animal patents, if the animals are made available to developing countries, pharmaceutical and biotechnology companies could grow by licensing and using these inventions to conduct their research. However, these products will not be made available if it is likely that these products will be copied and profits will be stolen from the com-

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<sup>101</sup> I.L. "Pep" Fuller, *Intellectual Property Rights Associated With Biotechnology - An International Trade Perspective*, 16 AM. INTELL. PROP. L. ASS'N. 529, 537 (1989).

<sup>102</sup> *Id.*

<sup>103</sup> Streltzer, *supra* note 93, at 283.

<sup>104</sup> Streltzer, *supra* note 93, at 283.

<sup>105</sup> Fuller, *supra* note 101, at 537.

<sup>106</sup> Schapiro, *supra* note 13, at 578.

<sup>107</sup> Gutterman, *supra* note 91, at 120.

pany making those products. Most importantly, however, the enabling provision of patent laws require full disclosure of an invention.<sup>108</sup> Thus, by granting patent protection for an invention, developing countries would have access to technological information. This information can help developing countries learn about various technologies, promoting their own development and growth. An alternative to patent law is trade secret law, which affords protection forever, as long as the owner takes certain measures to ensure the secret is kept.<sup>109</sup> Trade secret law prevents disclosure, does not promote information sharing and may limit availability of inventions out of fear of losing the secret.<sup>110</sup> If developing countries want access to technology, patent law provides this access, but trade secret law does not.

Finally, by granting patent protection, a developing country can minimize enforcement and transactions costs.<sup>111</sup> That is, if LDCs do not grant adequate patent protection, the United States or other countries might resort to unilateral actions, including sanctions. For the United States, Section 301 sanctions are one such device.<sup>112</sup> Under the Special 301 provision, the United States Trade Representative (USTR) identifies "priority countries" that do not provide adequate intellectual property protection to the United States.<sup>113</sup> The USTR then initiates unfair trade practice investigations.<sup>114</sup> If an agreement is not reached between the two countries within six months, the President may take retaliatory measures against the pirating country according to Section 301 of the Omnibus Trade and Competitiveness Act of 1988.<sup>115</sup> For instance, sanctions may be imposed, resulting in greater costs to the LDC than the initial patent protection. This type of unilateral action might be a good deterrent to pirating efforts; however, several countries have been critical of Section 301 procedures, including some trading partners of the United States.<sup>116</sup> Therefore, the United States must be careful not to overuse these procedures, which could potentially result in strained relationships.

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<sup>108</sup> Lane, *supra* note 47, at 91.

<sup>109</sup> Hecht, *supra* note 1, at 1065 n.251.

<sup>110</sup> Lane, *supra* note 47, at 96.

<sup>111</sup> Gutterman, *supra* note 91, at 120.

<sup>112</sup> 19 U.S.C § 2411 (1988).

<sup>113</sup> Schapiro, *supra* note 13, at 581.

<sup>114</sup> Schapiro, *supra* note 13, at 581.

<sup>115</sup> Schapiro, *supra* note 13, at 581.

<sup>116</sup> Schapiro, *supra* note 13, at 581.

C. Animal Patents and Their Importance for Developing Countries

The primary applications for transgenic animals are in the pharmaceutical, agricultural, and medical research industries. These industries are critical to the development of LDCs, because two of the largest problems faced by developing countries are starvation and disease.

Protecting animal patents for the promotion of the pharmaceutical industry can promote the availability of medicines, because many pharmaceutical products are produced by transgenic animals. Promoting the availability of these animals will lead to increased availability of pharmaceuticals. Developed countries with a wealth of resources in pharmaceutical manufacturing will be more willing to invest in the pharmaceutical industry of developing nations if they are likely to earn profits. This investment will enhance the growth and efficiency of the pharmaceutical industry, thereby enlarging the availability of pharmaceuticals in LDCs.

Protecting animal patents for the promotion of the agricultural industry will promote food supplies, reducing starvation in the LDCs. Some transgenic animals are able to produce healthier food in greater quantities than normal animals, with reduced nutritional requirements. Therefore, increased food production results, since it costs less to produce more food from these animals. This increased productivity could have great benefits for starvation in LDCs. However, industrialized countries that presently have the ability to create these animals are only likely to make the animals available to LDCs if they will receive profits in return.

Protecting animal patents for medical research will promote the health of citizens through an understanding of disease and the means for treating disease. Scientists within a developing country might be able to use transgenic animals to gain an understanding of illnesses specific to that country. Yet, the industrialized nations are only likely to let the LDCs use their inventions to gain such an understanding if the invention receives patent protection. Furthermore, the local knowledge base of scientists in an LDC can increase if they are able to observe and learn about such inventions. However, since patent laws are the only laws which favor full disclosure of an invention, the LDC will never gain the knowledge necessary to create transgenic animals unless patent laws are enacted, because the industrialized nations will have greater incentives to keep their inventions secret rather than risk stolen profits. Therefore, not only can the patent laws allow scientists



in an LDC to target their research to diseases specific to that country, but patent laws can also promote the flow of information to an LDC.

#### D. Individual Variations in Patent Protection Among Various LDCs

As developed countries try to improve worldwide patent protection, the biggest problem they face is that developing countries do not understand the importance of patent protection. One way to convince the LDCs to embrace patent protection may be to stress that patent protection will induce foreign investment and allow access to new technology.<sup>117</sup> Since different countries have varying levels of understanding of the importance of patent protection in general, bilateral agreements are necessary to make those individual countries appreciate the benefits of animal patent protection. Bilateral agreements involve negotiations between the United States and a single trading partner, and allow for a tailored agreement.<sup>118</sup>

A brief look at Mexico's, India's, and Brazil's approaches to patent law will point out the need for bilateral agreements. Mexico has appeared willing to grant patent protection on its own, while Brazil has needed threats before it has revised its patent laws. India still seems unwilling to change its patent laws.

Mexico initially adopted a utilitarian view toward patent protection. That is, Mexico viewed intellectual property rights as the common heritage of all citizens.<sup>119</sup> Intellectual property was to benefit national, not personal, developments.<sup>120</sup> This view conflicts with the view held by industrialized nations that intellectual property is private property.<sup>121</sup> Recently, Mexico has shifted its view of intellectual property, because of the realization that patent protection is essential to foreign investment and access to technology.<sup>122</sup> Mexico adopted a new "Industrial Property Law" in 1991, which provides for some progress.<sup>123</sup> Today, Mexico gives patent protection for some types of biotechnology: plant varieties and microorganisms.<sup>124</sup> Animal species

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<sup>117</sup> Fuller, *supra* note 101, at 537.

<sup>118</sup> Marshall A. Leaffer, *Protecting United States Intellectual Property Abroad: Toward a New Multilateralism*, 76 IOWA L. REV. 273, 295 (1991).

<sup>119</sup> Gretchen A. Pemberton & Mariano Soni, *Mexico's 1991 Industrial Property Law*, 25 CORNELL INT'L L.J. 103, 106 (1992).

<sup>120</sup> *Id.* at 106 n.17.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at 116.

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

<sup>124</sup> *Id.* at 117.

are not yet patentable subject matter. However, the new law indicates that Mexico wants to encourage foreign investment, and recognizes the importance of patent protection. Therefore, if the Mexican government were made aware of the problems presented by patent restrictions on animals, further reforms might result.<sup>125</sup>

Brazil has historically been staunchly opposed to patent protection, fearing that patent laws will prevent it from receiving the technology necessary for growth. Brazil has many restrictions on patentable subject matter.<sup>126</sup> In the area of computer software specifically, Brazil was forced to undertake bilateral negotiations as a result of threatened Section 301 sanctions.<sup>127</sup> During the negotiations, Brazil suggested a new software protection law. Although foreign investment in Brazil has not grown appreciably so far, Section 301 has been, thus far, a useful tool in improving protection for intellectual property rights in software.<sup>128</sup> In 1993, the USTR again threatened section 301 sanctions.<sup>129</sup> These actions, together with Brazil's recognition of the need for foreign investment, have induced Brazil to revise its intellectual property laws. The proposed laws will address deficiencies identified by the United States, including inadequate protection for plant and animal varieties and species.<sup>130</sup>

India is another staunch opponent of patent protection in general. Like Brazil, India fears patent laws will stop growth. Indian patent law restricts the subject matter for which patent protection is available and provides for short patent terms.<sup>131</sup> This inadequate protection stems from India's belief that developing countries should be given concessions in certain areas, and that, due to economic differences, India can not be expected to provide the same patent protection as industrialized countries.<sup>132</sup> Rather, all countries should design their patent laws to their own needs.<sup>133</sup> Furthermore, India sees patent laws as suppressing domestic research and development.<sup>134</sup>

As seen by these examples, each of these lesser-developed countries is at a different level of understanding of the importance of intellectual property protection. Mexico has seemed to promote patent

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<sup>125</sup> *Id.* at 130.

<sup>126</sup> Gutterman, *supra* note 91, at 129.

<sup>127</sup> Schapiro, *supra* note 13, at 580.

<sup>128</sup> Schapiro, *supra* note 13, at 580.

<sup>129</sup> Market Reports, September 15, 1993, available in Lexis, ASIAPC library, ALLASI file.

<sup>130</sup> *Id.*

<sup>131</sup> Gutterman, *supra* note 91, at 132.

<sup>132</sup> Gutterman, *supra* note 91, at 132.

<sup>133</sup> Gutterman, *supra* note 91, at 132.

<sup>134</sup> Gutterman, *supra* note 91, at 132.

protection on its own, Brazil has changed its laws only after threats, and India still refuses to grant patent protection. Since each country's views are unique, bilateral negotiations are the best approach for securing patent protection for transgenic animals.

## V. BILATERAL AGREEMENTS ARE THE PROPER STARTING PLACE

The different mechanisms traditionally used by the United States to reach agreements with its trading partners have been unilateral actions, bilateral agreements, or multilateral agreements. Bilateral agreements are the best short-term action for ensuring patent protection for transgenic animals. In the long run, the bilateral agreements may then be worked into multilateral agreements.

### A. Types of International Agreements

#### 1. *Bilateral Agreements.*

Bilateral agreements consist of direct negotiations with a given country to reach a desired goal. Such negotiations should be backed up by economic sanctions, if necessary.<sup>135</sup> In exchange for adequate intellectual property protection, the country receives the right to export to the United States with most favored nation status.<sup>136</sup> Adequate protection facilitates export to the United States, and results in direct investment from the United States.<sup>137</sup> If the bilateral negotiations fail, the United States can threaten to impose sanctions, otherwise known as unilateral action.<sup>138</sup>

The advantages of bilateral agreements are: 1) bilateral agreements are more likely to be reached in the short term, because fewer interests must be considered and negotiated,<sup>139</sup> 2) bilateral agreements offer flexibility in being able to address varying concerns of different nations,<sup>140</sup> 3) bilateral agreements can enable the United States to reach a compromise with a particular trading partner that might be undesirable with other partners,<sup>141</sup> and 4) bilateral agreements can be used to "break the ice" and convince skeptical nations

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<sup>135</sup> Leaffer, *supra* note 118, at 297.

<sup>136</sup> Leaffer, *supra* note 118, at 297.

<sup>137</sup> Leaffer, *supra* note 118, at 297.

<sup>138</sup> Leaffer, *supra* note 118, at 297.

<sup>139</sup> Senator Max Baucus, *A New Trade Strategy: The Case for Bilateral Agreements*, 22 CORNELL INT'L L.J. 1, 8 (1989).

<sup>140</sup> *Id.*

<sup>141</sup> Schapiro, *supra* note 13, at 579.

that agreements are good. Later, then, these nations might be more willing to enter into multilateral agreements.<sup>142</sup>

One argument against bilateral agreements is that they run counter to long-term interests of international trade. Bilateral agreements involve two nations, and thus result in a fragmented trading system.<sup>143</sup> This argument supports multilateral agreements, which involve many countries. However, bilateral agreements are much easier to reach in the short term, because the interests of only two countries must be considered, rather than the interests of many. In addition, during the course of bilateral negotiations, long term interests may be considered, and such agreements may be worked into a longer term multilateral agreement. The first step, however, must be the bilateral meeting.

The United States has successfully negotiated several bilateral agreements. For example, Taiwan has amended its copyright laws to provide for more stringent penalties against pirates.<sup>144</sup> Taiwan has also enacted a new patent law.<sup>145</sup> In addition, Korea has made several improvements in its intellectual property coverage.<sup>146</sup> Finally, Brazil has expanded its protection of computer software.<sup>147</sup>

## 2. *Multilateral Agreements*

An alternative to bilateral agreements are multilateral agreements. Multilateral agreements involve the United States and many trading partners.

Proponents of the multilateral approach espouse several reasons for multilateral agreements being more advantageous. First of all, proponents suggest that multilateral agreements involve many more nations, not just one, and therefore these agreements are more efficient.<sup>148</sup> Second, proponents suggest that multilateral agreements create far more uniformity, whereas bilateral agreements create a "patchwork" of laws.<sup>149</sup>

On the other hand, multilateral agreements take many years to finalize.<sup>150</sup> In negotiating a multilateral agreement, several countries

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<sup>142</sup> Baucus, *supra* note 139, at 7.

<sup>143</sup> Leaffer, *supra* note 118, at 297.

<sup>144</sup> Leaffer, *supra* note 118, at 297.

<sup>145</sup> Leaffer, *supra* note 118, at 297.

<sup>146</sup> Leaffer, *supra* note 118, at 297.

<sup>147</sup> Schapiro, *supra* note 13, at 581.

<sup>148</sup> Baucus, *supra* note 139, at 6.

<sup>149</sup> Leaffer, *supra* note 118, at 297.

<sup>150</sup> Schapiro, *supra* note 13, at 579.

might be unwilling to agree to particular provisions. Tailored bilateral agreements with such countries might "break the ice" and introduce them to the advantages of international agreements.<sup>151</sup> Using bilateral agreements as an intermediate step, these countries might be more willing later to participate in multilateral talks. In fact, eventually, the bilateral agreements may be worked into multilateral arrangements, and inconsistency would disappear.<sup>152</sup>

Examples of problematic multilateral agreements are the World Intellectual Property Organization (WIPO), the Biodiversity Treaty, and the GATT talks. WIPO is a United Nations body created to address intellectual property issues, including an attempt at patent harmonization.<sup>153</sup> Developing countries are generally in favor of WIPO, although some concern has been expressed over the broad range of inventions given protection.<sup>154</sup> On the other hand, industrialized countries remain opposed to WIPO, because the provisions would require the United States and other countries to stop patenting plant and animal varieties, among other detrimental changes.<sup>155</sup> Arguments also arose over the compulsory licensing provisions.<sup>156</sup> If the WIPO proposals were enacted, the United States would be required to make numerous changes to the existing patent system.<sup>157</sup> WIPO still remains unfinished.

The Biodiversity Treaty is an international treaty directed at protecting animals and plants on the verge of extinction. The treaty was open for signatures during the Earth Summit in Rio de Janeiro in June, 1992, but the United States refused to sign the treaty.<sup>158</sup> The refusal was due to concerns that the treaty would restrict biotechnology development in the United States. Moreover, the treaty would intrude on United States patent protection for the biotechnology industry, because the treaty did not give any concessions for patented

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<sup>151</sup> Schapiro, *supra* note 13, at 579.

<sup>152</sup> Seung Wha Chang, *Extraterritorial Application of U.S. Antitrust Laws to Other Pacific Countries: Proposed Bilateral Agreements for Resolving International Conflicts Within the Pacific Community*, 16 HASTINGS INT'L AND COMP. L. REV. 295, 310 (1993).

<sup>153</sup> Schapiro, *supra* note 13, at 576.

<sup>154</sup> Gutterman, *supra* note 56, at 349.

<sup>155</sup> Gutterman, *supra* note 91, at 105.

<sup>156</sup> Schapiro, *supra* note 13, at 578. Compulsory licensing laws allow third parties access to the patented invention if the prospective user complied with the terms of the compulsory license and pays the statutory fee. If the compulsory licensing fee is set too low, the patentee may not be able to recover its investment costs.

<sup>157</sup> Gutterman, *supra* note 91, at 105.

<sup>158</sup> *Bush Defends U.S. Position on Biodiversity Treaty*, Kyodo News Service, June 5, 1992, available in WESTLAW JAPANECON Database.

inventions.<sup>159</sup> This multilateral agreement also lacked consensus in recognition of the importance of animal patents.

Perhaps the most promising multilateral agreement is GATT. In the Uruguay Round of GATT talks, the developed nations were in favor of the intellectual property proposals, while the LDCs were opposed to the proposals.<sup>160</sup> In particular, the industrialized nations favored the proposed dispute resolution mechanisms, which were unlike provisions included in any other multilateral agreement.<sup>161</sup> Ultimately, the talks have not been ratified, largely due to differences relating to agricultural subsidies.<sup>162</sup> Twenty or more issues remain unaddressed, such as the level and nature of intellectual property protection and phase-in procedures for LDCs.<sup>163</sup> Thus, the GATT agreements also remain unfinished.

No consensus has been generated from any of these multilateral agreements. Therefore, in the short term, the United States should pursue bilateral agreements, especially in the area of animal patenting.

#### B. Bilateral Agreements are the Best Short-term Mechanism for Securing Patent Protection for Transgenic Animals

Bilateral, not multilateral agreements, are the proper starting place for patent protection of transgenic animals. The United States needs to prove to individual LDCs that animal patents can have significant benefits, without the concerns of other countries influencing the negotiations. Animal patents could be especially beneficial to countries with pervasive starvation problems and disease.

In summary, patent protection for transgenic animals is important, both for developed countries and developing countries. Transgenic animals provide benefits to the pharmaceutical, agricultural, and medical research areas. These industries can directly help to solve major problems facing third world countries.

Previous multilateral efforts to convince developing countries of these benefits of patent protection for transgenic animals have failed. Some developing countries have some understanding of the importance of patent protection to their development in general, while other developing countries still deny patent protection, claiming pat-

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<sup>159</sup> *Id.*

<sup>160</sup> Leaffer, *supra* note 118, at 303.

<sup>161</sup> Leaffer, *supra* note 118, at 300-01.

<sup>162</sup> Gutterman, *supra* note 56, at 354-55.

<sup>163</sup> Gutterman, *supra* note 56, at 354-54.

ent protection only undermines their economic growth. Bilateral agreements will allow the United States to account for the baseline understanding of the country in question in addressing patent protection for animals. The different viewpoints of the various countries can be acknowledged more accurately through bilateral agreements, and a better understanding can hopefully be reached. Bilateral agreements will not only benefit developing nations and provide protection for patentable transgenic animals, but may also be a first step towards regional, hemispheric, and global harmonization of patent laws.