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Agricultural Biotechnology and Genetically-Modified Foods: Will the Developing World Bite?

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I. Introduction

1. Agriculture is closely related to the rise of civilization itself. Indeed, it was only through the cultivation of crops that people were able to stay in one place long

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enough to establish more sophisticated social institutions. And this correlation seems to have continued into the modern day – those cultures with the most advanced agricultural practices also have the most sophisticated economies and societies, creating the most opportunities and highest standard of living for their citizens. It would seem to be in the best interests of developing countries, then, to adopt modern agricultural practices. Yet, there appears to be significant resistance to implementing the inventions made possible by agricultural biotechnology on the part of many in the developing world. This paper will explore recent advances in agricultural biotechnology, and address the reluctance of developing countries to embrace such technology.

II. Agriculture and the Techniques Used to Improve Crops

2. Agriculture, or the deliberate planting and cultivation of plants intended for food, began sometime around 9500 B.C.[1] For thousands of years, agricultural development focused on selective breeding.[2] In the hope of producing crops that were stronger, healthier, and higher yielding, farmers would choose for replanting ("selectively breed") seeds from plants that had the most desirable characteristics.[3] This straight-forward method of improving crop varieties continued for innumerable generations, without much modification. The seeds of change were planted in 1865, however, when the genetic basis of heredity was discovered by Gregor Mendel, an Austrian monk who conducted experiments with pea plants in his garden. [4] This pioneering work lay somewhat dormant until approximately 1900 when scientists began to apply the principles discovered by Mendel and to create some of the first hybrid crops.[5] This should be seen as the first major step beyond selective breeding in agricultural technology.

3. "Hybridization" occurs when there is a cross between two "inbred" lines.[6] An inbred plant is produced by repeated inbreeding through self-pollination of a single plant line so that a genetically-uniform, or homozygous, plant is developed.[7] When two inbred lines are crossed, the resulting hybrid plants have a blend of the parental traits and genetic material, making them more vigorous in

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[1] *See* Sara B. Blanchard, Comment, *The Muddled Law of Biotechnology: Frustrating Agricultural and Biomedical Progress*, 5 SAN JOAQUIN AGRIC. L. REV. 179, 179 (1995). Humans rely on approximately 5000 plant species for food, yet "fewer than twenty plant species are responsible for ninety percent of the world's food supply." David S. Tilford, *Saving the Blueprints: The International Legal Regime for Plant Resources*, 30 CASE W. RES. J. INT'L L. 373, 381 (1998).
[2] *See* Debra L. Blair, Note, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry,* 4 DRAKE J. AGRIC. L. 297 (1999) (noting that selective breeding, in its most rudimentary form, is the art of saving seeds of the best plants for next year's crop, and that this early form of man-made selection has likely been around for as long as humans have cultivated crops).
[3] Lara E. Ewens, Note, *Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*, 23 B.C. INT'L & COMP. L. REV. 285, 286 (2000).
[4] J.C. Forbes & R.D. Watson, PLANTS IN AGRICULTURE, 68-69, 78 (1992).
[5] *Id.*
[6] Elisa Rives, Comment, *Mother Nature and the Courts: Are Sexually Reproducing Plants and Their Progeny Patentable Under the Utility Patent Act of 1952?*, 32 CUMB. L. REV. 187, 192 (2002).
[7] *Id.* at 191.

the first generation.[8] This vigor, however, gradually drops off in subsequent generations, a phenomenon known as "hybrid vigor."[9] Early hybridization efforts soon advanced from the simple single-cross of two varieties of a particular crop to the art of crossing highly in-bred lines.[10] By the 1920s, American farmers were using hybridization[11] on a large scale.[12] In fact, American farmers eagerly accepted and planted the new hybrid crops, particularly corn, and by 1943 ninety percent of the corn planted in the United States was hybrid seed corn.[13]

4. Farmers depended on hybridization techniques to develop new crop varieties until approximately 1980, when plant scientists began to engage in a more specific form of crop development, relying on techniques made possible through the new science of biotechnology.[14] These new techniques depend, in large part, on the isolation and manipulation of particular genetic traits.[15] This is possible because scientists have learned to manipulate genetic information at the molecular level, working directly with genes as they are found in deoxyribonucleic acid, or DNA.[16]

5. Genetic information is stored in DNA in the form of sequences of four chemical bases (adenine, cytosine, guanine, and thymine).[17] Genes are discrete sequences comprised of combinations of these bases, and particular genetic traits are determined by the exact sequence.[18] Each gene "codes for" a particular protein.[19] These proteins generally serve either as enzymes to catalyze various biochemical reactions, or as structural or storage units for the cell itself.[20] A gene sequence, coding for a particular protein, can be cut from one strand of DNA and inserted into another strand of DNA, thus transferring the genetic trait from one organism to another, including transferring a trait from one species to another species.[21] Obviously, biotechnology has revolutionized the art of plant breeding.[22]

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[8] *Id.* at 192.
[9] *Id.*
[10] Blair, *supra* note 2, at 303. Inbred lines are lines of germplasm that are so nearly homozygous, or genetically stable, that when the plant self-fertilizes it will produce virtual clones of the parent plant.
[11] Blair, *supra* note 2, at 298.
[12] Blanchard, *supra* note 1.
[13] See A.R. Hallauer et al., *Corn Breeding,* American Socity of Agronomy Publication No. 18, Corn and Corn Improvement 463, 464 (3d ed. 1988).
[14] Ewens, *supra* note 3, at 286.
[15] Colorado State University Department of Soil and Crop Sciences, Transgenic Crops: How Do You Make A Transgenic Plant?, *at* http://www.colostate.edu/programs/lifesciences/TransgenicCrops/how.html (last visited Aug. 25, 2003) [hereinafter Transgenic Plant].
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *See* Jeremy P. Oczek, Note, *In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seed*, 41 B.C. L. REV. 627, 633 (2000).

6. Scientists are now able to insert foreign genes, which have the effect of introducing new traits, into existing crop species.[23] This process produces "transgenic plants" which can be engineered, for example, to be resistant to insect infestation, resistant to drought or frost damage, able to withstand herbicide application (to control undesirable weeds growing in the same field), and to generally provide for a higher yield in production.[24] So far, the two largest applications of agricultural biotechnology relate either to engineering crops[25] to better withstand herbicides or to having such crops produce their own pesticide.[26] And the most important transgenic crop at this point is soybean, followed by corn, cotton, and canola.[27] As of the year 2000, approximately half of the acreage planted with soybeans in the United States involved transgenic seeds, and twenty-five percent of the corn crop that year was transgenic.[28] The United States has by far more acres of transgenic crops than any other nation.[29]

7. While it appears that agricultural biotechnology is taking hold in the United States, this new technology is not without its opponents. A detailed analysis of the criticism will be discussed below.

III. Agriculture in the United States, the Rise of the Modern Seed Industry, and the Emergence of Transgenic Crops

8. American agriculture is traceable to the earliest settlers at Jamestown who tried to cultivate, without much success, seeds that they brought with them from Europe.[30] With the assistance of indigenous people who provided seeds of species native to North America such as maize, the colonists quickly adapted their agricultural techniques to the New World and were able to grow enough food to sustain themselves.[31] Later colonials, such as George Washington and Thomas Jefferson, formed or otherwise participated in "agricultural societies" whose purpose was to import seed from abroad and distribute to plantation owners.[32] By the early 1800s,

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[23] *See* NEIL A. CAMPBELL, BIOLOGY 411 (4th ed. 1996).
[24] Oczek, *supra* note 22, at 636.
[25] Agricultural biotechnology has been applied primarily, but not exclusively, to potatoes, corn, soybean and cotton.
[26] Ewens, *supra* note 3, at 294 (citing Michael Pollan, *Playing God in the Garden*, N.Y. TIMES, Oct. 25, 1998, § 6 (Magazine), at 44). An interesting example of bioengineering is the process whereby the gene from a deep-sea dwelling flounder that is especially adapted to cold water is transplanted into the genetic code of a strawberry plant, thus making it more resistant to frost damage. *Id.*
[27] Colorado State University Department of Soil and Crop Sciences, Transgenic Crops: Transgenic Crops Currently on the Market, http://www.colostate.edu/programs/lifesciences/TransgenicCrops/current.html (last visited Aug. 25, 2003).
[28] *Id.*
[29] *Id.* In fact, just three countries (the United States, Canada and Argentina), accounted for ninety-six percent of the total acreage planted with transgenic crops in 2001. *See* ETC Group, Ag Biotech Countdown: Vital Statistics and GM Crops (June 2002), *at* http://www.etcgroup.org/documents/biotech_countdown_2002.pdf (last visited Aug. 25, 2003). "GM" refers to "genetically-modified."
[30] Blair, *supra* note 2, at 299.
[31] *Id.* at 299.
[32] *Id.* at 300.

this effort to import seed for use in North America had become institutionalized to the point where American diplomats and naval officers were systematically acquiring seed from their postings and travelings abroad, helping to establish a seed bank, or germplasm,[33] for use by American farmers.[34]

9. By the mid 1840s, the United States government, working through the Patent Office, was engaged in the wide-scale distribution of plants and seeds to American farmers.[35] These farmers engaged in a fairly massive campaign to improve the land races[36] (sometimes known as "crop varieties") by screening out poorly performing seed lines and saving for future plantings those that showed more vigor and promise.[37] This effort was given a substantial boost in 1862 when Congress formed the Department of Agriculture (USDA), whose charter was to "… procure, propagate, and distribute among the people new and valuable seeds and plants."[38] The USDA took to its duties with verve and vigor, distributing over 1.1 billion packets of free seed to American farmers by the end of the 19th century.[39]

10. One of the unintended consequences of the availability of free seed was that there was not much of a market for those desiring to sell seed.[40] The availability of free seed thus inhibited not only the formation of a private seed market, but also worked as a disincentive to investment for research and development of new crop varieties.[41] Recognizing that the distribution of free seeds had become unnecessary and that it was actually stifling the development of a private seed industry, the U.S. government eliminated the free seed distribution program in 1924.[42]

11. Contemporaneous with the elimination of the free seed distribution program was the birth of the private seed industry in the United States. Much of the effort to develop and sell hybridized corn seeds, for example, was driven by an Iowa farmer named Henry Wallace who, in 1926, founded the Hi-Bred Corn Co.[43] This was the beginning of the modern seed industry, and Wallace's company, which

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[33] "Germplasm" refers to the genetic stock of a plant, the material that can be used to propagate a particular species. JOHN M. POEHLMAN, BREEDING FIELD CROPS 171-72 (3d ed. 1987).
[34] Blair, *supra* note 2, at 300.
[35] *Id.* (noting that by 1855 over one million packages of germplasm had been distributed by the U.S. government to American farmers).
[36] A "land race" is the result of selective breeding whereby only the seeds of plants with the most desirable characteristics are replanted, generation after generation, until a new "breed" emerges, distinguishable from other breeds and typically characteristic of a particular geographic region. FORBES & WATSON, *supra* note 4. Traditional land races are gradually being replaced by high-yielding but genetically narrow elite cultivars.
[37] Blair, *supra* note 2, at 300.
[38] See JACK R. KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY, 1492-2000, at 59 (1988).
[39] *Id.* at 64.
[40] *Id.* at 65.
[41] Blair, *supra* note 2, at 302.
[42] *Id.* at 303.
[43] *Id.* at 298.

later became known as Pioneer Hi-Bred International, Inc., is now the largest seed company in the world.[44]

12. In approximately 1980, the seed industry began to be transformed by the advent of biotechnology, which is dependent on capital-intensive research and development. This coincides with the 1980 Supreme Court case, *Chakrabarty*, which explicitly recognized the statutory right to "patent life."[45] Having the ability to protect biotechnology inventions through intellectual property law spawned many start-up biotech companies, whose seed capital depended upon their ability to develop patent portfolios and thereby attract investors. Genetically-engineered seeds were not approved for use until 1994, but by 1998 more than 45 million acres of U.S. farmland had been planted with such crops.[46] The agricultural biotech industry, expected to generate more than $5 billion in revenue in the year 2002, will reach annual sales of $20 billion by the year 2010.[47] To produce these results, obviously, substantial investment in research and development is necessary, which can only be undertaken if there is the opportunity to gain a return on the investment.[48] In other words, intellectual property law accounts for the rise of the biotechnology industry.

13. Because of how capital-intensive the agricultural biotechnology industry has become, few companies are able to compete – there are currently only five major companies in the industry.[49] And as patented biotechnology inventions gain more and more influence in the industry, many small family-run seed companies and co-ops are losing market share or simply being forced out of business.[50] They are unable to compete with the largest seed companies, which typically have quite sophisticated business strategies, positioning themselves to take more and more market share in the future.[51] In fact, a clear trend has emerged whereby the most successful seed companies share the following characteristics: (1) a robust research and development program, (2) aggressive and effective marketing, (3) comprehensive intellectual property protection, and (4) the willingness to enforce their intellectual property rights.[52] Traditional seed companies and co-ops just do not have the ability or desire to match that kind of effort and focus.

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[44] *Id.*
[45] Diamond v. Chakrabarty, 447 U.S. 303, 311-12 (1980) (clarifying that utility patent protection is available for living organisms, provided that they have been modified from their natural state).
[46] Ewens, *supra* note 3, at 294 (citing Pollan, *supra* note 26).
[47] Bruce Rubenstein, *Growing Agro-Biotech Business Fuels Patent Battles, Dominance of a New Industry at Stake*, CORP. LEGAL TIMES, Feb. 1999, at 29; ETC Group, Seed Industry Consolidation: Who owns Whom? (July 30, 1998), *available at* http://www.etcgroup.org/article.asp?newsid=186 (last visited Aug. 25, 2003).
[48] Rives, *supra* note 6, at 194.
[49] The five major agricultural biotechnology companies are Monsanto, Dupont, Syngenta, Bayer, and Dow. ETC Group, Ag Biotech Countdown: Vital Statistics and GM Crops, *supra* note 29. Of these companies just one, Monsanto, accounted for ninety-one percent of the total world area devoted to commercial GM crops in 2001. *Id.*
[50] Blair, *supra* note 2, at 320.
[51] *Id.* at 326.
[52] *Id.* at 330.

IV. Intellectual Property Protections for Agricultural Inventions

14. Plants which reproduce through seed have presented a particularly vexing intellectual property problem because such plants can reproduce through natural processes, in effect providing a free, renewable supply to the farmer.[53] Indeed, intellectual property protection is about controlling access to or use of a particular invention, and a self-propagating invention obviously presents unique problems in this context.[54] The use of hybrids operated to vitiate this effect somewhat, because hybrid plants, in succeeding generations, have gradually diminishing yields.[55] A farmer that plants hybrid seeds, therefore, must continue to use the hybrid (purchased from the seed company) each year in order to achieve the same results.[56] Some crops, such as soybean and cotton, are not subject to hybridization techniques because they are self-pollinating.[57] In response to the unique attributes of agricultural inventions, Congress has provided a variety of legal means to help protect this technology.

15. Various legal means are available to protect plant inventions such as trade secret law, the Plant Variety Protection Act (PVPA), the Plant Patent Act (PPA), and utility patents.[58] Historically, plant breeders made heavy use of state trade secret law to protect their innovations.[59] Trade secret law was particularly successful in protecting hybridized plant lines, given the difficulty in determining the genetic makeup of a plant hybrid.[60] As the industry started to be transformed by biotechnology and is now highly focused on transgenically[61] modified plants, utility patents have become the preferred mode of protection because they are thought to provide the broadest coverage.[62] At this point, the biotechnology industry seeks utility patent protection more often than any other form of intellectual property coverage.[63]

16. Agricultural biotech companies prefer utility patents because they allow the patent holder, without exception, to exclude others from making, using, or selling the

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[53] Rives, *supra* note 6, at 191.
[54] Ewens, *supra* note 3, at 286.
[55] Rives, *supra* note 6, at 191.
[56] *Id.* at 192.
[57] *Id.*
[58] *Id.* at 188.
[59] Blair, *supra* note 2, at 308. Farmers and plant breeders really had no other choice but to use trade secret law to protect their seeds because it was not until 1970 that intellectual property protection became available for such seeds, when the PVPA was enacted.
[60] *See* Peter J. Goss, Comment, *Guiding the Hand that Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 Cal. L. Rev. 1395, 1417 (1996).
[61] A "transgenic organism" is an organism that contains DNA from another organism which has been inserted through biotechnological processes. *See* Carrie F. Walter, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 Ind. L.J. 1025 (1998).
[62] Rives, *supra* note 6, at 187.
[63] *See* F.H. Erbisch & C. Velazquez, *Intellectual Property Rights in Agricultural Biotechnology*, Biotechnology in Agriculture Series, No. 20 (F.H. Erbisch & K.M. Maredia, 1998).

invention covered by the patent.[64] Moreover, plant utility patents allow the breeder to claim not just the entire plant but individual components of the variety.[65] Additionally, the inventor-plant breeder can also claim genes, DNA sequences, tissue cultures, and methods associated with plant breeding and genetic manipulation of the plant.[66] Finally, having multiple patents to a particular plant invention increases the licensing options for the patent-holder/plant-breeder.[67] In order to gain the increased protection of a utility patent, the plant breeder must meet requirements that are more stringent than the requirements under either the PVPA or PPA.[68]

17. Plant breeders did not always have the option of applying for utility patent protection for their innovations. Even though the concept of patent protection is enshrined in the Constitution,[69] and the first Patent Act was signed into law by President George Washington on April 10, 1790,[70] plants were excluded from patent protection until the 1930s because they were thought to be merely "products of nature" and not inventions.[71] Additionally, another problem with providing patent protection to plants was the "written description" requirement.[72] Both of these problems were solved by passage of the Plant Patent Act.[73]

18. The Plant Patent Act of 1930 made available patent protection for asexually-reproduced plants[74] (those that are reproduced through grafts and cuttings but not by seeds).[75] The PPA provided significant protection for plant breeders, particularly those specializing in ornamental plants and those in the fruit tree business. The PPA has significant limitations, however, such as the fact that it provides patent protection for only a plant in its entirety and does not permit separate claims for parts of the plant.[76] Moreover, protection under the PPA does not apply to the major crop species that are propagated sexually, or through seeds. Congress remedied this situation in 1970, however, when it passed the Plant Variety Protection Act, which does protect sexually-reproduced plants (those that are reproduced through seeds).[77] This was highly significant because most

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[64] Rives, *supra* note 6, at 187.
[65] Blair, *supra* note 2, at 318.
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] U.S. CONST. art. I, § 8, cl. 8, the "Limited Times" clause, gives Congress the constitutional power to enact laws which "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."
[70] Andrew F. Nilles, Comment, *Plant Patent Law: The Federal Circuit Sows the Seed to Allow Agriculture to Grow*, 35 Land & Water L.Rev. 355, 357 (2000).
[71] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[72] *Id.* at 311 (explaining that the general requirement for a "written description" in patent law is difficult to apply to patents because of their somewhat amorphous character).
[73] Nilles, *supra* note 70, at 357.
[74] Rives, *supra* note 6, at 192.
[75] *Id.* at 199.
[76] Nilles, *supra* note 70, at 360.
[77] The Plant Variety Protection Act is codified at 7 U.S.C. §§ 2321-2582. Protection under the PPA and PVPA is quite similar; both legal instruments give the right-holder the ability to exclude others from

agricultural cash crops, such as soybean, cotton, wheat, barley, oats, and rice, can only be efficiently propagated through the use of seeds.[78]

19. The purpose of the PVPA is to "encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promote progress in agriculture in the public interest."[79] In order to receive protection under the PVPA, the breeder must apply to the USDA for a certificate of protection and show that the plant is: (1) new and distinct, (2) novel, and (3) uniform and stable.[80] The PVPA certificate confers a legal right on its holder to exclude others from reproducing, selling, importing, or exporting the protected variety for a period of 20 years.[81] Even though the PVPA provides patent-like protection for sexually-reproduced plants, it permits two exceptions that seriously limit its coverage: (1) farmers' rights to save seeds, and (2) researchers' rights to use the protected plant for further development.[82]

20. The farmers' right to "save seed" was in particular viewed by industry as a disincentive to investment for developing new plant varieties.[83] With the increased costs of research associated with genetic engineering techniques, seed companies became increasingly aggressive in their desire to limit the farmers' exemption, and in 1994 Congress amended the PVPA to restrict but not eliminate the exception.[84] A farmer may in fact sell seed that is protected under a seed company's PVPA certificate, but only that amount of seed that could have been saved for his own replanting purposes.[85] This curtails the previous practice of "brown bagging," whereby a farmer was able to sell substantial amounts of seeds that he had saved but without paying royalties to the PVPA rights holder.[86] This policy change was necessary because there would be little incentive for researchers to invest in improved crop varieties so long as a farmer could purchase improved seed one time and then propagate that seed indefinitely without ever paying another royalty to the developer.[87]

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making, using, or using the protected plant or seed. The difference between the PPA and PVPA, then, is that PVPA provides protection for plant varieties that are sexually reproduced or tuber propagated, while the PPA is specific for asexually reproduced plants with a unique characteristic. Both provide for a 20-year term of protection.

[78] Blair, *supra* note 2, at 311.

[79] Susan E. Gustad, Casenotes and Comments, *Legal Ownership of Plant Genetic Resources – Fewer Options for Farmers*, 18 HAMLINE L. REV. 459, 464-65 (1995).

[80] 7 U.S.C. §§ 2402, 2422.

[81] 7 U.S.C. § 2483.

[82] *See* Goss, *supra* note 60, at 1397.

[83] David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 95 (1995)

[84] In 1994 Congress limited the farmers' right to save seed to replanting purposes only. Rives, *supra* note 6, at 203.

[85] *See* Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 192 (1995)

[86] Blair, *supra* note 2, at 313.

[87] Ewens, *supra* note 3, at 288.

21. Seed companies also place restrictions on the practice of "saving seed" through the use of licensing agreements[88] that operate to protect their seed inventions from unfair exploitation.[89] One of the most controversial aspects of these licensing agreements is that they have the effect of requiring the farmer to return to the seed company, year after year, if he wants to use the same variety of seed.[90] Moreover, these licensing agreements also place the farmer on notice of various legal rights and obligations, the violation of which may operate to dramatically increase the damages should there be a later lawsuit.[91] And seed companies have shown that they are not shy about bringing lawsuits against their own customers, the farmers themselves.[92]

22. Farmers are fighting back, however, indicated by the fact that legal challenges to patents granted for modified plants rank second only to challenges to software patents.[93] Indeed, the issue of whether utility patents should even be available for plant inventions was recently brought before the United States Supreme Court.[94] In J.E.M. AG Supply v. Pioneer Hi-Bred Intl., Inc., the Supreme Court decided that plant inventions were eligible for utility patent protection, and that neither the PPVA nor the PPA limited utility patent coverage.[95] The Supreme Court also found that utility patents for plants were by no means unusual since the U.S Patent and Trademark Office, as of 2001, had already issued more than 1800

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[88] A good example of agreements seed companies require is the license printed on tags affixed to seed bags distributed by Pioneer Seed Co., which reads as follows:

> The purchase of these seeds includes a limited license under patent(s) … to produce a single crop in the United States. This license does not extend to the use of seed from such crop or the progeny thereof for propagation or seed multiplication. Furthermore, the use of such seed or the progeny thereof for propagation or seed multiplication or for production or development of a hybrid or different variety of seed is strictly prohibited.

Nilles, *supra* note 70, at 356.

[89] *See* Neil D. Hamilton, *Why Own the Farm if You Can Own the Farmer (and the Crop)?: Contract Protection and Intellectual Property Protection of Grain Crops*, 73 NEB. L. REV. 48, 92 (1994).

[90] Nilles, *supra* note 70, at 356. Moreover, without a licensing agreement restricting use of seed gleaned from a harvest, farmers would be able to save such seed and "brown bag" it, or sell as surplus without providing compensation to the developer of the original seed variety.

[91] Patent law, for example, provides for treble damages if the infringer is shown to have had knowledge of the patent and deliberately infringes it. *See* 35 U.S.C. § 284.

[92] Nilles, *supra* note 70, at 362. Additionally, some of the seed companies such as Monsanto have an active monitoring program whereby investigators are deployed into farmers' fields to obtain samples for genetic testing. If DNA analysis reveals that a farmer has been using protected seed for which no royalty has been paid for the one-time-use which is typical in the industry, Monsanto may then sue the farmer for "seed piracy."

[93] Nilles, *supra* note 70, at 361-62.

[94] *See* J.E.M. AG Supply Inc. v. Pioneer Hi-Bred Int'l. Inc., 534 U.S. 124 (2001). The issue in this case was whether utility patents could be issued for plants or whether the sole protection for plant inventions was the Plant Variety Protection Act (PVPA) and the Plant Patent Act (PPA). *Id.* at 127. The Supreme Court held that newly-developed plant breeds were indeed eligible for utility patent protection under 35 U.S.C. § 101 and that neither the PPVA nor PPA limits the scope of such coverage. Moreover, the Court reiterated the rationale first enunciated in Diamond v. Chakrabarty, 447 U.S. 303 (1980), that 35 U.S.C. § 101 should be construed broadly. *Id.* at 145-46. The case came up through the Court of Appeals for the Federal Circuit, which has exclusive jurisdiction to hear patent appeals from the district courts.

[95] J.E.M. A.G Supply, 534 U.S. at 145.

utility patents for plant inventions.[96]

V. How Transgenic Crops are Regulated

23. As a preliminary matter, no evidence has yet surfaced that foods produced from transgenic crops are unsafe as a result of the manipulated genetic material.[97] Moreover, there is growing evidence that transgenic plants engineered for increased pest-resistance are actually beneficial to the environment because their cultivation results in a reduction of the total amount of chemical pesticides used, thus leading to less incidental damage to the environment and greater biodiversity in some areas.[98] In other words, there has yet to emerge any evidence that transgenic plants are harmful to either humans or the environment, and growing evidence that the cultivation of transgenic crops is more environmentally friendly. Nevertheless, there is considerable controversy over the level of regulation that should be brought to bear regarding the cultivation and use of bio-engineered crops.

24. It should be noted at the outset that transgenic crops are in fact "regulated at every stage in their development, from research planning through field testing, food and environmental safety evaluations, and international marketing."[99] There is, however, no single statutory scheme that regulates this process. Rather, there are various levels of review, many different statutes that apply, and several different agencies involved: (1) internal biosafety committees at most research institutions, (2) USDA's Animal and Plant Health Inspection Service (APHIS), (3) the Food and Drug Administration (FDA), (4) the Environmental Protection Agency (EPA), and (5) state regulations.[100] Each of these will be taken in turn.

25. Most research facilities have an Institutional Biosafety Committee (IBC) that ensures that safety procedures are being followed when potentially hazardous research activities are being conducted.[101] These procedures generally include four progressive levels of precautions: (1) the basic containment level which generally means use of a greenhouse and mechanisms to control access by insects and rodents, (2) addition of a concrete floor to prevent ground seepage and

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[96] *Id.* at 127.
[97] Colorado State University Department of Soil and Crop Sciences, Transgenic Crops: The Regulatory Process for Transgenic Crops in the U.S., http://www.colostate.edu/programs/lifesciences/TransgenicCrops/evaluation.html (last visited Aug. 25, 2003) [hereinafter Regulatory Process].
[98] *Id.*
[99] *Id.* There are in fact many different regulations which already cover genetically-modified crops. The real issue is whether the existing regulations are sufficient. Supporters of biotechnology contend that the current regulatory scheme is sufficient, that there is no need for further regulations given that what is currently on the books seems to be effective. Opponents of biotechnology, however, fear that disaster is lurking and that it is only a matter of time before some kind of catastrophe strikes. Increased monitoring and regulatory control of GM foods and crops is therefore necessary, at least from the perspective of biotechnology's opponents.
[100] *Id.*
[101] *Id.*

screening to filter our small insects, along with the autoclaving of tools used inside the greenhouse/lab, (3) addition of sealed windows, ventilation filters, protective clothing, and processing of any liquid runoff, and (4) even more stringent applications of precautions found at level 3.[102] Together, these precautions are intended to isolate the research that is being conducted, and to prevent the escape of research specimens into the wild. So far, there have not been any examples of organisms that have been inadvertently released into the environment and which have caused any untoward effects. It should be noted, however, that internal biosafety committees are largely self-regulating and therefore have no official reporting requirement. The first level of official review, mandated by statute, occurs when a researcher begins to conduct experiments outside of the controlled environment of the greenhouse or is preparing to commercialize the product.

26. The USDA's Animal and Health Inspection Service (APHIS) is charged under the Federal Plant Pest Act with the responsibility of determining whether a transgenic plant is likely to have any negative agricultural or environmental effects.[103] This is accomplished through a permitting process that requires researchers to gain permission from APHIS if they plan to import, transport, or field test a transgenic plant.[104] Before APHIS will issue a permit, researchers must demonstrate that the subject plant is (1) stable genetically, (2) non-pathogenic to humans or animals, (3) unlikely to be toxic to other organisms, and (4) unlikely to create any new plant virus.[105] After field testing, and before any new plant may be commercialized, the researcher must petition APHIS for non-regulated status by producing convincing evidence that the plant meets the requirements set forth above.[106] APHIS retains the jurisdiction to remove a plant from the market if there is any evidence that the plant is becoming a pest.[107]

27. While APHIS maintains a broad focus regarding a transgenic plant's overall effect on agriculture, the EPA focuses on any potential effects regarding environmental safety, and in particular whether transgenic crops are having a deleterious effect on the environment. For example, the EPA regulates new transgenic crops that are engineered for pest resistance.[108] The EPA's authority is derived from three separate statutory schemes: (1) the Federal Insecticide, Fungicide, and Rodenticide Act, (2) the Toxic Substances Control Act, and (3) the

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[102] *Id*. Institutional Biosafety Committee regulations are really more about industry standards than true "regulations" because each institution is free to establish its own set of guidelines. It is also probably worth mentioning that tort law itself provides a form of "regulation" inasmuch as any lab that conducts an activity which harms its neighbors will be liable for the damages.
[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] *Id.* Critics of agricultural biotechnology perhaps overlook the permitting process which is required by the USDA. This is a rigorous exercise that is intended to insure that no transgenic plant is released into the environment unless it is safe to do so. In other words, there is no merit to the argument that biotechnology inventions related to agriculture are being implemented without government scrutiny.
[107] *Id.*
[108] *Id.*

Federal Food, Drug and Cosmetics Act.[109] The EPA requires animal studies, and studies on non-target organisms, to show that the transgenic crop is safe.[110] If evidence is developed that a transgenic plant is harming the environment, the EPA has the authority to order the discontinuation of its cultivation. If a transgenic crop is not causing any deleterious effect on the environment, then it presumably can be cultivated like any other crop and ultimately be harvested for food at which point it will come under scrutiny by the FDA.

28. The Food and Drug Administration (FDA), under the Federal Food, Drug, and Cosmetics Act, determines the safety of food and its ingredients.[111] Transgenic foods are not treated any differently than any other food; for example, they are not subjected to any formal licensing or approval process by the FDA prior their being placed on the market.[112] The FDA and the producer of a transgenic food, however, do engage in informal consultations prior to such foods being distributed, addressing the issues of nutritional value and potential risk of allergy.[113] Even though there is technically no pre-market approval necessary before a transgenic food is introduced into the food supply, the FDA may order it off the market if evidence arises that the food is unsafe.[114] Again, transgenic foods are not treated any differently than any other food in this respect.

29. It might be useful to note at this point the difference between the European Union and the United States when it comes to regulating transgenic foods. In the United States, there is a presumption that genetically-modified (GM) foods are safe unless proven otherwise, while in the European Union it is just the opposite: GM foods are considered unsafe until proven otherwise.[115] U.S. government officials have said that the difference exists because the system in the United States is based on science while the system in the European Union is the product of political pressure.[116] Moreover, the United States permits substantially more self-regulation by industry than does the European Union, which typically requires a far more detailed regulatory scheme for a given industry.[117] Because of the fundamental difference between the two largest economic powers in the world, there is yet to be any specific international agreement on how to treat GM

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[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] *Id.* The FDA apparently considers GM foods to be like any other new food product – fundamentally safe. Moreover, since there is no scientific evidence to support the notion that GM foods may be risky, then there is no rational basis to require labeling of GM products.
[113] *Id.* The critics of biotechnology fear that transgenic crops could result in the transfer of allergens from one species of plant to another, and thereby surprise the unsuspecting – a person with a peanut allergy would not expect an allergic reaction from eating soy, but could theoretically suffer an allergic reaction if he eats soy that has been genetically altered to include proteins from peanuts. However, this is merely speculation at this point since there has not (yet) been any documented case of a transgenic plant causing an unexpected allergic reaction.
[114] *Id.*
[115] Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT'L. & COMP. L. 129, 142-43 (2000).
[116] *Id.* at 143.
[117] *Id.*

foods.[118]

30. In addition to federal regulation of transgenic crops, many states also have regulatory requirements.[119] Minnesota, for example, requires growers to obtain a permit before they can release genetically-modified organisms into the environment.[120] These state regulations should not be seen as qualitatively different from the federal regulations. Rather, they are best viewed as an individual state's desire to be kept informed, to stay "in the loop," regarding the development and use of a particular transgenic crop in its state.

31. Despite the lack of evidence of any deleterious effects of transgenic crops, and despite the existing regulations, which therefore appear to be effective without stifling further research, opponents to and critics of biotechnology argue that there should be far greater control exerted over the agricultural biotechnology industry in general. For example, some argue that the FDA should conduct pre-market safety testing and licensing, and that transgenic foods should at least be so-labeled.[121] The labeling issue seems particularly germane.

32. Some critics have pointed out that consumers are using and consuming transgenic foods without being properly informed and without being given sufficient information to evaluate such foods for their safety or impact on the environment.[122] This is sometimes put in terms of "rights" that are being violated, that the consumer has a right to be informed and a right to make decisions, both of which are being violated by the food industry's failure to label its bioengineered products.[123] The more strident critics allege that "[t]hese products are being forced on us with inadequate testing and since there's no labeling, we're given no choice."[124] There also seems to be widespread support among the public to require labeling of products that incorporate transgenic foods.[125]

33. The producers of GM foods seem to fear labeling, perhaps because they suspect consumers will shun their products and that sales will therefore suffer.[126] It would in fact be in the producers' best commercial interests, however, to institute policies of full disclosure and labeling. The tobacco industry, for example, is

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[118] *Id.* at 159.
[119] Regulatory Process, *supra* note 97.
[120] Minnesota Department of Agriculture, Regulation of Genetic Engineering in Minnesota, *available at* http://www.mda.state.mn.us/biotech/ (last visited Aug. 25, 2003).
[121] *See, e.g.,* State Public Interest Research Groups, New FDA Policy Fails to Require Testing or Labeling of Genetically Engineered Food (Jan. 17, 2001), *at* http://pirg.org/ge/GE.asp?id2=4806&id3=ge& (last visited Aug. 25, 2003).
[122] Freire de Oliveira Souza, *supra* note 115, at 131.
[123] *Id.*
[124] State Public Interest Research Groups, Halloween Report Documents Bizarre Genetically Engineered Food Combos (Oct. 31, 2000), *at* http://pirg.org/ge/GE.asp?id2=4809&id3=ge& (last visited Aug. 25, 2003) [hereinafter Halloween Report].
[125] *Id.* (stating that eighty to ninety percent of the public has indicated a desire for mandatory labeling of genetically engineered foods).
[126] Freire de Oliveira Souza, *supra* note 115, at 164.

currently being rocked by multi-billion dollar judgments arising from use of its products, and a central issue in those cases has been labeling, disclosure, and consumer awareness. In the event that there is an untoward effect from a transgenic food at some time in the future, it would not be in anyone's interest, to include the food industry, for there to be a history of anything less than full disclosure. The biotechnology industry should support labeling initiatives for GM foods.

VI. Opposition to Agricultural Biotechnology and the NGO Movement

34. Not everyone is convinced of the merits of biotechnology and the benefits of genetically-modified crops. Some of the opposition regarding agricultural biotechnology relates simply to the notion that the technology may not deliver on its promises, and that it might even lead to lower overall yields and increased pesticide use.[127] An additional factor is the perceived uncertainty that may arise when there is a gene transfer between unrelated species, and some have accused the biotechnology industry of "flying blind" because of the inability to predict all the effects of this type of technical research.[128] This criticism would seem a little misplaced, perhaps, if for no other reason than the fact that research activity is itself intended to increase knowledge and understanding in the first place – it is meant to reduce uncertainty. Criticizing scientists because they want to better understand the world around them and bring improvements to all of mankind does not seem particularly productive. Moreover, it is important to note that many of the fears expressed by the opponents of biotechnology, so far at least, are not supported by much, if any, evidence or substantiation.[129] In particular, no one has yet detected a health problem caused by a genetically-engineered food.[130]

35. Other critics are more than merely unconvinced of the merits of agricultural biotechnology. They are actually opposed to the wide-scale adoption of the technology, asserting that transgenic crops: (1) damage human health, (2) damage the natural environment, (3) disrupt current farming practices in developing countries, and (4) cause overall disruption to the economies of developing countries.[131] Various issues are implicated by this opposition, such as the role of

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[127] *See* Rubenstein, *supra* note 47. While there is no evidence (yet) that transgenic crops lead to increased resistance of insects to insecticide, there is some support to the allegation that herbicide-tolerant crops do not necessarily lead to a reduction in use of herbicides. Transgenic Plant*, supra* note 15. Some have alleged that farmers using transgenic crops are experiencing lower yields, continuing dependency on herbicides and pesticides, and loss of access to international markets. *See* Greenpeace, *GE Industry Breaking Farmers Backs* (Sept. 17, 2002), *at* http://www.greenpeace.org/features/details?features_id=27630 (last visited Aug. 25, 2003).

[128] Halloween Report, supra note 124.

[129] Nilles, *supra* note 70, at 372.

[130] *Id.*

[131] Colorado State University Department of Soil and Crop Sciences, Transgenic Crops: Risks and Concerns, *at* http://www.colostate.edu/programs/lifesciences/TransgenicCrops/risks.html (last visited Aug. 25, 2003) [hereinafter Risks and Concerns]. Many have raised concerns about possible allergic reactions caused by transgenic foods, but so far there is no evidence to support the allegation. *Id.* Tests of several dozen transgenic foods for potential allergy risk have so far only identified a variety of soybean, which was

intellectual property, the globalizing world economy, and the tension between the developed and developing world. These issues will be examined below, but first it is important to explore the role NGOs are playing in the debate.

36. Non-Governmental Organizations (NGOs) are spearheading the opposition to agricultural biotechnology. Their campaign is full of histrionics and scare tactics the effect of which should not be underestimated since political decisions are often driven by emotional concerns. Hence, it simply does not matter how technically promising genetically engineered crops are – if the public is afraid of them and unwilling to accept GM foods, then the technology will go nowhere. There will be no market for the crops, which means no funding for additional research. Ironically, some of the emotions surrounding biotechnology inventions are legitimate and understandable since, to the layperson at least, it might be alarming to discover that scientists have developed the ability to transfer genes from one species to another, or to create a seed that will produce just a single crop but that is otherwise sterile, actually unable to self-propagate.[132] A thoughtful examination of the details, however, serves to assuage most of these concerns. What may seem spectacular and threatening to the non-expert, generally turns out to be quite innocuous if not prosaic to those who are in the best position to evaluate the risks: the researchers themselves. Most agricultural scientists working in this field simply do not view biotechnology as a threat but rather see it

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never marketed, and Starlink corn which, as of the time of this writing, has not yet shown itself to present any particular risk of causing an allergic reaction. In other words, there is not yet any evidence to show that transgenic foods pose more of a risk than do conventional foods. *Id.* Another concern is something non-governmental organizations are calling "GM contamination" whereby farmers who desire to grow only "natural" seeds are unable to do so because "seeds have become almost completely contaminated with GMOs [genetically modified organisms]." Soil Association, Seeds of Doubt: Executive Summary (Sept. 2002), *at* http://www.soilassociation.org/web/sa/saweb.nsf/librarytitles/seedsofdoubt_summary.html (last modified June 20, 2003). The same organization also alleges that farm subsidies are rising because the export market for American grain is falling, due in part to the fact that many countries refuse to import GMO grain. *Id.*

[132] *See* Pollan, *supra* note 26. "Terminator" technology allows scientists to modify plants in order to prevent farmers from re-using harvested seed, "forc[ing] farmers to return to the seed corporations every year …." ETC Group, Defend Food Sovereignty: Terminate Terminator 2 (Jan. 2002), *at* http://www.etcgroup.org/documents/terminatorbrochure02.pdf (last visited Aug. 25, 2003). Opponents of biotechnology have characterized terminator technology as "immoral" as well as a "real and present danger for global food security and biodiversity." ETC Group, Sterile Harvest: New Crop of Terminator Patents Threatens Food Sovereignty 1 (Jan. 31, 2002), *at* http://www.etcgroup.org/documents/new_termpatent_jan2002.pdf (last visited Aug. 25, 2003). Moreover, some NGOs are so mistrustful of the modern seed industry that they have charged that its ultimate goal is "bioserfdom." ETC Group, Defend Food Sovereignty*, supra.* .Some have also argued that genetic engineering permits scientists to "manipulate genetic materials in ways that were once inconceivable … [causing] a disruption of complex gene interactions and unintended, potentially catastrophic results." Richard Caplan & Ellen Hickey, Weird Science: The Brave New World of Genetic Engineering 2 (Oct. 31, 2000), *at* http://pirg.org/ge/reports/weirdscience10_31_00.pdf (last visited Aug. 25, 2003). Combinations that have been cited as particularly alarming include inserting chicken genes in apples and corn; human genes in corn, potatoes, and rice; mouse genes in potatoes; cow genes in soy and sugarcane; and flounder genes in tomatoes.

as a technology holding great promise.[133] Yet, many NGOs seem to be unwilling to acknowledge the data and instead insist on distorting the facts and slandering the technology.

37. In order to try to establish their case and serve their political agenda, many NGOs present distorted information, inaccuracies, and scare tactics. For example, NGOs will often use inflammatory terms such as "franken-food" and "biopiracy," terms that are obviously designed to whip up emotional opposition – such terms certainly are not meant to convey a dispassionate evaluation of the technology. The unfortunate outcome of the NGO-induced hysteria may be to actually harm the very groups that the NGOs purportedly want to help – farmers in developing countries. As will be discussed later in this paper, many developing country farmers view agricultural biotechnology quite positively and want to reap its benefits. If NGOs have their way, however, the technology will not be made available to them.

38. Probably the best known and most active NGO in this field is Greenpeace.[134] As one of the loudest voices against biotechnology in general, Greenpeace has campaigned in favor of: (1) the precautionary principle which holds that GM foods are presumed to be unsafe until proven otherwise, (2) permitting sovereigns to give their explicit informed consent before allowing GM foods into their countries, (3) creating a system to assign liability in the event of damage or injury arising from use of GM foods, (4) requiring companies to label their GM foods, (5) preventing release of GM organisms into centers of genetic diversity or centers of origin, and (6) not allowing WTO rules to trump rules intended to regulate use of GM foods and organisms.[135] These arguments will be considered below, but first it is instructive to evaluate the quality of the criticism being levied by Greenpeace against the biotechnology industry, to determine how supportable their criticism really is. Often, once the emotions are stripped away, the facts are very different from how the NGOs present them.

39. A good illustration of this is Greenpeace's presentation of the case of a Canadian farmer, Percy Schmeiser, who has been portrayed as an example of how farmers are "finding it tough to elude the voracious grasp of genetic engineering companies."[136] Greenpeace has represented that Mr. Schmeiser's farmland was supposedly "contaminated" by transgenic crops growing on a neighbor's farm, and he was thereafter unjustifiably sued by a large multinational seed company

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[133] *See, e.g,,* Stephen B. Brush, *Sustainable Development, Agriculture, and the Challenge of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 135, 136 (2001).

[134] Freire de Oliveira Souza, *supra* note 115, at 150. Greenpeace describes itself as a "global environmental campaigning organization … [that] organise[s] public campaigns for the protection of oceans and ancient forests, for the phasing-out of fossil fuels and the promotion of renewable energies in order to stop climate change, for the elimination of toxic chemicals, against the release of genetically modified organisms into nature and for nuclear disarmament and an end to nuclear contamination." Greenpeace, How Greenpeace Works, *at* http://archive.greenpeace.org/report98/html/content/works.html (last visited Mar. 6, 2003).

[135] Freire de Oliveira Souza, *supra* note 115, at 161.

[136] Greenpeace, *GE Industry Breaking Farmers Backs, supra* note 127.

for patent infringement.[137] In reality, however, the court found that instead of there being inadvertent contamination, as was being portrayed by Greenpeace, Mr. Schmeiser's farmland had actually been deliberately planted with patent-protected seed:

> [I]n 1998 Mr. Schmeiser planted canola seed saved from his 1997 crop in his field number 2 which seed he knew or ought to have known was Roundup tolerant, and that seed was the primary source for seeding and for the defendants' crops in all nine fields of canola in 1998. … [He] grew canola in 1998 in nine fields, from seed saved from their 1997 crop, which seed Mr. Schmeiser knew or can be taken to have known was Roundup tolerant. That seed was grown and ultimately the crop was harvested and sold. … Growth of the seed, reproducing the patented gene and cell, and sale of the harvested crop constitutes taking the essence of the plaintiffs' invention, using it, without permission. In so doing [Mr. Schmeiser] infringed upon the patent interests of the plaintiffs.[138]

40. The controversy surrounding the case of the monarch butterfly also is illustrative of the distortions being presented by Greenpeace. A small preliminary study done in 1999 indicated that monarch butterflies might be harmed by eating Bt corn.[139] This study showed that monarch caterpillars, when exposed to Bt corn pollen at concentrations greater than 1000 grains/cm^2, were adversely effected.[140] Corn pollen in nature, however, averages only about 170 grains/cm^2.[141] Out of an abundance of caution, the U.S. Department of Agriculture (USDA) sponsored a research project on the issue, calling together scientists from agricultural biotech companies and associations to study the issue.[142] They found that there is no risk posed by Bt corn pollen to monarch butterflies at pollen concentrations found in nature.[143] Nevertheless, Greenpeace seized upon the preliminary study as evidence that agricultural biotechnology was dangerous and used it to further its campaign to discredit biotechnology.[144] Greenpeace has flat-out ignored the larger, more comprehensive study and instead continues to portray Bt corn as a threat to the environment.

41. Any consideration of agricultural biotechnology must include the political

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[137] *Id.*
[138] Monsanto Canada, Inc. v. Schmeiser, [2001] F.C. 256, *available at* http://decisions.fct-cf.gc.ca/fct/2001/2001fct256.html.
[139] USDA Agricultural Research Service, *Research Q & A: Bt Corn and Monarch Butterflies*, http://www.ars.usda.gov/is/br/btcorn/ (last visited Aug. 25, 2003). "Bt" refers to the fact that Bt corn hybrids produce an insecticidal protein derived from the bacterium "Bacillus thuringiensis," commonly called Bt.
[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] Greenpeace, *Engineered Corn Could Harm More Than 100 Butterfly Species, Greenpeace Warns*, http://www.greenpeaceusa.org/features/europebutterfly.htm (last visited Mar. 6, 2003).

dimension, and it is clear that NGOs such as Greenpeace are driving the debate. This is indeed unfortunate because the issues involved are susceptible to distortion and misinformation. It is clear that there is a larger political agenda at play, that NGOs such as Greenpeace apparently are opposed to various aspects of corporate capitalism, such as the intellectual property law protections that will be explored below.

VII. Intellectual Property as a Lightening Rod

42. It appears that many NGOs are opposed to biotechnology simply because they are opposed, as a general proposition, to intellectual property protections.[145] The biotechnology industry, as has been set forth previously in this article, relies heavily on intellectual property protections in order to recoup the large investments that are necessary to conduct research and development.[146] This includes not only private enterprise, but also government research agencies which make use of the patent system and intellectual property law as an aid in transferring technology. Because of the prevalence of intellectual property (and the concept of private rights) in this field, and because many in the developing world and their NGO supporters believe genetic resources (such as crop seeds) are "public goods," there is a natural tension between these two groups. This reflects a general ideological divide, pitting the creators against those who desire to regulate and rein them in. In other words, there is a larger political issue involved. Some have even argued that the very idea of intellectual property protection is "antithetical to the concept of liberal democracy."[147]

43. This ideological divide seems to be a central motivating factor for many of biotechnology's opponents. It appears that many NGOs oppose the globalizing economy, corporate capitalism, and the use of intellectual property rights because of its connection to corporate growth. This would seem to be a fundamental and intractable difference, given that advances in technology are dependent upon intellectual property protections – large expenditure of research dollars would not be possible without patent rights. Therefore, opposing intellectual property rights, *per se*, is essentially opposing progress and creativity. There is an argument, however, that government-sponsored technology ought to be made freely-available to the public. But there is even a stronger argument that the government has a poor record of transferring its technology to the public in the absence of partnerships with private industry and the intellectual property devices that make such partnerships possible. Hence, intellectual property protections such as the licensing of government-owned patents result in a net gain to the public, irrespective of whether the invention came out of a government or private laboratory.

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[145] *See* PAUL B. THOMPSON, FOOD BIOTECHNOLOGY IN ETHICAL PERSPECTIVE 163 (1997)
[146] *See* Brush, *supra* note 133, at l35.
[147] See JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY 12 (1996).

44. Still others argue that acquiring intellectual property rights to living organisms is somehow immoral.[148] This has always been a difficult argument to grasp because the concept of property rights associated with the products of farming seems completely acceptable to virtually everyone, including the opponents of intellectual property rights. Why, then, would it be acceptable to support chattel ownership of plants and animals which are used for human consumption, but to oppose intellectual property rights which are used mainly to improve the use of those plants and animals?

45. Finally, some have argued that agricultural research is being distorted because of intellectual property protection.[149] This argument hinges on the notion that private firms that conduct agricultural research will require a market for their products, and because poor farmers in the developing world cannot provide a market, then potential products for that market are not being developed.[150] Moreover, agricultural research traditionally was left to public sector institutions with the results of that research being made freely available to the public, given that it was the public's tax dollars that funded the research.[151] The reality, however, is that there is little tax revenue in the developing world to fund public sector research and, with not much of a market to tap, few incentives for private research. This is not, however, valid criticism of intellectual property law in general as much as it is evidence that non-market (or non-functioning market) economies do not generate much in the way of either tax revenue or opportunities for entrepreneurs to engage in private research.

46. As to whether it is appropriate for government agencies to take advantage of intellectual properties tools, there is considerable evidence that intellectual property rights secured by government labs and licensed to private firms result in much greater technology transfer than simply doing the research and publishing the results. This is so because private firms are in a much better position to commercialize and disseminate the technology than are government agencies. In order for private firms to engage in the distribution of agricultural technology, however, they must have the ability to protect their investment, which is made possible through the licensing of government-owned patents.

VIII. "Biopiracy," or Simply Dog-in-the-Manger Syndrome?

> A dog lay in a manger, and by his growling and snapping prevented the oxen from eating the hay which had been placed for them. "What a selfish dog!" said one of them to his companions; "he cannot eat the hay himself, and yet refuses to allow those to eat who can." – Aesop

[148] Freire de Oliveira Souza, *supra* note 115, at 135.
[149] Brush, *supra* note 133, at 159.
[150] *Id.* at 161.
[151] *Id.* at 159.

47. Various NGOs have asserted that farmers in developing countries have been exploited and are the victims of "biopiracy" because they have traditionally provided free access to germplasm (*e.g.*, seeds and cuttings) which is then modified by Northern companies and patented.[152] This is perceived to be somehow unethical, that there is a problem with using ingenuity to convert raw materials into something that is more useful to mankind, and to profit from one's labor, unless the inventor remits some kind of tax-like payment to those making a claim on the raw materials even though they are not using the materials themselves.[153] Some have also argued that there has been a disproportionate and unfair "flow of germplasm" from South to North,[154] that developed countries are notoriously "gene poor," and that almost every economically important crop has originated in the developing countries of the Southern hemisphere [155] – Northern societies, therefore, should provide compensation to those who live in the tropics simply because they *live in the tropics*. There are several major problems with this "biopiracy" argument.

48. First, it is at odds with basic precepts of intellectual property law, as set forth in Article I, Section 8, Clause 8 of the U.S. Constitution, which is the basis for the U.S. patent system.[156] Intellectual property law in general, and patent law in particular, permits an individual to profit from his initiative and individual effort in exchange for the benefits he can provide to the public. An inventor receives a patent and the right to exclude others from practicing his invention, for example, in exchange for his full disclosure as to how he made his invention so that others may improve upon it. This generalized dissemination of technical information ratchets up not only the state of technology but also the public's standard of living. Requiring an inventor to pay a tax on his raw materials, which is the suggestion of those who believe that "biopiracy" is a problem, would seem to be neither fair nor appropriate, given the fact that inventive activity itself should have as few impediments as possible, given that it is something that benefits everyone.

49. The second major flaw with the "biopiracy" argument is related to the first – the reach and scope of intellectual property law appears to be poorly understood in the developing world. For example, one author has asserted that "with genetic engineering, corporations are patenting seeds that are based almost entirely (minus one or two genes) on a product created through farmers' innovations over many years."[157] The problem with this argument is that any patent, should one be granted in the first place, is only valid on the incremental advance over the prior art. Seeds as they occur in nature cannot be patented. Only if they are somehow

[152] *Id.* at 154.
[153] *See* Kloppenburg, *supra* note 38, at 10-11.
[154] *See id*.
[155] *Id.* at 14.
[156] "Congress shall have power … to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8.
[157] Ewens, *supra* note 3, at 306.

modified would they, in their modified form, be eligible for patent protection. In other words, unmodified seeds as they are used by traditional farmers would not be subject to patent exclusion. Moreover, farming practices that have been known for many years are part of the "prior art" and therefore cannot be patented.

50. Furthermore, any patent that is secured will only be effective against others who are making, using, or selling the covered invention within the territorial jurisdiction of the authority that granted the patent. For example, a Mexican farmer has free and full access to his maize seed, irrespective of what a researcher in the United States is doing, which includes securing patents on improved varieties of Mexican maize. Moreover, that same Mexican maize farmer would be free to export his maize crop to the United States irrespective of any patent that may exist on the modified maize in the United States. The notion that developing country farmers are somehow being exploited because of research that is being done in developed countries is misplaced. Alleging that such farmers are the victims of "biopiracy" is essentially begrudging someone else for taking the initiative and developing something new and useful from the raw materials.

51. In fact, the biopiracy argument is evocative of Aesop's story about the "dog in the manger" – even though local industry in developing countries is unable to conduct biotechnology research and produce improved crop varieties, some NGO activists would prevent everyone from conducting such research in the first place unless a tax is levied for the "privilege" of trying to improve crop varieties. This would appear to be directly antithetical to the long-held belief and practice among farmers that germplasm is their common heritage, to be shared by all.

52. The concept of "biopiracy" also raises the issue of the ongoing tension between the developed and developing worlds. This relates directly to globalization, international trade agreements, and the how the developing world is trying to respond.

IX. TRIPS and CBD Are a Microcosm Reflecting the Difference between the Developed and Developing Worlds.

53. The Convention on Biological Diversity (CBD) was, in part, an effort to address the issue of "biopiracy" since it asserts that the germplasm ("genetic resources") found within the territory of a sovereign belongs to the citizens of that country.[158] The CBD attempts to assert control over a sovereign's germplasm through use of contracts and material transfer agreements.[159] Although more than 160 nations have signed the treaty, the United States has not, apparently having reservations

[158] *See* KRISTIN G. ROSENDAL, THE CONVENTION ON BIOLOGICAL DIVERSITY AND DEVELOPING COUNTRIES (2000). Plant Genetic Resources, or "PGR," have traditionally been considered to be the "common heritage of mankind." In recent years, interests in developing countries and their supporters have withdrawn from this "common heritage" concept, and have been advancing the argument that PGR should be a profit center for the source countries.

[159] WALTER V. REID ET AL., BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT 24 (1993).

about CBD's lack of intellectual property protection.[160] In contrast to the CBD is the World Trade Organization TRIPS Agreement (Trade Related Aspects of Intellectual Property Rights) which the United States has signed.[161] TRIPS provides for intellectual property protection, including biotechnology inventions.[162] Moreover, TRIPS specifically provides for plant inventions.[163] Various NGOs have asserted that the CBD and TRIPS agreements are at odds with each other. These agreements can, in fact, be mutually complementary.

54. At first blush, it might seem that TRIPS and the CBD are incompatible. CBD relates to common rights and TRIPS is about private rights. Upon further analysis, however, the agreements actually are complementary, or can at least both be implemented without there being a direct conflict. CBD essentially is about control of raw materials; TRIPS is much more about manipulating that raw material. Patent protection, as enshrined by TRIPS and as traditionally understood, does not really become an issue until *after* raw material has been converted, in some form or fashion, into a product or new composition of matter. As long as CBD is implemented in such a way so as to affect only control of raw material, and not in any way affect patent (or other intellectual property) rights, then both CBD and TRIPS can peacefully coexist.

55. CBD could be implemented by using a combined system of export controls, material transfer agreements, and prospecting licenses. If a sovereign desires to control access to its territory and the raw materials to be found there, that is certainly appropriate and beyond debate. CBD should be seen as merely a control placed on territorial access. If CBD is implemented in such a way so as to impair intellectual property rights, however, then it would be offensive to TRIPS. Some developing countries, for example, have suggested that patents should be invalidated unless the holder of a patent for an invention related to genetic resources can prove that he had legitimate possession of his starting materials. This would in effect be a new requirement on patentability, beyond what TRIPS requires and which would therefore be a violation of TRIPS. Moreover, requiring patent offices worldwide to become a type of police and customs agency would be incredibly burdensome and simply beyond their mandate. It would indeed be folly to require patent offices to examine patent applications for political, and not merely technical, sufficiency.

56. It should also be pointed out that the CBD is not only about access to genetic resources but that it was also negotiated with the express objective of conserving

[160] Scalise & Nugent, *supra* note 83, at 110. Apparently, the United States was reluctant to sign the biodiversity treaty because its technology transfer provisions might not provide for full payment for any technology that is transferred.
[161] Ewens, *supra* note 3, at 301.
[162] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27, LEGAL INSTRUMENTS - RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994).
[163] *Id.*

the world's biological diversity.[164] There is concern that genetically-engineered crops may accelerate the loss of biodiversity[165] which has been underway for many years due to the modern practice of farmers who use just one variety of seed instead of many different varieties.[166] In other words, large scale production of a single, uniform crop variety, like the current trend in the United States, bears an inherent risk.[167] When crops are genetically similar, they tend to react the same to environmental stresses, thus increasing the risk of massive crop failure.[168] Many fear that this loss of biodiversity will increase the chances of a widespread crop failure, leading to famine and general social dislocation.[169] Again, some of this would seem to be valid criticism initially, but upon further analysis there is a case to be made that agricultural biotechnology actually *promotes* biodiversity.

57. A key element of agricultural biotechnology is the concept of isolating particular genetic traits. Characteristics that are favorable to agriculture, such as drought or pest resistance, are isolated on a genetic level. Once isolated, the genes can be transferred to other crops, and thereby transfer the favorable characteristic. The germplasm that is used as the starting material for this gene research is obviously vital, and there has been a long-standing practice of preserving samples of germplasm to insure that there will always be raw materials available for further research. Biotechnology researchers, therefore, have a powerful incentive to preserve as many germplasm samples as possible, from as many different varieties as possible. There is an argument, therefore, that agricultural biotechnology operates to preserve biodiversity, not diminish it.

58. On the other hand, there is a risk of large-scale crop failure (which is distinguishable from a loss in biodiversity) if a single cultivated crop variety comes under attack by pests or disease and is not able to resist. This would pose a serious and immediate economic challenge to the farmers in the region affected, but that is different from the threat of losing "biodiversity," per se. Obviously, it would be to everyone's benefit to insure that a wide variety of crops is under cultivation in a particular region at any given time in order to minimize the risk of

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[164] Ewens, *supra* note 3, at 298. The CBD's express purpose is to: (1) to conserve the world's biological diversity, (2) to sustain use of biological components, and (3) to share, fairly and equitably, the benefits arising from the utilization of the world's genetic resources. *Id.* Biological diversity is important in the agricultural context because, simply, the larger the pool of genetic resources, the greater the options farmers have to meet changing conditions. In the medical sector, many pharmaceuticals have their origin in plant materials, such as aspirin which is found in the bark of the willow tree – it is therefore important to preserve biological diversity in order to preserve possible sources of medicines.

[165] Jean Christie et. al., *Of Monopolies and Meltdown (Intellectual Property Rights Over Living Things)*, CANADIAN DIMENSION, Jan.-Feb. 1998, at 16. "Biodiversity" refers to the number of different species that coexist, as well as the variety within a species. The more varieties that exist, the greater the likelihood of survival of the species.

[166] *Id.*

[167] Goss, *supra* note 60, at 1403. Biotechnology perhaps accelerates a trend that has been underway for some time – for farmers to plant ever more extensive tracts of land, with ever fewer varieties of crops. This represents a loss of biodiversity, and a turn toward a "monoculture" which increases the susceptibility to a crop disaster, in the event of a crop-specific infestation of disease or insect damage. *Id.*

[168] *Id.*

[169] Nilles, *supra* note 70, at 371-72.

having a single crop failure result in an economic disaster. Agricultural biotechnology is being used to address and solve the problems faced by farmers, such as crop failure caused by pest and disease. If one particular crop comes under attack, agricultural biotechnology is intended to provide responses and options. Biotechnology as applied to crop science, in and of itself, is an aid to preserving biodiversity, not diminishing it.

X. Agricultural Biotechnology, If It Is Allowed To Mature in the Developing World, Holds the Promise of Creating Stronger Economies and Healthier People.

59. Biotechnology holds huge promise for the developing world. Africa barely feeds its people now, and often has food shortages. In order to keep pace with current consumption levels in Africa, farmers will have to double their production by the year 2020.[170] Kenya, for example, a country where over eighty percent of the population is involved in farming, cannot provide adequate food for a population of 30 million people.[171] Africa also needs food that is more nutritious in general, and there are several crop varieties that have been bio-engineered to meet this need and which are in final development.[172] In short, biotechnology could be a key part in helping the developing world feed itself.

60. In addition to providing improvements in crop production, biotechnology also offers great capacity to alleviate multiple health problems in the developing world. For example, cholera vaccine has been incorporated into bananas using biotechnology techniques.[173] There is also a genetically-engineered rice variety that has been bred to have a high concentration of beta-carotene that is expected to substantially alleviate if not eliminate the current problem of 250,000 to 500,000 school children who go blind each year from vitamin A deficiency.[174] In other words, transgenic crops not only hold the promise of dramatically improving the nutrition of the world's hungry, but also of addressing many of their health problems.[175]

61. Whether or not biotechnology will be allowed to address many of the problems facing the developing world is still an open question. Many in the developed world condemn biotechnology and genetically modified organisms because of the perceived problems that they may cause to health, the environment, and social institutions.[176] Most agricultural scientists, however, understand the value of biotechnology and do not view it as a threat.[177] This includes many African

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[170] Alex Kirby, *Africa Needs GM Crops to Survive*, BBC News (May 14, 2002), *at* http://news.bbc.co.uk/1/hi/sci/tech/1985543.stm (last visited Aug. 25, 2003).
[171] *Id.*
[172] Brush, *supra* note 133, at 139.
[173] Kirby, *supra* note 170.
[174] Brush, *supra* note 133, at 139.
[175] *Id.* at 140.
[176] *Id.* at 136.
[177] *Id.*

scientists who are convinced that biotechnology can stave off starvation.[178] Still, significant opposition to the technology exists. One aspect of this opposition in the developing world stems from the perception that biotechnology will not only alter agriculture but that it will also alter the overall economy, perhaps adversely. Moreover, whenever there has been new technology introduced into agriculture, there has been resistance, although the opposition to modern biotechnology is unprecedented.[179] Perhaps this issue can be better understood if it is placed in historical context.

62. Technological change has been part of agriculture from the very beginning.[180] Modern crop breeding, for example, has made it possible to feed over six billion human beings.[181] In fact, it is clear that the current population could not be sustained without modern agricultural practices.[182] Without modern crop science, it is beyond doubt that many more people would be hungry than the current number, which is universally condemned as being unacceptable.[183] And despite exponential population growth in the 20th century, a smaller proportion of the human population is malnourished than ever before.[184] Aware of the increasing demands that are being placed on food production, most crop scientists agree that if wide-scale famine is to be avoided in the future, farmers must use the newest technology available, to include transgenic plants.[185] Indeed, transgenic crops are to the early 21st century what hybrid plants, chemical pesticides, and synthetic fertilizers were to the early-mid 20th century.[186] Despite the natural progression of agricultural technology, biotechnology seems different, in part because of its impact on or connection to larger economic changes.

63. Some have opposed the adoption of farm technology in general because they fear it leads to the need for large, well-funded farms in order to compete, and this, in turn, is highly dislocating to small, traditional farm operations.[187] This is exacerbated by the fact that biotechnology corporations, with their need to secure a return on their research dollars, must create a market for their products that may not be well suited for the small, traditional farmer.[188] These would seem to be legitimate concerns – that agriculture continues to evolve and at this point the industry is adjusting to the changes related to the advent of transgenic crops and biotechnology. Even though there might be legitimate reasons to resist adoption of biotechnology, developing countries are taking a huge risk if they do not take advantage of what the technology has to offer.

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[178] Kirby, *supra* note 170.
[179] Brush, *supra* note 133, at 145.
[180] *Id.* at 136.
[181] *Id*. at 137.
[182] *Id.*
[183] *Id.* at 138.
[184] LLOYD T. EVANS, FEEDING THE TEN BILLION: PLANTS AND POPULATION GROWTH (1998).
[185] Brush, *supra* note 133, at 138.
[186] *Id.* at 145.
[187] *See* WILLARD W. COCHRANE, THE DEVELOPMENT OF AMERICAN AGRICULTURE: A HISTORICAL ANALYSIS 387-95 (1979).
[188] Freire de Oliveira Souza, *supra* note 115, at 138.

64. If agricultural biotechnology is not permitted to fully flower in the *developed* world, it will not be critical since food production in developed nations is not a problem.[189] In the *developing* world, however, biotechnology might mean the difference between having enough food and starvation.[190] Already, hunger is most severe in exactly those areas where advanced agricultural techniques are not being practiced.[191] Therefore, denying farmers access to biotechnology in poor countries might very well cause the problems that so many would like to avert: hunger and starvation.[192]

XI. Conclusion

65. Agricultural biotechnology is a technical marvel but politically controversial. It promises to feed the hungry and to reduce disease. Yet, because it is so closely associated with large corporations, it faces significant resistance from groups that oppose corporate capitalism and the globalizing culture. It is unclear whether those who need the technology the most will be able to take full advantage of it. If the agricultural biotechnology industry is not able to win over the hearts and minds of the public, its potential will not be realized. This would indeed be a tragedy, particularly for those living in the developing world, who are most in need of agricultural improvements.

8 Va. J.L. & Tech. 7 (2003), *at* http://www.vjolt.net

[189] Brush, *supra* note 133, at 136.
[190] *Id.*
[191] *Id.* at 138.
[192] *Id.* at 136.