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I. INTRODUCTION

The advent of recombinant genetic engineering techniques has revolutionized biotechnology. The biomedicine and biotechnology industries have extensively employed these techniques to improve the quality of agricultural crops and livestock and to create genetically modified organisms ("GMOs") in order to produce drugs. Since as much as twenty-five percent of the world's intellectual property-related trade involves biotechnology, many countries have realized the importance of providing intellectual property protection for biotechnological technologies, including GMOs.[1]

In the past decade, China's booming economy has helped make its biotechnological market the fastest growing market in the world. To stimulate innovation and attract private investment in its biotechnology industry, China has rapidly transformed its intellectual property laws to conform with western models in the last two decades. However, plants and animals are not patentable in China. While plant varieties enjoy *sui generis* system protection, animal varieties are not protected by any law. This poses a serious problem for biotechnology firms that have heavily invested in the research and development of genetically modified animals.

This article focuses on whether China should provide intellectual property protection for new animal varieties, including genetically modified animals. Section II offers a brief introduction to the development of recombinant genetic engineering techniques. Section III discusses the benefits and risks of GMOs. The ethical issues of animal patenting are

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[1] *See* Ramona L. Taylor, *Tearing Down the Great Wall: China's Road to WTO Accession*, 41 J.L. & TECH. 151 (2001).

discussed in section IV. Sections V and VI present an overview of international and China's intellectual property protection for GMOs, respectively. Section VII concludes with a discussion of why and how China should provide intellectual property protection for genetically engineered animals.

II. THE DEVELOPMENT OF RECOMBINANT GENETIC ENGINEERING TECHNIQUES

The genetic material of living organisms has long been manipulated to produce desired characteristics in new organisms. Plant and animal breeders have employed intraspecies crossings and selections for desirable characteristics and eventual stabilization of the new traits for centuries.[2] Since the discovery that deoxyribonucleic acid (DNA) is the genetic material which encodes all biological information, scientists have used induced mutagenesis to modify DNA and select desirable traits.[3] This new method accelerates the conventional breeding process that may normally take generations unaided.[4] However, both approaches present the same challenge: the selection process can be extremely painful and fruitless because the modification of DNA is random and the outcome is unpredictable.[5]

Recombinant genetic techniques employed during the past three decades have revolutionized biotechnology. The creation of a transgenic organism involves the introduction of a foreign gene into the organism. A living organism may generally be genetically transformed after four steps: (1) a desired gene is isolated in its native form; (2) the gene is characterized and modified into a shorter DNA form at the molecular level; (3) the desired DNA sequence is inserted into an appropriate vector which can be integrated into the chromosomal DNA of the target organism; and (4) the vector containing the foreign DNA is introduced into the organism.[6] The foreign gene, which can either add to or replace the native gene, remains part of the transformed organism permanently.[7]

The rapid development of modern molecular biology techniques has made recombinant genetic engineering a feasible and routine practice in numerous laboratories around the world. Compared to the traditional genetic approaches, recombinant genetic engineering has two major advan-

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[2] *See* STEPHEN A. BENT ET AL., INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE 19-28 (1987).

[3] *See id.* at 20 (for instance, chemical agents and irradiation have been used to induce mutagenesis of DNA).

[4] *Id.* (induced mutagenesis allows breeders quicker and more direct access to genetic materials than the traditional process, where breeders only can artificially select mutants based on organismic criteria).

[5] *Id.*

[6] E.S. VAN DE GRAFF, PATENT LAW AND MODERN BIOTECHNOLOGY 20 (1997).

[7] *Id.* at 29.

tages. First, it is time and cost efficient. Most of the equipment and facilities required for genetic transformation are commercially available and relatively inexpensive. Also, modern DNA vectors are highly efficient at delivering the foreign DNA into the chromosomal DNA of the target organism.[8] Second and more importantly, equipped with the knowledge about the functions and characteristics of foreign DNA, a genetic engineer may predict the traits of the transformed organism and thus "overcome the randomness of heritability associated with conventional plant and animal breeding."[9]

Recombinant genetic engineering has profoundly changed agriculture as well as the biomedical and pharmaceutical industries. In plant agriculture, researchers have successfully added disease resistance genes, herbicide tolerance genes, and pest resistance genes into various crops.[10] Crops can also be engineered to be more nutritious and productive.[11] Furthermore, through genetic engineering, livestock animals have become more productive and have acquired more disease resistance.[12] For example, transgenic swine consume significantly less feed but arrive at market weight faster than their native counterparts.[13] The pharmaceutical industry has also increasingly utilized genetically modified animals or microorganisms to produce drugs to cure or alleviate diseases,[14] such as AIDS, cancer and hepatitis B.[15]

China's biotechnological market has grown faster than any other in the world in the past decade.[16] To narrow the gap between its biomedical industry and those of developed countries, China has employed two main approaches. First, China decided to focus its research and resources in several key fields, one of which is genetic engineering.[17] For example, China's State Science and Technology Commission ("SSTC") launched several programs to support biotechnology research, development, and commercialization.[18] Second, China has vigorously campaigned for investments from foreign pharmaceutical companies and has enjoyed tremendous suc-

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[8] *Id.* at 22.

[9] Reid G. Adler, *Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting*, 1 HARV. J.L. & TECH. 1, 18 (1988).

[10] *Id.*

[11] *Id.*

[12] *Id.* at 18-21.

[13] *Id.* at 21.

[14] Akim F. Czmus, *Biotechnology Protection in Japan, the European Community, and the United States*, 8 TEMP. INT'L. & COMP. L.J. 435 (1994).

[15] *Id.* at 436.

[16] *Market Research Studies: Expert Market Devises Improving 1997 Global Market*, BIOMEDICAL MARKET NEWSL., Apr. 30, 1997.

[17] *Development of Biomedicine in China*, MARKETLETTER, Sept. 8, 1997.

[18] Andrew Beckman, *Biomed & Biotech New Business Opportunities in China (PRC)*, BIOMEDICAL MARKET NEWSL., Apr. 1, 1996.

cess. For example, by 1997 China had received a $4.1 billion capital investment from about 1,500 foreign pharmaceutical companies,[19] including Merck from the United States, Genset from France, and Kirin Brewery Co. from Japan.[20] As a result, China is viewed in the international biotechnology arena as an emerging power.

III. THE BENEFITS AND RISKS OF GMOS

GMOs, like any other innovation, provide both benefits and risks. Many of the major benefits of GMOs have already been mentioned. For example, genetic engineering can significantly increase the productivity of crops and livestock, which may be extremely vital to deal with the expected food shortfalls accompanying the rapid expansion of the world's population. Genetic engineering can also be used to improve the quality of food.[21] Furthermore, the drugs produced by GMOs have been tremendously beneficial to human health because of their high quality, ability to be produced in large quantities and relatively low prices. In addition, adding certain disease genes to animals can provide researchers with non-human models to research the cures for diseases such as hypertension and AIDS.[22]

The risks associated with GMOs can be divided into three categories: environmental, economic and those affecting human health.[23] The environmental arguments against patenting GMOs focus on GMOs' effects on the ecosystem and the reduction of biodiversity.[24] Some commentators argue that the introduction of GMOs "into an ecosystem might affect the dynamics of the ecosystem or the gene pool of wild relatives."[25] For example, crops with herbicide resistance genes may transfer these genes to weeds, thus creating a major threat to the environment.[26] Furthermore, patenting opponents point out that humans often lack the wisdom and foresight as to

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[19] Dan Gallagher, *China Offering Biotech Firms Big Opportunities*, SAN DIEGO DAILY TRANSCRIPT, June 17, 1997, at A1.

[20] Leslie Cataldo, *A Dynasty Weaned from Biotechnology: the Emerging Face of China*, 26 SYRACUSE J. INT'L L. & COM. 151, 164-66 (1998).

[21] Carrie F. Walter, *Intellectual Property Law Review 1999*, 31 INTELL. PROP. L. REV. 195, 219 (1999).

[22] *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. On Courts, Civil Liberties and the Administration of Justice of the House of Representative Comm. On the Judiciary*, 100th Cong. 36-37, 47-49 (1988) (testimony of Thomas E. Wagner, Professor of Molecular Biology and Director, Edison Animal Biotechnology Center, Ohio State University).

[23] Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L & COMP. L. 129, 138 (2000).

[24] Adler, *supra* note 9, at 38-43.

[25] Souza, *supra* note 23, at 139.

[26] Michael A. Whittaker, *Reevaluating the Food and Drug Administration's Stand on Labelling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1220-21 (1998).

the disastrous consequences of interfering with the environment.[27] For instance, humans released the gypsy moth and kudzu vine into the environment and caused extremely serious damages.[28]

The view that GMOs represent an environmental threat is not necessarily the predominant view, however. For example, a report prepared for the National Academy of Sciences concluded that there was "adequate knowledge of the relevant scientific principles, as well as sufficient experience with recombinant DNA engineered organisms, to guide the safe and prudent use of such organisms outside research laboratories."[29] Furthermore, it is relatively easy for scientists to monitor and control the transfer of genes between GMOs and wild organisms by mating.[30]

Opponents of animal and plant patenting also argue that the introduction of GMOs might result in loss of biodiversity if such new varieties dominate.[31] The loss of biodiversity could have disastrous consequences in agriculture because high genetic uniformity means that the agricultural crops and livestock are more susceptible to common diseases or pest infestation.[32] For example, more than ninety-five percent of chicken eggs are from a single breed, White Leghorns, and more than ninety percent of milk is from the breed Holstein.[33] Thus, a lethal disease to either breed could ruin the milk or chicken egg industry.[34]

Patenting advocates respond that there is no causal link between patents and a decrease in biodiversity.[35] As one commentator points out, there already has been a decrease in biodiversity in the livestock industry because of increased corporate consolidation; genetic engineering might reverse this trend by adding foreign genes into crops and creating new varieties.[36]

The main economic argument against the patenting of GMOs is that the initial acquisition prices and subsequent royalties of GMOs will increase costs for both farmers and consumers.[37] However, this view fails to consider the basic principles of economics, as farmers would not acquire or

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[27] Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 411-12 (1988).

[28] *Id.*

[29] Report from Committee on the Introduction of Genetically Engineered Organisms into the Environment to the Council of the National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues* 6 (1987) (on file with author).

[30] Dresser, *supra* note 27, at 414.

[31] *See* Adler, *supra* note 9, at 43.

[32] *Id.* at 44.

[33] Barry Hoffmaster, *The Ethics of Patenting Higher Life Forms*, 4 I. P. J. 1, 14 (1988). (Intellectual Property Journal?)

[34] *Id.*

[35] Adler, *supra* note 9, at 44-46.

[36] *Id.* at 45-46.

[37] Walter, *supra* note 21, at 211.

use GMOs if their economic benefits did not outweigh the costs.

The question of whether GMOs may be safely used as food for humans remains unanswered. As of today, there is no answer because of a lack of scientific data and a lack of uniformity in the safety standards of different countries.[38] However, the bottom line is that there are already many lawful but unsafe foods on the market.[39]

IV. ETHICAL ISSUES OF ANIMAL PATENTING

Opposition to animal patenting is mainly based on ethical grounds. In general, patenting critics express concern about several issues: human arrogance, devaluation of human life, and animal welfare.[40]

Patenting opponents argue that patenting reflects a view of life which is completely human-centered.[41] Animal patents allow the commercialization of animals' lives and reflect the view that all natural resources are for human exploitation and animals are no different from chemical products.[42] However, this argument is not persuasive because for thousands of years humans have treated animals as properties by buying, selling, and using them for humanity's commercial and consumer needs.[43]

Patenting opponents also argue that by creating and patenting genetically engineered animals, humans violate animals' right to exist as separate species.[44] In response, patenting advocates point out that there are no absolute rules to separate species, and humans have already created many genetically altered animals through traditional breeding techniques.[45]

A stronger argument against animal patenting is that patenting animals would eventually lead to the patenting of human life and the creation of human-animal hybrids.[46] One commentator analogizes the problem to a slippery slope by pointing out that humans will inevitably become patentable subject matter if animals are patentable because it is theoretically and empirically impossible to draw a clear distinction between animal and human life.[47] Furthermore, adding human genes to animals may create human-animal hybrids.[48] As they have successfully created a "geep," a hybrid of goat and sheep, scientists may as well create a hybrid of human and

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[38] Souza, *supra* note 23, at 139-40.
[39] *Id.* at 140.
[40] *See* Dresser, *supra* note 27, at 410; Adler, *supra* note 9, at 46-50.
[41] *See* Dresser, *supra* note 27, at 411.
[42] *Id.*
[43] *Id.* at 413.
[44] *See* Adler, *supra* note 9, at 48-49.
[45] *See* Dresser, *supra* note 27, at 413-14.
[46] *See* Hoffmaster, *supra* note 33, at 11; Dresser, *supra* note 27, at 415.
[47] *See* Hoffmaster, *supra* note 33, at 11-12; Dresser, *supra* note 27, at 416.
[48] Dresser, *supra* note 27, at 415-16.

chimpanzee.[49] Patenting opponents argue that this disturbing scenario will not only reduce the value of human life to chemical molecules, but also "violate the cultural taboo against procreation between animals and humans."[50]

In responding to this line of criticism, the proponents of animal patenting argue that currently the quantity of human genes added to animals is too small to create human-animal hybrids.[51] More importantly, they argue that the genuine ethical concern about human-animal hybrids should be addressed in the policies regulating genetic engineering research, not in patent law.[52]

Finally, patenting opponents argue that allowing animal patenting would stimulate transgenic research and result in more animal suffering.[53] However, this line of argument overlooks the beneficial side of genetic manipulation.[54] Transgenic research can produce animals with stronger resistance to diseases.[55] Patenting will also benefit animals because genetic engineering usually results in less unplanned negative results occurring in traditional breeding.[56]

In summary, many of the ethical arguments against animal patenting are not compelling. Furthermore, many of these concerns should be addressed in policies regulating transgenic research, not patent law.

V. INTERNATIONAL INTELLECTUAL PROPERTY PROTECTION FOR GMOS

The patentability of GMOs, especially genetically modified animals, is a highly controversial issue. Most countries either allow plant varieties to be patented, provide an effective *sui generis* system, or some combination of the two. They probably find that the need to provide more food to the geometrically expanding population outweighs potential environmental risks. However, many countries refuse to provide any protection, patent or otherwise, to new animal varieties, despite the fact that the creation of new animal varieties involves very similar techniques to those used to produce new plant varieties.[57] The discrepancy of treatment between these countries is mainly due to varying conceptions about humanity's ethical duties toward animals.

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[49] *Id.*
[50] *Id.* at 416.
[51] *Id.* at 416-17.
[52] *Id.* at 417.
[53] *See id.* at 422-23.
[54] *See* Adler, *supra* note 9, at 37.
[55] *See id.*
[56] *See* Dresser, *supra* note 27, at 423.
[57] BENT ET AL., *supra* note 2, at 24-25.

A. GMOs Patentable in the U.S.

In the landmark decision *Diamond v. Chakrabarty*,[58] the U.S. Supreme Court held that a living microorganism is patentable subject matter under § 101 of the Patent Act.[59] The Court further held that living matter is patentable if it is the result of human intervention.[60] In 1987, the Commissioner of the Patent and Trademark Office ("PTO") announced that animals may be patented.[61] The first animal patent was issued in 1988 to a transgenic non-human mammal, which was genetically engineered to be more susceptible to carcinogens.[62]

Plant varieties are also protected by a variety of Acts. Asexually reproduced plant varieties are patentable under the Plant Patent Act ("PPA").[63] The Patent Variety Protection Act ("PVPA") of 1970 provides patent-like protection to sexually reproduced plants.[64] Additionally, according to *Chakrabarty*, plants may also be patented.

B. Union for the Protection of New Varieties of Plant ("UPOV")

In many civil law countries, plant varieties are not patentable because they lack novelty, invention, utility, or the ability to replicate or reproduce.[65] Instead, these countries established "separate legal regimes for special protection of plant varieties" which later developed into UPOV.[66] UPOV protects biological innovations which do not meet the requirements of patent protection.[67] Thus, both plant and animal varieties fall within the protection zone of UPOV. It should be noted, however, that UPOV protects only the whole plant or animal, not its genes or constituent chemicals.[68]

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[58] 447 U.S. 303 (1980).
[59] 35 U.S.C. § 101 (1952).
[60] Diamond, *supra* note 58, at 309.
[61] 1077 OFFICIAL GAZ. PAT. OFF. 24 (1987).
[62] U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).
[63] 35 U.S.C. §§ 161-164 (1954).
[64] 7 U.S.C. § 2321-2583 (1982).
[65] *See* Geertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 J.L. & TECH. 143, 148 (1999).
[66] Lester Ross & Libin Zhang, *Agricultural Development and Intellectual Property Protection for Plant Varieties: China Joins the UPOV*, 17 UCLA PAC. BASIN L.J. 226, 229 (1999).
[67] *See* Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 122-23 (1996).
[68] *Id.* at 124.

C. Trade Related Aspects of Intellectual Property Rights ("TRIPS")

TRIPS, a division of the World Trade Organization ("WTO"), requires member states to provide intellectual property protection for all biotechnological inventions.[69] Concerning plant varieties, TRIPS requires WTO members to "provide for the protection of plant varieties either by Patents or by an effective *sui generis* system or any combination thereof."[70] Developed countries embrace TRIPS because this universally-accepted system provides much needed protection for their advanced biotechnology industries.[71] In 1990, TRIPS proposed to allow patenting living organisms, which include microorganisms, plants and animals.[72] However, this proposal was opposed by developing countries and did not pass.[73] Since its entry into the WTO in November 2001, China has been bound by TRIPS to provide required intellectual property protection for biotechnological inventions.[74]

VI. INTELLECTUAL PROPERTY PROTECTION FOR GMOS IN CHINA

China has experienced tremendous economic growth since it opened its doors to western countries in 1978. China has also rapidly transformed its intellectual property laws according to western models. In 1984, China passed its first patent law that was compatible with international standards.[75] That law extended fifteen years of patent protection to inventions and five years to utility models and designs after the patent applications were filed.[76] Pharmaceuticals were not patentable subject matter under the 1984 law.[77] The 1993 amendments to the patent law extended protection to chemicals and pharmaceuticals.[78] In addition, patent terms were extended

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[69] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

[70] Agreement on Trade Related Aspects of Intellectual Property Rights [hereinafter TRIPS agreement], Art. 27.3(b).

[71] *See* David G. Scalise & Daniel Nugent, Comment, *International Intellectual Property Protection for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 114-115 (1995).

[72] *Id.*

[73] Cataldo, *supra* note 20, at 158.

[74] *See* Thomas T. Moga, *China Changes Patent Law to Comply with TRIPS*, NAT'L L.J., July 23, 2001, at C15.

[75] *See* Jill Chiang Fung, Note, *Can Mickey Mouse Prevail in the Court of the Monkey King? Enforcing Foreign Intellectual Property Rights in the People's Republic of China*, 18 LOY. L.A. INT'L & COMP. L. REV. 613, 627 (1996).

[76] *See* David B. Dreyfus, Note, *Confucianism and Compact Discs: Alternative Dispute Resolution and its Role in the Protection of United States Intellectual Property Rights in China*, 13 OHIO ST. J. ON DISP. RESOL. 947, 952 (1998).

[77] *Id.*

[78] *See* Fung, *supra* note 75, at 632.

under the 1992 amendment.[79] Inventions are entitled to a twenty-year protection while utility models and designs are protected for ten years. Thus, the amended Patent Law of 1993 was in greater conformity with international standards.

Despite this greater conformity, however, plant and animal varieties are not patentable, although China permits the patenting of microbiological processes and their derivative products.[80] The reasons to deny patent protection for plant and animal varieties are not clear.[81]

VII. PLANT VARIETY RIGHTS

With an enormous and ever expanding population, China has realized that the focus of agricultural science and technology is on developing, through genetic engineering, new animal and plant varieties with higher quality and productivity.[82] However, the lack of a patent or *sui generis* protection system deprives breeders of the incentive to expend resources on research and development of new plant or animal varieties. As a result, the technical level of China's agricultural and life sciences lags behind that of developed countries and the gap is still widening.[83]

In 1997, China passed the Regulations on the Protection of New Varieties of Plants (the "Plant Variety Regulations") with the objective of promoting the development of agriculture and forestry.[84] To qualify for Variety Rights, the plant varieties must be (1) novel, (2) distinctive from all other varieties prior to application, (3) stable with regard to their relevant properties after reproduction, (4) properly named, and (5) belonging to a plant species included in the State plant varieties catalogue.[85]

Once awarded Variety Rights, the breeder enjoys an exclusive right to the plant variety. Specifically, "no unit or individual may for commercial purposes (i) produce or sell any breeding material for which Variety Rights have been awarded or (ii) make repeated use of such breeding material to create new varieties."[86] A Variety Rights holder can subject infringers to

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[79] *See* Patent Law of the People's Republic of China, art. 45 (1993) (P.R.C.) [hereinafter China Patent Law].

[80] *See* Davis Hill & Judith Evans, *Chinese Patent Law: Recent Changes Align China More Closely With Modern International Practice*, 27 GEO. WASH. J. INT'L L. & ECON. 359, 364 (1993-1994).

[81] *See* China Patent Law, art. 25 (1993) (P.R.C.).

[82] Ross & Zhang, *supra* note 66, at 230-31.

[83] *See* Bosselmann, *supra* note 67, at 121-22.

[84] *See* the Regulations of People's Republic of China on the Protection of New Varieties of Plants [hereinafter Plant Variety Regulations], art. 1 (1997), *available at* http://www.cnpvp.net/old-www/rules_and_regulations.htm.

[85] *See* Plant Variety Regulations, art. 13-17.

[86] Ross & Zhang, *supra* note 66, at 232-33.

both civil litigation and administrative mediation.[87]

Variety Rights provide narrower protection for plant varieties than patents.[88] For instance, anyone can use a plant variety under the protection of Variety Rights for breeding or other scientific research activities without compensating the Variety Rights holder.[89] Farmers can also freely utilize the "breeding material for their own use."[90] Furthermore, once awarded the Rights, most plant varieties are protected for only 15 years compared to the 20-year term under the Patent Law.[91] In China, both the Patent Law and the Plant Variety Regulations have a compulsory licensing provision.[92] Under this provision, the approving authority can compel an awardee to license his patent or new plant variety even at below-market prices or to his competitors.[93] This provision is rather problematic because it fails to clearly state restrictions on the exercise of compulsory licensing.[94]

Despite any shortcomings, the Plant Variety Regulations comply with the TRIPS agreement, which requires WTO member nations to provide at least one effective protection system for plant varieties.[95] Although it is not very clear as to why China chose the Plant Variety protection over patent protection, most developing countries oppose the idea of patenting living organisms because they cannot afford the expensive licensing fees of GMOs and also because much of the starting genetic material used for GMOs is native to their lands.[96]

VIII. RESOLUTION OF PATENT DISPUTES

China developed a two-track system to enforce intellectual property rights. The first track is the administrative resolution where the infringed party files a complaint with local administrative offices that are responsible for patent-related affairs.[97] Once a complaint is filed, the administrative authorities first mediate the disputing parties to a reconciliation or settlement. If mediation fails, the patent administrative authorities have the power to order either monetary compensation or an injunction against the infringer.[98]

Administrative resolution remains the dominant method for patent-

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[87] *See* Plant Variety Regulations, *supra* note 84, at art. 39.
[88] Ross & Zhang, *supra* note 66, at 233.
[89] *Id.*
[90] *Id.*
[91] *See* Plant Variety Regulations, *supra* note 84 at art. 34.
[92] *See id.* at art. 11. *See also* China Patent Law, supra note 79, at art. 57-58 (1993).
[93] Ross & Zhang, *supra* note 66, at 233.
[94] *Id.* at 233-34.
[95] *Id.* at 230.
[96] *See* Cataldo, *supra* note 20, at 155.
[97] *See* Moga, *supra* note 74, at C16. These offices are also called Patent Administrative Authorities. *See* Hill & Evans, *supra* note 80, at 372.
[98] *See* Hill & Evans, *supra* note 80, at 373.

related disputes in China for various reasons. The Chinese have a tradition of preferring conciliation between adversarial parties over litigation because of their long-held concept of "amity above all."[99] The administrative approach is also fast and efficient—a dispute can be resolved within days after the complaint is filed.[100] Part of the reason for the efficiency is that the local authorities are closely connected to other local agencies, whose cooperation is instrumental to the enforcement.[101] Furthermore, the administrative approach is an inexpensive alternative to litigation because of its relatively low costs.[102]

The administrative approach cannot replace the judicial approach, however. Importantly, it lacks the deterrent feature of the judicial approach because the Patent Administrative Authorities cannot impose criminal penalties on the infringers. In addition, the administrative approach often results in limited temporary relief because the victim of a government raid is usually not the source of the infringing products, but the distributor.[103]

On the other hand, the second track, the judicial approach, offers lasting and deterrent remedies, including compensatory damages, punitive damages, or criminal punishment.[104] However, the judicial approach is not the preferred method of patent disputes. The process is slow and many judges are not adequately trained with regard to patent-related issues.[105] In addition, the financial burden on the aggrieved party can be substantial because the complaint filing fees are proportional to the requested amounts of damages.[106]

IX. THE EFFECTS OF THE 2001 AMENDMENTS TO CHINA'S PATENT LAW

The 2001 amendments brought China's Patent Law more in line with the TRIPS agreement.[107] Specifically, there are four major changes worth noting. First, the pre-2001 Patent Law allowed compulsory licensing of patents under a broad provision,[108] which was inconsistent with Article 31 of the TRIPS agreement.[109] The 2001 amendments define the subject mat-

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[99] *Id.* at 392.
[100] *See* Moga, *supra* note 74, at C16.
[101] *See* Hill & Evans, *supra* note 80, at 392.
[102] *Id.* at 376.
[103] *See* Moga, *supra* note 74, at C17.
[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] *Id.* at C15.
[108] *See* China Patent Law, *supra* note 79, at art. 53 (1993) (permitting compulsory licensing to a patent when the exploitation of a later and more advanced patent depends on the exploitation the earlier patent).
[109] TRIPS agreement, *supra* note 70, at art. 31 (permitting compulsory licensing only under reasonably well-defined circumstances).

ter and relative value of a patent that could be subject to compulsory licensing.[110] Furthermore, the time, scope, and duration of compulsory licenses have also been amended to be consistent with the TRIPS agreement.[111]

Second, the 2001 Patent Law provides a patentee with the exclusive right of sale.[112] Although the TRIPS agreement requires WTO member nations to award patent holders the right to "exclude others from offering for sale the patented products or products directly obtained by patented processes," China's former Patent Law did not have such a provision.[113] The 2001 amendment to Article 11 of the Patent Law erased the inconsistency.[114]

Third, the amended Patent Law shifts the burden of proof to the alleged patent infringer in infringement cases. Article 57 of the new Patent Law states that "[f]or any dispute as to infringement regarding the patent for invention which relates to a process for the manufacture of a new product, the entity or individual that produces the same products has responsibility to provide evidence demonstrating that its process is different from the patented process."[115] This change makes China's Patent Law compliant with the TRIPS agreement.[116]

The last major change to the Patent Law is the allowance of injunctive relief as a critical mechanism of patent enforcement.[117] This amendment is also consistent with Article 44(1) of the TRIPS agreement.[118]

The 2001 amendments notwithstanding, challenges for the inventors still remain. Under the new Patent Law, animals and plants are still not patentable subjects.[119] Although plant varieties enjoy protection under the Plant Variety Regulations, animal varieties are not protected by any law. Furthermore, the provisions regarding compulsory licensing in both the Patent Law and the Plant Variety Regulations are too broad and thus not in compliance with the TRIPS agreement. For example, the Patent Law does not clearly define the restrictions on the exercise of compulsory licensing power.[120] The Patent Law also fails to state that a patent holder shall be paid "adequate remuneration in the circumstances" as required by Article 31(h) of the TRIPS agreement.[121]

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[110] Moga, *supra* note 74, at C15.
[111] *See id.* at C16. *See also* China Patent Law, *supra* note 79, at art. 52 (2001).
[112] *See* Moga, *supra* note 74, at C15.
[113] *Id. See also* TRIPS agreement, *supra* note 70, at art. 28.
[114] *See also* China Patent Law, *supra* note 79, at art. 11 (2001).
[115] *See* China Patent Law, *supra* note 79, at art. 57 (2001).
[116] *See* TRIPS agreement, *supra* note 70, at art. 34(1).
[117] *See* China Patent Law, art. *supra* note 79, at 61 (2001).
[118] *See* TRIPS agreement, *supra* note 70, at art. 44(1).
[119] *See* China Patent Law, *supra* note 79, at art. 25 (2001).
[120] *See* Moga, *supra* note 74, at C16.
[121] TRIPS agreement, *supra* note 70,at art. 31(h).

Because the 2001 Patent Law remains silent about the patentability of animal varieties, the next section will mainly discuss whether new animal varieties should enjoy intellectual property protection in China.

X. SHOULD NEW ANIMAL VARIETIES BE PROTECTED IN CHINA?

China's ever growing population and increasing demand for food might require the country to provide intellectual property protection for new animal varieties. Such protection of animal varieties may encourage both domestic and foreign investment in biotechnology research and development in China. Furthermore, protection would promote the transfer of biotechnologies to China. However, due to economic concerns, animal patents might be unwise. A *sui generis* protection system such as the Plant Varieties Regulations might be more appropriate.

XI. INTELLECTUAL PROPERTY PROTECTION FOR ANIMAL VARIETIES IMPORTANT TO CHINA

Patent protection grants an inventor exclusive rights to make, use, and sell the patented invention.[122] The promise of protection induces inventors to spend resources on research and development, thus advancing technology by stimulating innovation.[123] This is especially true for the biotechnology industry because the costs of developing new drugs or GMOs can be intimidating.[124] The absence of intellectual property protection for new animal varieties, including genetically modified animals, can harm animal research. For example, the biomedicine and biotechnology industries would have no incentive to develop and commercialize the genetically modified animals used to produce important drugs to cure human diseases.[125] Farmers may also suffer economic losses where intellectual property protection does not exist because there would be fewer transgenic livestock animals with higher productivity or improved resistance to diseases.[126] Intellectual property protection for new animal varieties is particularly important to China because of its growing need for food.

XII. CHINA'S POPULATION EXPANSION NECESSITATES MORE FOOD ANIMALS

Animals provide the major source of protein for human beings. [127] The

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[122] *See* Adler, *supra* note 9, at 12.
[123] *Id.*
[124] *See* VAN DE GRAAF, *supra* note 6, at 38.
[125] *See* Adler, *supra* note 9, at 7-8.
[126] *Id.* at 8.
[127] *Id.* at 33 (although the data about the composition of the Chinese diet are not available, in the United States, "food animals provide seventy percent of the protein, thirty-five

world's population is expanding geometrically; therefore, the demand for food animals is also increasing rapidly.[128] The problem of inadequate food supplies becomes more pressing as the use of land has reached saturation level.

With 1.25 billion people, China is the most populated country in the world.[129] Although China is currently able to feed its population, the traditional agricultural crops and livestock will probably not be able to meet the increasing demand of food coupled with its expanding population. The most viable solution to this problem is the development and adoption of more productive and nutritious crops and livestock.[130] Modern genetic engineering technologies can create transgenic livestock that grow faster, consume less food, and are leaner and more nutritious than traditional breeds.[131] Furthermore, transgenic cattle produce more milk per animal while consuming less food.[132]

Without intellectual property protection of genetically modified animals, however, the biotechnology industry in China would have little incentive to invest in the research and development of more productive livestock. Furthermore, without protection, foreign biotechnology companies have little incentive to introduce their new animal varieties into China. Therefore, transgenic animals should be protected in China to stimulate agricultural innovation and promote cross-border technology transfers, which will in turn help solve the anticipated food shortfall.

XIII. INTELLECTUAL PROPERTY PROTECTION FOR GENETICALLY MODIFIED ANIMALS WILL ACCELERATE THE DEVELOPMENT OF CHINA'S BIOMEDICINE AND PHARMACEUTICAL INDUSTRIES

The advent of DNA recombinant technologies and genetically modified animals promises major breakthroughs for the biomedicine and pharmaceutical industries. Many human genes have been transferred into laboratory animals to study their regulations and functions. For example, the cellular receptor for the AIDS virus only exists in humans and chimpanzees.[133] While experiments on chimpanzees are extremely expensive, introducing the receptor gene into mice can produce an inexpensive animal

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percent of the energy, eighty percent of the calcium, sixty percent of the phosphorus, and significant proportion of vitamins and minerals consumed").

[128] *Id.*

[129] *See* Taylor, *supra* note 1.

[130] OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, PUB. NO. OTA-F-285, TECHNOLOGY, PUBLIC POLICY, AND YHE CHANGING STRUCTURE OF AMERICAN AGRICULTURE 3 (1986).

[131] *See* Adler, *supra* note 9, at 5.

[132] *Id.*

[133] *Id.* at 21-22.

model to study AIDS and to screen AIDS drugs.[134] Research on transgenic animals bearing human genes can greatly enhance our ability to understand human and animal physiology, including the immune system, genetic deficiencies, embryonic development, and viral diseases.[135]

Transgenic animals may also function as molecular farms to produce drugs to cure or alleviate human diseases. For example, transgenic sheep were created to produce human blood clotting factors used for the treatment of hemophiliacs.[136] Transgenic mice were also created to produce tissue plasminogen activator ("TPA") used to treat heart attacks.[137] Compared to the chemical synthesis approach, the "molecular farming" approach is much more accurate and cost-efficient.

Intellectual property protection is the decisive reason why pharmaceutical companies invest in research and development.[138] Because of the high commercial stakes involved, pharmaceutical companies need to protect their products against imitations after they introduce the products into the market. Given the fact that the costs of GMO development are extremely high and many biotechnological innovations are made by small start-up companies, intellectual property protection is necessary to allow small companies to recover their expenses.[139]

China has invested heavily on genetic and protein engineering during the last decade in order to raise its biotechnology industry level to that of the developed countries.[140] For example, China's State Science and Technology Commission established the "Torch Program" to promote the commercialization, industrialization, and globalization of China's new technologies.[141] The biotechnology part of this program focuses on the research and development of biopharmaceutical products, such as hepatitis B vaccines and anti-tumor drugs.[142] The Chinese Academy of Sciences has also sponsored many biomedical projects, including the development of interleukin-2, interferon alpha, and hepatitis B vaccines.[143]

Although the majority of China's biomedical research is funded by the government, China plans to significantly decrease governmental funding and eventually make private firms, both foreign and domestic, finance the

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[134] *Id.*
[135] Camper, *Research Application of Transgenic Mice*, 5 BIOTECHNIQUES 638 (1987).
[136] Adler, *supra* note 9, at 5.
[137] *Id.*
[138] *See* VAN DE graff, *supra* note 6, at 37.
[139] *Id.* at 38.
[140] *See Development of Biomedicine in China, supra* note 17.
[141] *See* Beckman, *supra* note 18.
[142] *Id.*
[143] *See Development of Biomedicine in China, supra* note 17.

research and development of biomedical products.[144] However, without proper intellectual property protection for new animal varieties, private firms have little incentive to risk the intimidating costs of research and development. As a result, not only will China's agriculture suffer the absence of more productive, nutritious, and disease resistant livestock, but also the Chinese people will be deprived of the access to the high-quality and inexpensive drugs produced by transgenic animals. The lack of intellectual property protection for new animal varieties will directly defeat China's goal of developing a competitive biotechnology industry.

XIV. TRADE SECRET LAW NOT A SUFFICIENT PROTECTION FOR GENETICALLY MODIFIED ANIMALS

In the absence of appropriate intellectual property protection for genetically modified animals, inventors will have to resort to trade secret law to safeguard their investment on research and development. Even if trade secret law can provide sufficient protection for genetically modified animals, it will deprive society of cutting-edge biotechnological information and cause people to waste resources in penetrating commercial secrecy.[145]

The more troubling problem, however, is that trade secret law is not a sufficient protection for genetically modified animals because of the nature of genetic engineering techniques. Trade secret law requires some degree of secrecy and also requires the inventors undertake spend reasonable efforts to protect the secrecy. However, some of the unique attributes of genetically modified animals make them very difficult to protect.[146] For example, a misappropriator can easily recreate a transgenic animal by stealing the DNA sequence written in a piece of paper.[147] Advances in genetic engineering techniques make gene transformation a routine practice in an adequately equipped laboratory. Therefore, once a competitor misappropriates a genetic code, he can easily recreate the transgenic animal.

In addition, once a misappropriator obtains a genetically engineered animal, he can regenerate many offspring without even understanding the genetic information embodied in the animal. The self-generating nature of organisms is the exact attribute that makes transgenic animals highly desirable, but it also inevitably makes the protection of animal variety property difficult.[148]

Trade secret laws in the United States and some other countries also require a trade secret to have "an established commercial value at the time

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[144] *See* Beckman, *supra* note 18.
[145] R. POSNER, ECONOMIC ANALYSIS OF LAW 2d 53 (1977).
[146] *See* BENT ET AL., *supra* note 2, at 346.
[147] *Id.*
[148] *Id.* at 346-47.

of theft."[149] This requirement poses another problem for the protection of genetically modified animals, because many biotechnological inventions do not have established commercial values if they are still in the basic research stage.[150] Although they contain substantial research information and are on the verge of being developed into commercial products,[151] some countries have denied such genetically modified animals trade secret protection.[152]

Thus, trade secret law cannot provide sufficient protection for genetically modified animals because of their unique attributes. A more exclusive protection system is needed to safeguard the high costs biotechnology companies spend on the research and development of transgenic animals.

XV. INTELLECTUAL PROPERTY PROTECTION FOR GENETICALLY ENGINEERED ANIMALS PROVIDED IN MANY COUNTRIES

Many developed countries have provided patent protection for living organisms, including genetically modified animals. In 1969, Hungary enacted a law to extend patent protection to animals if they met the requirements of "distinguishable, novel, homogenous and stable."[153] Germany in 1969 decided that animals were patentable if their production is repeatable.[154] Higher life forms, including animals, are also patentable in Australia.[155]

In the landmark *Chakrabarty* decision,[156] the U.S. Supreme Court concluded that Section 101 of the Patent Act should be broadly construed and patentable subject matter includes "anything under the sun that is made by man."[157] Following the *Chakrabarty* decision, PTO issued the first animal patent to a genetically engineered mammal in 1988.[158] In 1982, Canada also followed the *Chakrabarty* decision and treated living organisms as patentable subject matter.[159] Due to the high economic stakes involved with genetically modified animals in biomedicine and biotechnology industries, many more countries are expected to join the trend to include animals in patentable subject matter.

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[149] *Id.* at 348.
[150] *Id.*
[151] *Id.*
[152] *Id.* at 355.
[153] Hungarian Patent Law, art. 71 (1969).
[154] *See* Adler, *supra* note 9, at 30.
[155] *Id.* at 31.
[156] 447 U.S. 303 (1980).
[157] *Id.* at 309, (*citing* S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952)).
[158] U.S. Patent No. 4,736,866 (issued Apr. 12, 1988) (patent issued to a transgenic non-human mammal which was genetically engineered to be more susceptible to carcinogens).
[159] *See* Adler, *supra* note 9, at 30-31.

XVI. CHINA SHOULD PROVIDE *SUI GENERIS* SYSTEM PROTECTION FOR GENETICALLY MODIFIED ANIMALS

Although intellectual property protection for genetically modified animals is important to China's agriculture and biotechnology industries, China should not adopt patent protection because of economic reasons. Due to historical reasons, the technical level of China's life sciences research lags behind that of developed countries and China's intellectual protection system is geared more towards the importation of advanced technologies. As a developing country, China prefers to receive free transfer of cutting-edge biotechnologies.[160] Without the benefit of receiving free technology transfer, China cannot afford the rights to use costly biotechnology products.[161] This is particularly true for the biotechnological inventions concerning agricultural livestock. Genetically engineered livestock can be more productive, nutritious, and disease resistant. However, Chinese farmers may be deprived of the benefits of these improved livestock because of the costly acquisition and royalty fees.

A *sui generis* protection system such as the Plant Variety Regulations may serve China better. An animal variety protection system, similar to the Plant Variety Regulations, would award an animal breeder exclusive rights to his new animal variety. Under such a system, other units or individuals cannot for commercial purposes produce or sell the protected variety, or use it to create new varieties. In this way, a *sui generis* protection system may adequately protect the intellectual property rights of biotechnology firms and safeguard their investment on the research and development of transgenic animals.

A *sui generis* protection system, however, should impose some limitations on the animal variety rights. Like the Plant Variety Regulations, it should allow farmers to utilize genetically engineered livestock for their own use without compensating the animal variety rights holder. Furthermore, it should allow others to freely use the protected variety for breeding or other scientific research activities. In this way, a *sui generis* protection system would alleviate China's financial burden to pay for the rights of new biotechnological inventions.

XVII. CONCLUSION

China should extend intellectual property protection for genetically modified animals for a variety of reasons. The increasing demand for food animals can only be met by the development and adoption of genetically improved agricultural livestock that are more productive, nutritious, and

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[160] Cataldo, *supra* note 20, at 155.
[161] *Id.*

disease resistant. Intellectual property protection for new animal varieties can also protect the investment of biotechnological companies and accelerate the development of China's biomedicine and pharmaceutical industries. Furthermore, trade secret law cannot provide sufficient protection for GMOs due to their unique attributes. In addition, many countries have realized the importance of extending intellectual property protection for new animal varieties and have enacted laws to do so.

However, a patent protection system is not economically feasible for China. Because the initial acquisition prices and subsequent royalty fees can be very costly, China may not be able to afford the rights to many biotechnological inventions. In particular, Chinese farmers may be deprived of the benefits of genetically improved agricultural livestock. Instead, a narrower *sui generis* protection system similar to the Plant Variety Regulations would be more appropriate.