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Pride and 'Prejudice to the Environment': An Application of TRIPS Article 27.2 to Genetically Modified Seeds

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"Where there is a real superiority of mind, pride will be always under good regulation."[1]

- JANE AUSTEN

INTRODUCTION

In the small village of Capulalpan, located in the foothills of the Mexican state of Oaxaca, production of native corn varieties is an important cultural activity.[2] Around the turn of the century, village elders discovered a wild strain of corn that was invading their native "Creole" crops.[3] Though it has been illegal since 1998 to cultivate genetically modified (GM) corn within Mexico, the country still imports GM corn for human consumption.[4] Biologists tested the DNA[5] of this wild strain in 2002 and discovered it was genetically modified.[6] Genetically altered corn had been delivered to villages on trucks, so the natives assumed that kernels fell off the trucks during their journey and started to grow wherever they landed.[7] The GM corn quickly took over the native crops. According to Antonio Serratos of the Mexico-based International Center for the Improvement of Maize and Wheat, if a farmer with a one-hectare[8] plot plants a single row with this invasive GM seed, sixty-five percent of the plot will be GM in only seven years.[9] Though the genetically modified corn grew larger and quicker than the native varieties, it was highly

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1. JANE AUSTEN, PRIDE AND PREJUDICE (1813).
2. Carmelo Ruiz-Marrero, *Genetic Pollution: Biotech Corn Invades Mexico*, CORP WATCH (Mar. 20, 2002), https://perma.cc/JNV8-Y234.
3. Pav Jordan, *Mysterious 'Alien' Corn Invades Mexico Countryside,* INST. FOR AGRIC. & TRADE POL'Y (Jan. 30, 2002), https://perma.cc/7LKT-XEMZ.
4. *Id.*
5. Genes are units of DNA (deoxyribonucleic acid) which encode the necessary information for cells to reproduce and to produce specific proteins.
6. Jordan, *supra* note 3.
7. *Id.*
8. A hectare is a unit of measurement in the metric system, equivalent to 10,000 square meters, or 2.471 acres. *Hectare*, ENCYCLOPEDIA BRITANNICA, https://perma.cc/AZL4-7MH8 (last visited Dec. 19, 2017).
9. Ruiz-Marrero, *supra* note 2.

susceptible to the diseases once ripe.[10] Scientists and environmentalists are concerned the transgenic corn could completely usurp the Creole variety, which has become largely resistant to local plagues and diseases.[11] The uncontrollable nature of genetically modified crops is no longer speculative. Once released into the wild, it is almost impossible to track these crops as they crossbreed with other varieties.

Now consider if the crop in Mexico[12] had been genetically modified to contain "terminator technology," which is a suicide mechanism inserted into seeds that causes them to terminate upon completion of the first production cycle.[13] Inventors developed this trait with the purpose of protecting their rights in the patented seeds, as it would force farmers to return to the seller each year for new seed. Once released into the environment, this technology could be passed through interbreeding with the native varieties and eventually eliminate a major native food source. Mexico, a nation that has consciously taken steps to ban all GM crops but not GM commodities, could still fall victim to the vast negative environmental impact caused by these seeds. Borders and legislation cannot keep genetically modified seeds out of the country. The international spread of this dangerous terminator technology must be stopped before it is too late.

Countries all around the world share the responsibilities of care and preservation of the environment. When faced with the choice of protecting the future environment versus encouraging innovation and progress through issuance of patents, countries should turn to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for guidance. Enacted in 1997, this Agreement completely changed the landscape of international intellectual property rights.[14] TRIPS regulates the patenting of life forms through Article 27, which sets forth general provisions regarding patentable subject matter and three subparagraphs describing exemptions:[15] "Subject to the provisions of paragraphs 2 and 3, patents

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10. The reliance on a single crop of one genetic makeup may make the same crop more vulnerable to disease. If a plague wipes out this single crop, it can devastate a society. This occurred during the Irish potato famine in 1845; more recently in the United States, blight hit many cornfields with certain hybrid varieties of corn producing only half of projected yields. David Daniel, *Seeds of Hope: How New Genetic Technologies May Increase Value to Farmers, Seed Companies, and the Developing World*, 36 RUTGERS COMPUTER & TECH. L.J. 250, 260 (2010).

11. Jordan, *supra* note 3.

12. MARGARET MELLON & JANE RISSLER, GONE TO THE SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY 45, 47 (2004).

13. Daniel, *supra* note 10.

14. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

15. *Id.*

shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application . . . ."[16]

Most relevant to the issue at hand is Article 27.2, which provides some exclusions from patentability. The words of this clause are vague, and the standard is muddled; overall, this clause raises many practical questions.[17] Yet, one point is clear: member nations have the authority to refuse to grant patents to environmentally risky inventions.[18]

Members may exclude inventions from patentability within their territories if preventing the commercial exploitation of those inventions is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[19]

Article 27.2 allows concerned countries to discourage the development of dangerous terminator technology,[20] while still incentivizing the creation of beneficial GM agriculture. As countries take advantage of this provision, they will hopefully encourage more countries to follow suit. Cooperation among concerned countries is necessary because the mitigation of environmental damage is not a job that can be completed within the borders of a single country. Through use of Article 27.2, countries can encourage companies to develop more beneficial GM crops, while discouraging the production of terminator technology.

In interpreting the TRIPS Article 27.2 exceptions to patentability, a bright-line rule should be implemented that classifies genetically modified crops inserted with terminator technology as inherently "prejudicial to the environment." This rule would allow all Member States to refuse such patents without further analysis, which would protect the long-term status of the environment. Not all genetically modified organisms are fully understood by the scientific community, but there is plenty of evidence that destruction could be caused by GM crops embedded with terminator technology as they spread uncontrollably through cross-pollination.

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16. *Id.*

17. M. Bruce Harper, *TRIPS Article 27.2: An Argument for Caution*, 21 WM. & MARY ENVTL. L. & POL'Y REV. 381, 383 (1997).

18. *Id.* at 383-84.

19. TRIPS Agreement, *supra* note 14.

20. Biotechnology companies recently developed a direct intellectual property enforcement mechanism referred to as "terminator" technology that causes plants to effectively self-destruct at the end of their cycle. *See* Debra M. Strauss, *The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology*, 45 STAN. J. INT'L L. 287, 299 (2009).

Part I of this article will lay out the foundation of genetically modified organisms and terminator technology. Part II will examine the patent system and how it offers incentives for inventors. Part III will outline the history of TRIPS Article 27.2 and its purpose. Part IV will discuss interpretation of Article 27.2, with emphasis on the phrase "serious prejudice to the environment," and apply the interpretation to genetically modified crops. Part V will suggest solutions that promote the protection of the environment, including a proposed bright-line rule regarding the interpretation of Article 27.2. Implementation of this standard is urgent: humans may have a moral obligation to protect the environment for future generations.

I. GENETICALLY MODIFIED CROPS

A. An Introduction to Genetically Modified Crops

Hungarian engineer Kal Ereky coined the term "biotechnology" in 1919[21] and paved the way for the discovery of the DNA double helix in 1953.[22] His research also led to the development of recombinant DNA[23] technologies in the 1970s; these events formed the cornerstones of modern biotechnology.[24] In 1989, Australia was the first nation in the world to approve the sale of a genetically modified organism.[25] Over time, the introduction of GM products into the daily lives of many Americans has increased exponentially. By 2016, ninety-three percent of cotton, ninety-four percent of soybean, and ninety-two percent of corn acreage in the United States was genetically modified.[26]

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21. *Policy Brief: Modern Biotechnology and the OECD*, OECD OBSERVER (Org. for Econ. Co-operation & Dev.), June 1999, https://perma.cc/6YEE-6NEW.

22. *See* Leslie G. Restaino et al., *Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?*, 2 UCLA J. L. & TECH. 1 (2003).

23. Recombinant DNA is a molecule consisting of segments of DNA from different genomes that have been joined end-to-end outside of living cells and have the capacity to infect some host cell being maintained therein. Anthony J.F. Griffiths, *Recombinant DNA Technology*, ENCYCLOPEDIA BRITANNICA, https://perma.cc/KWE8-6HB9 (last visited Dec. 19, 2017).

24. Restaino et al., *supra* note 22.

25. Carlos Scott Lopez, *Intellectual Property Reform for Genetically Modified Crops: A Legal Imperative*, 20 J. CONTEMP. HEALTH L. & POL'Y 367, 370 (2004).

26. *Recent Trends in GE Adoption*, U.S. DEP'T OF AGRIC. ECON. RES. SERV., https://perma.cc/AP5G-6F63 (last updated July 12, 2017).

1. Benefits of Genetically Modified Crops

There are vast potential benefits to the use of GM crops: more productive harvests, improved food quality—such as vitamin-enriched products, and decreased dependence on environmentally dangerous chemicals and pesticides.[27] Higher quality crops, including those genetically modified to resist disease, can be produced in greater quantities, more than meeting market demand and leading to decreased hunger.[28]

Concerns about environmental impacts of GM foods have tended to be regulated by applying or adapting existing provisions of environmental law.[29] Today, many crops are genetically modified to be resistant to pests, grow more quickly, and produce higher yields.[30] Because they often require fewer natural resources to grow, these crops are also less taxing on the environment.[31] Yet, a heated debate continues regarding whether planting genetically modified crops actually increases yields. For example, a 2008 article published in Britain's *The Independent* referenced an authoritative new study demonstrating that genetically modified soy produced ten percent less food than the non-genetically modified variety.[32] However, no conclusive scientific evidence has surfaced to indicate significant health or environmental threats unique to GM crops.[33]

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

28. *See* George E.C. York, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agricultural Trade,* 7 COLUM. J. EUR. L. 423, 429 (2001).

29. Dr. Andrew W. Torrance, *Intellectual Property as the Third Dimension of GMO Regulation*, 16 KAN. J.L. & PUB. POL'Y 257, 262 (2007).

30. Julie Teel, *Rapporteur's Summary of the Deliberative Forum: Have NGOs Distorted or Illuminated the Benefits and Hazards of Genetically Modified Organisms?,* 13 COLO. J. INT'L ENVTL. L. & POL'Y 137, 146 (2002).

31. Lopez, *supra* note 25, at 375.

32. Geoffrey Lean, *Exposed: The Great GM Crops Myth,* INDEPENDENT, Apr. 19, 2008, https://perma.cc/7TSQ-5P4G.

33. Torrance, *supra* note 29, at 271 n.77; *see, e.g.,* Philip J. Dale et al., *Potential for the Environmental Impact of Transgenic Crops*, 20 NATURE BIOTECH. 567 (2002). Evolutionary theory suggests that the probabilities of GM organisms spreading their genes into natural populations are very low. Given the rigors of natural selection, and the unlikelihood that human tinkering will be superior to millions of years of evolution at selecting genetic traits advantageous for survival and reproduction, GM organisms will tend to be less, rather than more, likely to survive in the wild than their unmodified wild cousins. By corollary, any wild organism to which GM genes do spread will tend to survive less well because of those GM genes than their purely non-GM wild cousins. Evolutionary theory suggests that, far from becoming superorganisms that supplant wild biodiversity,

Biotechnological advances might help to meet the goal of sustainable development by improving the efficiency of land use and increasing the amount of available food.[34] Some scholars suggest that genetically engineered crops will reduce world hunger and the likelihood of famine.[35] Yet, other experts say that the cause of world hunger is not the overall lack of food but the lack of accessibility.[36] In fact, eighty percent of the people suffering from hunger live in food-exporting countries.[37]

2. The Negative Impact of Genetically Modified Organisms

"Genetically modified organism" (GMO) refers to a life form that has been altered using recombinant DNA techniques.[38] Biotechnology and GMOs may be a double-edged sword involving both promises for sustainable use or resources through environmentally sound technologies and perils to biodiversity through unexpected harmful interaction with the environment.[39] Genetic drift most commonly occurs through a process called outcrossing, in which domesticated plants hybridize with wild relatives.[40] Modified DNA, like any other form of DNA, is transferred to other plants by cross-pollination.[41] Cross-pollination is the biggest problem, as pollen can stay airborne for hours and be carried by the wind or insects for distances of several kilometers.[42]

GM organisms and the genetic material they carry will tend to disappear quickly after entering natural ecosystems.

34. Yvonne Cripps, *Patenting Resources: Biotechnology and the Concept of Sustainable Development*, 9 IND. J. GLOBAL LEGAL STUD. 119, 127 (2001).

35. *Id.* at 121. *See* ROYAL SOC'Y OF LONDON ET AL., TRANSGENIC PLANTS & WORLD AGRICULTURE (2000), https://perma.cc/SC6E-RVK8.

36. *GMOs: The Wrong Answer to the Wrong Problem, Interview with Rafael Mariano, Head of the Peasant Movement in the Philippines, in* VOICES FROM THE SOUTH, THE THIRD WORLD DEBUNKS MYTHS ON GENETICALLY ENGINEERED CROPS 6-7 (Ellen Hickey & Anuradha Mittal eds., 2003), https://perma.cc/E5N4-RH7D.

37. *Id.*

38. Ramesh Karky & Mark Perry, *The World Trade Organization Obligations and Legislative Policy: Choices in Developing Countries for Biotechnology*, 22 CURRENTS INT'L TRADE L.J. 13, 14 (2013).

39. Cripps, *supra* note 34, at 121-23.

40. Daniel, *supra* note 10, at 262.

41. *Id.*

42. Peter Straub, *Farmers in the IP Wrench – How Patents on Gene-Modified Crops Violate the Right to Food in Developing Countries*, 29 HASTINGS INT'L & COMP. L. REV. 190-91 (2006).

Outcrossing is unavoidable and cannot be stopped by physical barriers or country borders.[43] Sometimes farmers must create buffer areas around their crops in order to protect non-target crops, but these buffer zones are not the solution to genetic drift. In some instances, the Environmental Protection Agency (EPA) has concluded that the imposition of buffer zones is not the most "scientifically appropriate" method for mitigating the risk of exposure to pesticide drift.[44] It only takes one breeding cycle for crops to stray from expectation.

Another problem is that genetically modified crops are inconsistently and inadequately managed.[45] Specifically, the intellectual property rights associated with GM crops are often muddled, inconsistent, or unclear, which could contribute to the interests of key inter-regional, interstate, and international constituents being either ignored, misunderstood, or unprotected.[46] Genetically modified crops cannot be managed; once they are released into the environment, the consequences of their uncontrolled reproduction in the face of decreased biodiversity cannot be predicted.[47]

Food products are modified for many different purposes such as the insertion of antibiotic-resistant genes as marker genes during the research and development process.[48] In recent decades, studies have shown that consumption of animals treated with antibiotics contributes to strains of antibiotic-resistant bacteria in humans.[49] These antibiotic-resistant strains of bacteria cause humans to become more virulently ill for a longer period of time than do antibiotic-susceptible bacteria.[50] The application of biotechnology to farming practices may result in a vicious cycle: GM crops give rise to a contaminated ecological system; the contaminated ecological system to contaminated agricultural products; contaminated products to contaminated food; and contaminated food to contaminated human bodies.[51]

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43. *Id.*

44. *See* Pesticide Action Network N. Am. v. U.S. EPA, 654 F. App'x 887, 888 (9th Cir. 2016).

45. Lopez, *supra* note 25, at 369.

46. *Id.*

47. *Id.* at 377.

48. Tore Midtvedt, Antibiotic Resistance and Genetically Modified Plants, Sept. 25, 2014, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4176670/.

49. Ariele Lessing, *Killing Us Softly: How Sub-Therapeutic Dosing of Livestock Causes Drug-Resistant Bacteria in Humans*, 37 B.C. ENVTL. AFF. L. REV. 463, 464 (2010).

50. *Id.* at 464-65.

51. Young-Gyoo Shim, *Intellectual Property Protection of Biotechnology and Sustainable Development in International Law*, 29 N.C.J. INT'L L. & COM. REG. 157, 206 (2003).

In many countries, the public has already expressed concerns over the regulation of biotechnology, particularly GM crops, and the risks of this technology on health and the environment.[52] In this age of globalization and technology transfer, a recipient nation may receive much more than it bargained or even wished for when it imports organisms or organic material from overseas.[53] The herbicide-resistant crops may lead to increased environmental pollution and increased risks to human health.[54]

Environmentalists argue that it should not be overlooked that diffusions of GM crops can threaten biological diversity because of their unanticipated environmentally unfriendly effects.[55] While the widespread planting of GM crops has led to a decrease in pesticide use, there is an upward trend of herbicide use to prevent weeds.[56] Herbicides can be applied broadly and in significant quantities across wide areas without fear of damage to the crops in question, but there is a risk of chemical infiltration into water supplies.[57] Powerful pesticides can produce undesirable new creatures such as new resistant pests that humans cannot control and ultimately lead to serious imbalances in ecology.[58] These pesticides pose a significant environmental problem because large doses of the chemicals can harm biodiversity and increase water and air pollution over time.[59] Most of the long-term effects of GM crops are uncertain. Pests that are targeted by these agricultural methods can adapt to pesticides in addition to the DNA changes in GM plants that make them "resistant."[60] This means that pesticide-resistant crops will not always be effective, and their toxic legacies could remain.[61]

Pest-resistant crops often fail to distinguish between harmful and ecologically desirable insects, and thus cause imbalance in ecosystems.[62] Because GM crops are often bred to be resistant or immune to pesticides and herbicides, farmers feel more free to use these toxic substances, which

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52. Karky & Perry, *supra* note 38, at 20.

53. Cripps, *supra* note 34, at 126-27. For example, various countries were concerned about seemingly environmentally sound cattle and cattle embryos imported from the United Kingdom at the height of the "mad cow" epidemic.

54. *Id.* at 122.

55. Shim, *supra* note 51, at 164.

56. Caroline Newman, *Largest-Ever Study Reveals Environmental Impact of Genetically Modified Crops*, PHYS.ORG (Sept. 16, 2016), https://perma.cc/2WMJ-LE8S.

57. Cripps, *supra* note 34, at 122.

58. Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOs Imperil Biosafety?,* 9 IND. J. GLOBAL LEGAL STUD. 461, 475-76 (2001).

59. Newman, *supra* note 56.

60. Emily Glass, *The Environmental Impact of GMOs*, ONE GREEN PLANET (Aug. 2, 2013), https://perma.cc/2RC9-X7VT.

61. *Id.*

62. Cripps, *supra* note 34, at 122.

often negatively affect non-target beneficial organisms, such as bees and butterflies.[63] In 1999, a Cornell University study found that GMOs containing pesticides, such as Bt-corn,[64] caused harm to Monarch butterfly larvae, which are beneficial insects.[65] Genetic engineering also leads to the use of fewer varieties of crops in favor of those deemed most efficient.[66] Monoculture also greatly enhances risk from pests and diseases.[67]

Farmers and consumers, especially in Europe and developing countries, who worry about genetically modified products' unidentified hazards to human health and the environment, among other impacts, often oppose the extensive introduction of GMOs.[68] Thailand has extended a ban on all GMOs and decided to maintain the ban until national biosafety regulations are developed.[69] India has limited cultivation of GM cottonseeds since 2002 and postponed Bt-eggplant cultivation until it is proven safe for human health and the environment.[70] There is doubt as to these developing countries' ability to conduct thorough risk assessments of GM products.[71]

Without the promise of exclusivity, no biotechnology company would have the financial incentive to commit to research and development.[72] There is evidence that allowing such patents inevitably creates monopolies of biotech companies, which hampers scientific progress and is therefore not in the public interest.[73] When inventors—including universities—have a direct financial stake in the outcome of their research, this patent protection

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63. Glass, *supra* note 60.

64. Bacillus thuringiensis ("Bt") is a naturally-occurring bacterium found in soil that possesses an unusual property: it produces a protein that kills certain crop-destroying insects. While the Bt protein is a natural pesticide, it is not harmful to humans, animals, or beneficial insects like bees and ladybugs. Monsanto Co. v. Mycogen Plant Sci., Inc., 61 F. Supp. 2d 133, 140 (D. Del. 1999).

65. Carol Kaesuk Yoon, *Altered Corn May Imperil Butterfly, Researchers Say*, N.Y. TIMES, May 20, 1999, http://www.nytimes.com/1999/05/20/us/altered-corn-may-imperil-butterfly-researchers-say.html.

66. Cripps, *supra* note 34, at 122.

67. *Id.*

68. Shim, *supra* note 51, at 177.

69. Karky & Perry, *supra* note 38, at 17-18; *See GMO Update: US-EU Biotech Dispute; EU Regulations; Thailand*, BIORES (Sept. 10, 2004), https://perma.cc/7Q4A-X8N4.

70. *India Puts on Hold First GM Food Crop on Safety Grounds*, BBC NEWS (Feb. 9, 2010), https://perma.cc/5NK5-8JL2.

71. Karky & Perry, *supra* note 38, at 18.

72. Strauss, *supra* note 20, at 302.

73. *Id.; see* FOOD SAFETY DEP'T, WORLD HEALTH ORG., MODERN FOOD BIOTECHNOLOGY, HUMAN HEALTH & DEVELOPMENT: AN EVIDENCE-BASED STUDY 55 (2005), https://perma.cc/YWC9-ESJC.

may discourage the inventors' inquiry into the risks of their developed technology. This practice can potentially divert research from sustainability and environmentally friendly alternatives.[74]

B. Terminator Technology

In 1998, Delta and Pine Land Company (D&PL) and the United States Department of Agriculture (USDA) acquired a patent for a genetically modified seed called Technology Protection System.[75] This became known as "terminator technology."[76] Terminator technology[77] is a genetically engineered suicide mechanism that causes the next generation of a seed to self-destruct through self-poisoning.[78] This technology can replace the "technology agreement" that seed manufacturers, such as the powerhouse Monsanto, require farmers to sign.[79] Terminator technology works by creating lots of toxic protein in the embryo of the seed that will kill the cells of the plant's seeds.[80]

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74. 35 U.S.C.A. §§ 200-211 (2012); 37 C.F.R. § 401 (1989); 45 C.F.R. § 650 (1992).

75. Samantha M. Ohlgart, *The Terminator Gene: Intellectual Property Rights vs. The Farmer's Common Law Right to Save Seed*, 7 DRAKE J. AGRIC. L. 473 (2002). *See* U.S. Patent No. 5,723,765 (issued Mar. 3, 1998).

76. Strauss, *supra* note 20.

77. *Id.* This technology has since been purchased by Monsanto. U.S. Patent No. 5,977,441 (filed Nov. 2, 1999); U.S. Patent No. 5,925,808 (filed July 20, 1999); U.S. Patent No. 5,723, 765 (filed Mar. 3, 1998).

78. Ohlgart, *supra* note 75.

79. A Technology Agreement must be signed by farmers prior to seed purchases for a range of crops and Monsanto patents. It is described as a "limited license" between the grower and Monsanto to use RR soybeans, etc. The grower agrees to: (1) Acquire seed only from a seed company licensed by Monsanto; (2) Use seed "solely for planting a single commercial crop;" (3) "Not to save or clean any crop produced from Seed for planting, not to supply Seed produced from Seed to anyone for planting, not to plant seed for [seed] production" and; (4) Not to plant or transfer "for crop breeding, research, or generation of herbicide registration data." *See* Monsanto Technology/Stewardship Agreement, Monsanto (2011), https://perma.cc/MZE9-TK5R (providing, at clause 14, the several patents to which the farmers were to be bound).

80. Martha Crouch, *How the Terminator Terminates: An Explanation for the Non-Scientist of a Remarkable Patent for Killing Second-Generation Seeds of Crop Plants*, EDMONDS INSTITUTE (Revised ed. 1998), https://perma.cc/S3RK-RL2J. The preferred toxin is the ribosome inhibitor protein because it is non-toxic to organisms other than plants. *Id.*

1. History of Terminator Seeds

Previously, farmers relied on saved seeds with the most beneficial characteristics for the production of the next year's crop, a right given to them by the Plant Variety Protections Act.[81] In its decision in *Asgrow Seed Co. v. Winterboer*, the 1995 U.S. Supreme Court narrowed this common law right to save seeds to only cover farmers who saved seeds to replant on his or her own property.[82] Since the terminator gene does not allow a seed to germinate, the farmers that plant those seeds can no longer save any to replant next season.[83]

In 1998, Monsanto agreed to buy D&PL, then withdrew its application and instead announced that it would not use the terminator technology.[84] Monsanto made this decision in response to insistent protests by farmers, environmental groups, and development agencies. Terminator technology would have severe consequences on farmers around the world, especially those in developing countries who depend on saving seeds to replant from year to year.[85]

Other companies, such as Pioneer Hi-Bred, Rhone Poulenc, and DuPont, have developed similar techniques to produce sterile seeds.[86] With the recent news of the merger of Monsanto and Bayer,[87] along with some other biotech companies, there is little doubt that the initial promises not to deploy terminator seeds have been overthrown by new realities.[88]

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81. Plant Variety Protection Act, 91 Pub. L. No. 577, § 113, (84 Stat. 1542); *see also* Jeremy P. Oczek, *In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seeds*, 41 B.C. L. REV 627, 647 (2000).

82. Asgrow Seed Co. v. Winterboer, 513 U.S. 179 (1995).

83. Ohlgart, *supra* note 75.

84. Yves Savidan, *Terminator Genes: Fertility Rights*, THE ECONOMIST, Oct. 9, 1999, at 104. At the time the announcement was made, Monsanto's Chief Executive Officer explained that "Though we do not own any sterile seed technology, we think it is important to respond . . . by making clear our commitment not to commercialize gene protection systems that render seed sterile."

85. Paul Brown, *Monsanto Drops GM "Terminator,"* THE GUARDIAN (Oct. 4, 1999), https://perma.cc/GKF5-RUFL.

86. Ohlgart, *supra* note 75.

87. Krishnadev Calamur, *Bayer and Monsanto's Mega Merger*, THE ATLANTIC, Sept. 14, 2016, https://perma.cc/ZK47-FREY.

88. Ikechi Mgbeoji, *The "Terminator" Patent and Its Discontents: Rethinking the Normative Deficit in Utility Test of Modern Patent Law,* 17 ST. THOMAS L. REV. 95, 121 n.111 (2004).

> Two new terminator patents that were applied for and issued after the promises were made include: US Patent 6,297,426, issued October 2,

As the use of genetically modified seeds has increased and the development of these seeds has become more competitive, large manufacturers have realized there is more long-term value in the use of terminator technology.[89] A Monsanto spokesperson claimed that the technology is simply "a way to protect their [company's] billions of dollars of investment into research on biologically-engineered products."[90]

2. Purpose of Terminator Seeds

While patents are generally designed to transfer valuable information to the public after the duration of the patent term, terminator seeds ensure that the ultimate control of the genetic traits of the patented life form remains in the hands of the seed developer, at least until the patent expires.[91] Because the seeds cannot reproduce, this technology ensures that a farmer cannot use the seed for his own crop and also sell the seed for a profit. This mechanism encourages manufacturers to spend more time and money developing new and helpful farming techniques, but in the long term, farmers suffer harm because they have to rely more heavily on technology developers to supply their seed. While this technology may be beneficial for the manufacturers that develop it, the effects of these seeds reach farther than the farmers that plant them. Spreading of these seeds through common cross-pollination could have a catastrophic impact on the global food supply.[92] If the terminator gene is crossbred with conventional crop varieties through outcrossing, the gene could wipe out entire fields.

2001 and US Patent 6,228,643, issued May 8, 2001. According to the ETC Group, the former describes "the identification and inactivation of a native gene critical to female fertility. This gene is cloned, linked to an inducible promoter and inserted into the plant. The result is a plant that is functionally female sterile with inducible female fertility. This approach involves chemical control of female fertility and its extension to other seed lines …." Id. Another concern about terminator patents is that they probably help to consolidate the seed industry in a few powerful conglomerates such as Monsanto, Mycogen, Novartis. However, there is considerable debate on whether such consolidation is necessarily harmful to society.

89. Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World*, 3 NW. J. TECH. & INTELL. PROP. 160, 168 (2005).

90. *Id.*

91. Mgbeoji, *supra* note 88, at 97.

92. Strauss, *supra* note 20, at 300 n.89.

3. Recent Reactions to Terminator Technology

In 2000, the United Nations' Convention of Biological Diversity (CBD) implemented a de facto moratorium on sterile seed technologies under the term "Genetic Use Restriction Technologies" (GURTs).[93] In 2006, parties voted to extend the moratorium.[94] Despite pressures over time from Canada, Australia, New Zealand, the United States, and from the biotechnology industry as a whole, the CBD has nevertheless maintained its stance.[95] Yet, a large and growing body of scientific studies into the human health and environmental safety of GMOs and GM crops has failed to reveal significant justification for the extreme precautionary approach adopted by the United Nations.[96] There is a fear that the moratorium will not last much longer, especially as long as the United States continues to pressure the UN; a long-term solution is needed.

In 2000, a group of more than three hundred scientists voiced concern about genetically modified seed plants, as well as related terminator technology, in a letter to the Fifth Conference of the Parties (COP) Convention on Biological Diversity, stating: "we call for the immediate suspension of the release of [terminator] crops and products, both commercially and in open field trials."[97] Numerous environmental non-governmental organizations condemned the technology as a threat to agricultural food security.[98] Some countries such as India, Ghana, and Panama have gone so far as to take steps to place a moratorium on the so-called terminator seed technology in their own countries.[99] Even the USDA, which was a former developer of terminator technology, was instructed by the Clinton Administration to discourage further terminator research.[100]

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93. *Id.* at 300.

94. Mario Osava, *Ban on Terminator Seed Field Trials Continues*, INTER PRESS SERVICE (Mar. 24, 2006), https://perma.cc/5FVL-C6WT.

95. Strauss, *supra* note 20, at 300. *See also UN Upholds Moratorium on Terminator Seed Technology*, ETC GROUP (Mar. 31, 2006), https://perma.cc/KPY3-BCQV.

96. Torrance, *supra* note 29, at 284.

97. Wandera Ojanji, *Suspend GM Crops for Five Years - Scientists,* THE EAST AFRICAN, May 29, 2000.

98. Nigel Hawkes, *War on Killer Seed*, TIMES, Nov. 4, 1998; *See also* Rob Edwards, *US Officials Fear a Backlash Over 'Terminator Technology,'* NEW SCIENTIST, 2121, Feb. 14, 1998.

99. Press Release, ETC Group, Traitor Resolutions? (June 25, 1999), https://perma.cc/E9Q6-FZGV; Hawkes, *supra* note 98; *See also* Edwards, *supra* note 98.

100. Edwards, *supra* note 98.

C. The Benefits and the Burdens of Balancing Crops with Terminator Technology

There are two main benefits to terminator seeds: incentivizing research and reducing the need for contracts.

1. Benefits of Terminator Seeds

Plant breeders benefit from increased appropriation of research benefits from new products.[101] Terminator seeds may increase productivity from improved inputs due to increased research and development investment.[102] Also, there is evidence of increased agricultural productivity.[103] Terminator technology seeds enable farmers to activate or deactivate genetic traits such as disease resistance.[104] The self-destruct mechanism embedded in each plant containing the terminator demonstrates the essence of corporate domination over these natural resources and may offer better monopoly control than patents.[105]

Part of the attraction of terminator seeds for biotechnological seed merchants is that they dispense with the need for license agreements and end-user contracts between seed merchants and farmers.[106] Until recently, the U.S. Department of Agriculture not only freely developed and distributed seeds but also encouraged farmers to save seeds.[107] Seed saving is an ingrained part of agriculture, and today over eighty percent of farmers in developing nations rely on saved seeds for survival.[108] In fact, the American agriculture industry is built upon sharing seeds from around the world.[109] Yet, the introduction of terminator technology effectively eliminates the opportunity for farmers to save seed. Without the ability to save seeds, farmers in developing countries lose a large part of their livelihood.

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101. Mgbeoji, *supra* note 88, at 103.
102. *Id.*
103. *Id.*
104. Derek Eaton et al., *Economic and Policy Aspects of "Terminator' Technology*, 49 BIOTECHNOLOGY & DEV. MONITOR 19-22 (2002).
105. Strauss, *supra* note 20, at 301.
106. Mgbeoji, *supra* note 88, at 114.
107. Oczek, *supra* note 81, at 631.
108. Ohlgart, *supra* note 75.
109. Oczek, *supra* note 81, at 631.

2. Harms of Terminator Seeds

There are both moral and health-related downsides to this technology. Risks of terminator seeds include risks of misuse of technology by plant breeders, danger of corporate vertical integration, increased risk of seed insecurity, impediment to access to genetic improvements, and genetic pollution and sterilization of otherwise fertile seeds.[110] The Food and Agriculture Organization of the United Nations' Panel of Eminent Experts on Ethics in Food and Agriculture noted "the Panel unanimously stated that the 'terminator seeds' generally are unethical, finding it unacceptable to market seeds."[111]

Experts are also concerned about human and animal health; the introduction of one or more genes from completely unrelated organisms might produce toxins or allergens in the final food product.[112] Plant genetic engineers desirous of creating a terminator gene and expressing it in a plant would take the promoter from a gene normally activated late in seed development and fuse that promoter to the coding sequence of a protein that will kill an embryo going through the last stages of development.[113] The engineers often use a promoter from a cotton gene, which is toxic, so when this gene is embedded to create terminator technology, the final crop may not be edible to either humans or animals because of the increased toxicity of the seeds.[114] There are potential changes to the nutritional contents and value of the seeds that have had several proteins in them destroyed by artificially induced toxic agents.[115] The toxins in these seeds may cause allergic reactions, particularly if they are mixed up in the general food supply chain without adequate warning or notice to the public.[116]

In order to activate the toxin gene in seeds with terminator technology, the germinating seeds are soaked in antibiotics, such as tetracycline, before

110. Mgbeoji, *supra* note 88, at 103.

111. *Id.* at 115 n.77.

112. Karky & Perry, *supra* note 38, at 17. Soybeans, for example, are low in the amino acids methionine and cysteine, so people whose diets are soybean-based face a nutritional deficiency. Researchers responded by transferring a gene from Brazil nuts which codes for large amounts of these acids. While they initially saw a great opportunity, these researchers were ultimately disappointed by the fact that the protein was *also* an allergen.

113. Mgbeoji, *supra* note 88, at 101.

114. *Id.* at 119.

115. *Id.*

116. *Id.*; *see* Convention on Biological Diversity, Consequences of the Use of the New Technology for the Control of Plant Gene Expression for the Conservation and Sustainable Use of Biological Diversity, U.N. Doc. UNEP/CBD/SBSTTA/4/9/Rev.1 (May 17, 1999).

the seeds are sold to the farmers.[117] Throughout this process, there is a lot of tetracycline to handle and dispose, and large-scale agricultural uses of antibiotics are already seen as a threat to the overall well-being of society.[118] Further, soil ecology can suffer due to the increased tolerance of bacteria, residual, or waste antibiotics.[119]

D. Summary of Balancing

There is no clear and undisputed scientific evidence that GM products are either good or bad for human, animal, and plant health and life.[120] Not all genetically modified organisms are inherently "evil," yet the potential unknown harms of GM crops embedded with terminator technology are cause for concern. The risk of cross-pollination is most concerning because once crops with the terminator gene are planted in an open air environment, there is no way to prevent cross-pollination of that destructive gene.

Unfortunately, there is no international mechanism to deal with the danger that accompanies GM crops embedded with terminator technology. It is too unrealistic to expect each individual country to recognize and mitigate this danger on its own.[121] Since it is impractical to confront this issue on a country-by-country basis, an international regime would be the ideal solution. Yet, knowing that such a vast international change may be difficult and time-consuming, nation-by-nation action is still beneficial and will hopefully encourage other countries to follow suit.

II. PATENTS AS INCENTIVES

A. Patent Theory

Since the government generally rejects raw natural material for patent approval, scientists are unable to receive patents for agriculture until they can prove that the food was truly "man-made" through genetic engineering.

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117. Mgbeoji, *supra* note 88, at 101.
118. *Id.*
119. *Id.*
120. Karky & Perry, *supra* note 38, at 17.
121. Even if a country recognizes this danger and sees fit to rid their land of this technology, the elimination process would not be easy. The lack of hard evidence, combined with the limited political desires to implement such a regime, adds difficulty. Countries could seek to ban all types of patents, but doing so would remove the incentive for scientists to research and develop beneficial inventions. Alternatively, countries could seek to ban all GMOs, but, again, that would be too unrealistic to implement, as there are some GMOs that offer benefits to society.

Today, one of the main motivations for developers of GM crops is the promise of patent protection and control, even if only for a limited period of time. Patents are a type of indirect funding for genetically engineered agriculture in that they provide incentives for parties to undertake expensive and risky research; they also induce upfront funding of projects with the expectation that monopoly profits can be generated over the long term.[122]

The quick-paced development process of GM crops leaves little time to fully determine the potential harms of releasing these seeds into the environment. Once harmful GM crops are released into the environment on a broad scale, their potential impact is unknown, and any chance to reverse any resulting environmental degradation dramatically decreases.

B. The History of Plant Patenting, Biotechnology, and Genetically Modified Crops

1. The Global Development of Biotechnology

Biotechnology, as defined by the United Nation's Convention of Biological Diversity, is "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[123] The CBD acknowledges an implicit value in nature itself, recognizing: "biological diversity is about more than plants, animals, and microorganisms and their ecosystems – it is about people and our need for food security, medicines … and [a] healthy environment in which to live."[124]

2. Plant Patents in the United States

Until 1930, plants and seeds were not considered patentable material in the United States because they were a product of nature and therefore not amenable to the written description requirement for patents.[125] This changed in 1930 when Congress passed the Plant Protection Act (PPA), which granted patent rights to plant breeders as long as the plant met the three eligibility requirements of a patent: novelty, utility, and non-obviousness.[126]

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122. Margo A. Bagley, *Patents First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 474 (2003).

123. United Nations Convention on Biological Diversity art. 3, June 5, 1992, 31 U.N.T.S. 818.

124. Strauss, *supra* note 20, at 308.

125. Stein, *supra* note 89, at 164-65.

126. *See* U.S. Plant Patent Act of 1930, 35 U.S.C. § 161 (2003).

For forty years, the PPA served as the only source of intellectual property rights for inventions that contained living matter, but these rights only extended to asexually reproduced plants.[127] Congress enacted the Plant Variety Protection Act (PVPA) in 1970, which gave plant breeders twenty years of patent protection for any plant variety that is new, distinct, uniform, and stable; this protection, though, came with a few exceptions.[128] The series of biotech patenting cases that followed in the 1980s and 1990s expanded the legal boundaries of patentable living matter but also narrowed the traditional seed-saving exemption codified by the PPA.[129]

3. Patenting Genetically Modified Organisms

As the creation and production of biotechnology products has rapidly grown, courts in the U.S. and all over the world have been confronted with issues regarding whether these organisms should qualify for patent protection. In the landmark case *Diamond v. Chakrabarty*, the Supreme Court of the United States held that a live, genetically engineered microorganism came within the scope of patentable subject matter under 35 U.S.C. § 101.[130] The Court declared that "anything under the sun that is made by man" is patentable.[131] In *Ex Parte Hibberd*, the U.S. Board of Patent Appeals and Interferences held that the PPA and PVPA were not the only sources of patent protection for plants.[132] The broad category of utility patents also allowed plant patents. Currently in the United States, most biotechnology applications are pursued under utility rather than plant patents.[133]

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127. *Id.*

128. The PVPA did not allow protection for seeds saved by farmers and seeds used for research purposes. Strauss, *supra* note 20, at 293.

129. Stein, *supra* note 89, at 166; *see also* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

130. *Diamond*, 447 U.S. 303. 35 U.S.C. § 101 states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

131. *Diamond*, 447 U.S. at 309.

132. Ex Parte Hibberd, 227 U.S.P.Q. (BNA) 443 (1985).

133. Lara E. Ewens, *Seedwars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*, 23 B.C. INT'L & COMP. L. REV. 285, 293 (2000). Instead of only protecting the plant, utility patents make protection of plant genes possible, as well as allow the breeder to protect the use of the genetic material of a number of plants and to protect for multiple uses such as pharmaceutical, pest protection, and herbicide resistance.

In 1986, the United States allowed the first patent covering a genetically engineered variety of corn that was modified to have increased nutritional value.[134] By 1996, the first patented genetically modified and commercially-grown food crops were planted in America.[135] The Supreme Court confirmed patentability of plants and seeds in the U.S. in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, which emphasized that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[136]

4. History of Patenting Genetically Modified Crops Around the World

The U.S. has taken a more lenient position than Canada or the European Union (EU) in allowing patents of plants and plant varieties. Over time, the U.S. consistently expanded its definition of patentable plant material, while the EU has expressed more caution. A major goal of the United States during the TRIPS negotiations was to obtain comprehensive intellectual property protection for its agricultural biotechnology industry.[137]

In 2004, the EU enacted a fundamentally revised legal system for regulating GMOs, which served as the foundation of the EU's policies of tight safety standards and freedom of choice for consumers and farmers.[138] Canada does not consider animals and plants—genetically modified or otherwise—to constitute subject matter statutorily eligible for patent protection.[139]

C. Considering Morality

1. The Development of the Morality Doctrine

Under early American case law, courts developed and applied a doctrine of "moral utility," which rejected patents for inventions that were considered "injurious to the well-being, good policy, or sound morals of

134. Lopez, *supra* note 25.

135. Stein, *supra* note 89, at 164.

136. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 130 (2001) (quoting *Diamond*, 447 U.S. at 313) (upholding the patentability of hybrid corn seed and newly developed plant breeds).

137. Straub, *supra* note 42, at 187.

138. JOANN CHIRICO, GLOBALIZATION: PROSPECT AND PROBLEMS 420 (2013).

139. Torrance, *supra* note 29, at 265.

society."[140] Later, in *Juicy Whip v. Orange Bang*, the Federal Circuit held that a product's deceptive nature has no effect on its utility, and therefore, its patentability.[141] In place of the concept of negative utility, courts support a concept of beneficial or nominal utility; a nominal showing of any beneficial use is enough for patentability in the U.S.,[142] regardless of arguably negative effects.[143] Over time, courts rejected the past practice of denying patentability on the grounds of morality, such as with gambling devices, or because the invention might injure health, such as with drug safety.[144] Instead, the United States Patent and Trademark Office (USPTO) primarily considers the positive utility of the invention, employing a "patent first, ask questions later" approach.[145] Through employment of this method, the U.S. has decided to issue patents to all useful inventions, even if they could have potential to create a hazard.[146]

On the other hand, the EU exercises extreme caution when it comes to patenting potentially hazardous inventions, taking the "ask questions first, then patent" approach.[147] There are numerous other countries with statutory provisions allowing inventions to be excluded from patentability on the basis of morality; thus, it is not surprising that in the TRIPS negotiations, this large group of countries was able to incorporate a morality provision into the agreement despite opposition from the United States.[148]

2. Application of the Morality Doctrine in the United States

A combination of the demise of the moral utility doctrine and the expansive judicial interpretations of the scope of patent-eligible subject

140. Carolyn Abbot & David Booton, *Using Patent Law's Teaching Function to Introduce an Environmental Ethic into the Process of Technical Innovation*, 21 GEO. INT'L ENVTL. L. REV. 219, 227 (2009).

141. Juicy Whip v. Orange Bang, 292 F.3d 728, 745 (2002).

142. *See, e.g.,* Brenner v. Manson, 383 U.S. 519 (1966).

143. Harper, *supra* note 17, at 414.

144. *Id.*; *see generally* Ex Parte Murphy, 200 U.S.P.Q. 801 (Bd. App. 1977) (declaring a slot machine patentable despite the fact that gambling devices are generally harmful to the morals of the public); *see also* Application of Anthony, 414 F.2d 1383 (C.C.P.A. 1969) (holding that an anti-depressant drug satisfies the usefulness requirement despite the fact that it causes some unwanted side effects).

145. Bagley, *supra* note 122.

146. The only exception to this general rule is found in the American Invents Act, passed in 2011, which prohibits the issuing of patents on a claim directed to or encompassing a human organism. *See* American Invents Act, § 33 (125 Stat. 284) (2011).

147. Bagley, *supra* note 122, at 480.

148. TRIPS Agreement, *supra* note 14, art. 27.2.

matter has resulted in virtually no basis on which the USPTO or U.S. courts can deny patent protection to morally controversial, but otherwise patentable, subject matter.[149] Instead, patent applicants and scientific inventors are deciding matters of public policy through the contents of the applications they file with the USPTO.[150] Some experts argue that denying patents on morally controversial inventions will not stop the underlying research that is the source of public apprehension.[151] While morally controversial inventions may cause temporary ethical concern, these experts believe that, in the end, the underlying research could reap beneficial results.[152] Failing to grant patents on promising technology because of public misunderstandings of science may hinder important discoveries and deny life-saving cures to millions of people.[153] Yet, when it comes to the dangerous terminator technology, it is necessary for individual countries to take steps toward determining that these inventions are immoral and therefore do not meet the basic requirements for patenting.

D. Patents are Beneficial to Society

Patents are beneficial to society because they encourage innovation and progress. By offering exclusive use and distribution of an invention for a period of time, patents reward inventors with funding they can use for research and development of future beneficial inventions. Countries

149. Bagley, *supra* note 122, at 470.

150. *Id.*

151. *See, e.g.,* Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 459 (1999) ("The ethical concerns . . . about biotechnology inventions do not actually relate to the patenting of such inventions, but to whether these inventions should be created at all."); *see also* Carrie F. Walker, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1026 (1998) (arguing that eventually, it will become apparent that the root of the debate about patents for biotechnology has less to do with patent law and more to do with fundamental concerns about the science itself).

152. Magnani, *supra* note 151.

153. *See*, *e.g.*, Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1075 (1988) (arguing that patents on new technology should be granted, reserving the right to regulate specific applications; "this is the only sensible course"); Keith Schneider, *Harvard Gets Mouse Patent, A World First*, N.Y. TIMES, Apr. 13, 1988, at A22 (quoting then-Commissioner of Patents Donald J. Quigg as citing the transgenic mouse's potential to hasten the development of cancer treatments as an important factor in granting the patent and saying, "but how can anybody say this kind of development is unethical or wrong?").

should continue to allow the issuance of patents for most beneficial GM crops, but countries should also have the ability to cut off the incentives for the development of GM crops embedded with terminator technology. Once these crops are no longer patentable, the economic value of developing such inventions diminishes, leading inventors to seek development of more beneficial agriculture technology instead. It is best to allow countries to refuse patenting of terminator technology, which is justified by the TRIPS Agreement, an international agreement that already has such a refusal mechanism in place.

III. THE HISTORY AND PURPOSE OF THE TRIPS AGREEMENT

In 1994, the Uruguay Round of the General Agreement on Tariffs and Trade (GATT)[154] officially recognized that there is a relationship between free trade and environmental quality. GATT created the TRIPS Agreement with the intent to unify international intellectual property rights as a step towards the liberalization of trade.[155] Twenty-two years later, many questions are still unanswered regarding the implications of this Agreement. To best protect the future of the environment on a global level, a clear international interpretation of this Agreement is necessary.

A. The Creation and Purpose of the TRIPS Agreement

Before TRIPS, the preeminent authority pertaining to international patent law was the Paris Convention for the Protection of Industrial Property, but this Convention was mainly procedural.[156] At that time, countries basically had freedom to create their own rules and regulations regarding the power to patent. International patent law changed when the 1994 Uruguay Round of GATT negotiations resulted in both the World Trade Organization (WTO) and the TRIPS Agreement. TRIPS, a combination and expansion of multiple forms of pre-existing intellectual property standards, was the first multinational agreement to address these issues, including the scope of international intellectual property rights, the

154. The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 17, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 154, 33 I.L.M. 1144.

155. TRIPS Agreement, *supra* note 14, pmbl. (explaining the desire "to reduce distortions and impediments to international trade").

156. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305. The Paris Convention entrusted the protection of industrial creations primarily to the various kinds recognized by the laws of the countries of the Union.

means to enforce those rights, dispute resolution, the applicability of earlier international agreements, and transitional arrangements.[157]

One of the most controversial aspects of the Uruguay Round of GATT negotiations was the United States' insistence in intellectual property jurisdiction based on the goals articulated for its own private interests.[158] The goals of both the most-developed and least-developed countries were codified in the TRIPS Agreement. This Agreement harmonizes and strengthens international intellectual property protection by protecting technological inventions that meet general conditions, provided they do not fall within the few exceptions for inventions that are contrary to the Member State's morals.[159] There was sufficient support among the GATT member nations to include this restrictive provision in Article 27.2, even though it is contrary to the municipal law of the United States and other industrial countries.[160]

1. Implementation of the TRIPS Agreement

Article 7 of TRIPS mentions that the protections and enforcement of intellectual property rights should contribute to social and economic welfare.[161] By linking intellectual property rights to trade, the WTO made compliance with TRIPS mandatory for member countries.[162] Under Article 16.4 of the WTO agreement and Article 1.1 of the TRIPS

157. Harper, *supra* note 17, at 391; *see also* TRIPS Agreement, *supra* note 14, pmbl.

158. *See generally* Susan K. Sell, *Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS, and Post-TRIPS Strategies*, 10 CARDOZO J. INT'L & COMP. L. 79 (2002). Throughout 1985 and 1986, lobbyists pressed the government to follow through with trade pressure to force countries to increase their protection of intellectual property rights. The lobbyists expressed their sentiments more formally through the report of the Advisory Committee for Trade Negotiations' Task Force on IP Right, a task force including the CEO of IBM, John Opel, Vice President and Counsel of the Motion Picture Industry Association, Fritz Attaway, and President of the International Division of Merck & Company, Inc. (at that time, America's largest pharmaceutical corporation), Abraham Cohen.

159. Cripps, *supra* note 34, at 131.

160. Although early U.S. patent law embraced the concept of negative utility, modern cases have rejected it. In its place, courts in the twentieth century have established a new test of utility based on whether the invention is "used or is designed and adapted to be used to accomplish a god result." *See generally* Mills v. Industry Novelty Co., 230 F. 463 (N.D. Ill. 1963).

161. TRIPS Agreement, *supra* note 14, art. 7.

162. J.M. Spectar, *Patent Necessity: Intellectual Property Dilemmas in the Biotech Domain & Treatment Equity for Developing Countries*, 24 HOUS. J. INT'L L. 227, 235-36 (2002).

Agreement, WTO Member States are required to fulfill the obligation prescribed by the Agreement in their domestic law.[163] Implementation of domestic policies regarding Article 27.2, though, is optional. Unlike the case of compulsory licenses, which must be granted case-by-case, Article 27.2 allows each Member State to freely determine that a certain type or category of inventions is not patentable as long as the category falls into one of the exceptions.[164]

2. An Overview of the Structure of TRIPS

TRIPS contains a total of seventy-three articles, yet only two paragraphs in a single article touch on environmental issues.[165] All 159 Member States, including developing and least-developed countries, are obligated to patent all qualified inventions and include some forms of biotechnology law by year 2021, unless TRIPS Articles 27.2 or 27.3 or another exception is used.[166] Generally, the regulatory framework needs to address the following areas of biotech: (1) scope of patentability of biotech innovation; (2) commercialization of genetically modified plants, crops, foods, and other products and scientific risk assessment; and (3) co-existence of genetically modified, conventional and organic farming.[167] TRIPS established a minimum twenty-year term of protection for patents in all WTO member countries.[168]

B. The Morality Doctrine as Interpreted in TRIPS

Throughout history, countries have refused to issue certain kinds of patents due to their moral convictions. Since morality is a vague concept,

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163. Karky & Perry, *supra* note 38, at 15. *See* Marrakesh Agreement, *supra* note 154, art. XIV(a).

164. For example, all inventions relating to cloning of humans are patentable. CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, A COMMENTARY TO THE TRIPS AGREEMENT 291 (2007).

165. *See* TRIPS Agreement, *supra* note 14.

166. Karky & Perry, *supra* note 38, at 15. *See* Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS), *Extension of the 'Transition Period under Art. 66.1 for Least Developed Country Members*, WTO Doc. IP/C/64 (June 11, 2013), https://perma.cc/R2LE-4H2D (providing least-developed countries an extended transitional period up to 2013 to fulfill TRIPS obligations. Now this transitional period has been extended to July 1, 2021.).

167. Karky & Perry, *supra* note 38, at 16 n.59.

168. *See* TRIPS Agreement, *supra* note 14, at 314. Article 33 states, "[t]he term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."

its definition is dependent on national perceptions by patent offices or judges.[169] In the TRIPS Agreement, the only avenue available for Member States to legislate regarding a patent with immoral character is through Article 27. Morality is important to interpretation of Article 27.2 because it allows the individual culture and customs of each country to be considered.

1. Other Countries' Approaches to the Morality Doctrine

Countries that have taken "ask questions first, then patent" approaches to morally controversial subject matter provide an illustrative alternative to the haphazard course the U.S. is currently pursuing.[170] The Canadian Supreme Court demonstrated this approach in its 2002 decision that excluded higher life forms from patent protection, since there was no express statutory authorization for protection from Parliament.[171] Yet, in 2004, the Supreme Court of Canada seemed to take a conflicting route when it extended protection to a patent that claimed genes and cells but not a plant per se.[172] This case presented a way for manufacturers of GM crops in Canada, such as Monsanto Canada, to gain patent protection for the genetically modified components of their plants, even if they could not receive protection for the plant as a whole. On the other hand, India has taken advantage of the patent exception provided in TRIPS Article 27.3 by refusing to allow pharmaceutical patents.[173] In efforts to reduce costs by allowing the production of generic drugs, India has chosen a patent system that brings the most benefit to its citizens.[174]

2. The EPO's Balancing Test

When considering morality, the Examining Division of the European Patent Office (EPO) employs a balancing test, noting that "[f]or each individual invention [involving higher life forms] the question of morality has to be examined and possible detrimental effects and risks have to be

169. CORREA, *supra* note 164, at 288.

170. Bagley, *supra* note 122, at 480.

171. *See* Harvard Coll. v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45 (Can.) (considering the patentability of the Harvard Oncomouse under the Patent Act, the Supreme Court of Canada held that the Oncomouse and higher life forms in general are not patentable subject matter in Canada).

172. Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902.

173. John LaMattina, *India's Solution to Drug Costs: Ignore Patents and Control Prices – Except For Home Grown Drugs*, FORBES (Apr. 8, 2013), https://perma.cc/Y74V-7CC8.

174. *Id.*

weighed and balanced against the merits and advantages aimed at."[175] One problem with the test is that the Examining Division never defined morality or stated a basis, other than instructions from the Technical Board, for choosing those particular factors to balance as opposed to other possible concerns.[176] Different bodies within the EPO articulated two additional morality tests: the unacceptability test and the public abhorrence test.[177]

According to Article 53(a) of the European Patent Convention (EPC), inventions are to be excluded from patentability as being contrary to morality if the exploitation of that invention is not in conformity with the conventionally accepted standards of conduct pertaining to this culture.[178] In *Greenpeace v. Plant Genetic Systems*, the EPO concluded that none of the claims in the patent violated this morality provision of Article 53(a) because they concerned activities (such as production of plants and seeds) and products (plant cells, plants, and seeds) which cannot be considered to be morally wrong.[179] The EPO Board ignored the more specific concerns regarding the patent's subject matter and focused only on the general type of products and activities the patent concerned.[180] Today, TRIPS Article 27.2 seems to be the most natural path through which countries can demonstrate the morality balancing test as applied to genetically modified crops with terminator technology.

IV. INTERPRETATION OF ARTICLE 27.2

A. Interpreting TRIPS Article 27.2 in an Effort to Protect the Environment

When it comes to interpreting the TRIPS Agreement in an effort to protect the environment, much is unclear. For example, TRIPS authorizes the patenting of plants and animals,[181] but it fails to discuss how nations might prevent the destruction of biodiversity.[182] According to the

175. Harvard/Onco-mouse, [1990] E.P.O.R. 501, 527.

176. Bagley, *supra* note 122, at 521.

177. Howard Florey/Relaxin, [1995] E.P.O.R. 541 (Opposition Div.); Lubrizol Hybrid Plants, [1988] E.P.O.R. 173 (Tech. Bd. App.).

178. Harvard/Onco-mouse, [1995] E.P.O.R. 357, 366 (Tech Bd. App.).

179. *Id.* at 370.

180. Bagley, *supra* note 122, at 523.

181. TRIPS Agreement, *supra* note 14, art. 27.3; *see also* Jennifer Schultz, *The GATT/ WTO Committee on Trade and the Environment – Toward Environmental Reform*, 89 AM. J. INT'L L. 423, 436-37 (1995).

182. "Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity

fundamental principle of international treaty interpretation set out in the Vienna Convention, a treaty and the meaning of a term in that treaty shall be determined in accordance with the ordinary meaning to be given to the term in its context and in light of the object and purpose of the treaty.[183] TRIPS accommodates the American view that "anything under the sun made by man" is patent-eligible, as well as the views of many other countries that deny patents on morally controversial inventions.[184]

There are no clear guidelines or standards to use when interpreting the TRIPS Agreement in its entirety. The plain meaning of the statutory language suggests a State may exclude an invention from patent protection if prevention of "commercial exploitation" of that invention in their territory is "necessary" in order to "protect *ordre public* or morality."[185] So far, each Member State has been free to interpret each of these phrases as it sees fit, but there is no evidence that any countries have taken advantage of Article 27.2 in efforts to avoid prejudice to the environment. A universal interpretation needs to be declared so that the Agreement is implemented in similar fashion around the world. There is no official interpretation of Article 27.2 of TRIPS as a whole, but several experts consider 27.2 to be analogous to Articles XX(a) and XX(b) of GATT.[186] In order to derive the most logical interpretation of Article 27.2, each phrase must be analyzed separately.

1. The Geographic Limitations of Article 27.2

The plain meaning of Article 27.2 suggests risks to *ordre public* or morality must come from the commercial exploitation of the inventions and not the invention in itself.[187] While one isolated use of harmful technology may have little impact on the environment as a whole, once aggregated through commercialization, the impact greatly increases. Article 27.2 does not intend to prevent the creation of every single invention that poses a potential risk to *ordre public*, but rather seeks to allow countries to align their patent law with a regime for preventing the commercial exploitation of such inventions. The phrase "within [a Member's] territory"

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within species, between species, and of ecosystems. United Nations Convention on Biological Diversity, *supra* note 123.

183. Shim, *supra* note 51, at 224 n.367.

184. Bagley, *supra* note 122, at 530.

185. Timothy G. Ackermann, *Dis'ordre'ly Loopholes: TRIPS Patent Protection, GATT, and the ECJ,* 32 TEX. INT'L L.J. 489, 492 (1997).

186. Marrakesh Agreement, *supra* note 154.

187. Chris R. Byrnes, *Patenting Life: TRIPS Article 27 & Bolivia's Proposal to Ban the Patenting of all Life Forms*, 24 GEO. INT'L ENVT'L. L. REV. 245, 258 (2012).

also suggests that the impact of the risk must be within the territory of the concerned Member and not that of another.[188] This language creates an environmental protectionism issue because a Member State could implement policies regarding protection of the environment, yet still be negatively affected by a neighboring state's lack of such policy. Over time, these conflicting policies can lead to negative impacts on the environment, even in the Member States that have banned commercial exploitation and patenting. To best prepare for the future, a more comprehensive interpretation of Article 27.2 is needed.

2. Members May Exclude Patents When "Necessary"

A Member State may exclude an invention from patentability if it finds exclusion "necessary" to prevent commercial exploitation of that invention in order to protect *ordre public* or morality.[189] TRIPS gives little guidance when allowing each Member State to decide for itself whether or not the prevention of commercial exploitation of any particular invention fulfills the definition of "necessary."[190]

Articles XX(a) and XX(b) of the GATT exceptions parallel the structure of Article 27.2 with use of the language "necessary to protect public morals" and "necessary to protect human, animal or plant life and health."[191] Beyond acknowledging this parallel structure, GATT dispute resolution does not provide much guidance as to the interpretation of "necessary."[192] Patent restrictions would be considered "necessary" in terms of Article XX(b) only if there were no alternative measures through which a contracting party could reasonably be expected to achieve its policy objectives.[193] Similar to the Article XIV(a) exception in *United States v. Gambling*, Article 27.2 of TRIPS requires a "necessity" test for its exceptions.[194] Therefore, when determining if the exclusion of a biotechnology patent is "necessary," a Member State should consider any

188. *Id.*

189. TRIPS Agreement, *supra* note 14, art 27.2.

190. Ackermann, *supra* note 185, at 493.

191. Byrnes, *supra* note 187, at 254; *see also* Harper, *supra* note 17, at 400-02; UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 378 (2005).

192. Ackermann, *supra* note 185.

193. Robert Weissman, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1103-05 (1996) (discussing the tests and concluding that they are the same).

194. Byrnes, *supra* note 187. "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect . . . ." TRIPS Agreement, *supra* note 14, art. 27.2.

alternatives to excluding the patent and the impact of such alternatives, and then it should compare the impact of the alternatives to the impact of the proposed patent.

3. To Protect Ordre Public

Originally from the French Law,[195] the term *ordre public* is related to the concept of public policy as used in Anglo-American doctrine.[196] The concept of *ordre public* has been derived from "public order" or "public interest" or "wellbeing of the society," and has been incorporated into patent legislation in some jurisdictions like the European Union and the United States.[197] WTO Member States have considerable flexibility in defining the concept depending upon each country's social values.[198]

a. Considering Ordre Public

Member States may only exclude an invention on the basis of *ordre public* where the failure to provide such protection results in exploitation or an offense against the forum's concept of fundamental norms.[199] For example, some countries have expressed the belief that all life forms are sacred and should not be owned through traditional property rights.[200]

195. "Community common sense and common conscience, extended and applied throughout the state to matters of public morals, health, safety, welfare . . . ." *Orde Public*, BLACK'S LAW DICTIONARY (6th ed. 1990).

196. "Courts will not enforce contracts the performance of which would contravene fundamental moral principles . . . or which would offend against some other overriding public interest." M. Forde, *The "Ordre Public" Exception and Adjudicative Jurisdiction Conventions*, 29 INT'L & COMP. L.Q. 259 (1980).

197. Asanka Perera, *The TRIPS Agreement and Protection of Plant Varieties: A More Intense Scrutiny*, 18 SRI LANKA J. INT'L L. 223, 230 (2006).

198. *Id.*

199. Ackermann, *supra* note 185, at 496.

200. For example, Brazil and Thailand refused to recognize pharmaceutical patents but relinquished under pressure by the United States. *See*, *e.g.,* Thammasat Resolution, Dec. 5, 1997, https://perma.cc/NSS8-Z9QC (organizational representatives from 19 countries—including Thailand, Brazil, Costa Rica, Ethiopia, Ecuador, Columbia, Indonesia, Philippines, India, South Africa, and Zambia—opposing the privatization of biodiversity, life forms, and traditional knowledge by TRIPS with nonbinding resolution); *see also* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 65 (2001) (discussing the belief of some developing states that life forms "were considered special and different and not reducible to property rights that might be possessed by some and denied to others"); COMM'N ON INTELL. PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 5-6 (2002), https://perma.cc/GGQ5-6E88 (criticizing "the patenting of life forms on ethical

TRIPS provides a non-exhaustive list of acceptable justifications, including protection of human, animal, or plant life or health and avoidance of serious prejudice to the environment.[201]

Arguably, a country could try to resist granting biotechnology patents through Article 27.2 on the grounds of strong public interest or to protect human health and the environment. However, a similar argument was unsuccessful in the *Harvard Oncomouse* case decided by the EPC.[202] While the WTO standards and EPC standards do not always align, the standards could be applied in an analogous manner. When researchers from Harvard Medical School sought patent protection for a mouse that was genetically modified to be highly susceptible to cancer, the application raised ethical concerns.[203] In considering this patent, the EPO discussed whether patents should be extended to life forms as a whole, particularly for higher-order animals such as mammals.[204] While the United States quickly granted the patent for the mouse in 1988, the EPO took longer to analyze the dilemma but reached its final decision in 2004.[205] The EPO applied Article 53(a) of the European Patent Convention and developed a utilitarian balancing test, assessing the potential benefits of the claimed invention against negative aspects.[206] In this particular case, the EPC weighed the suffering of the mice against the expected benefits to humanity through new cancer research techniques. Ultimately, the patent was granted, setting the precedent that any patent on a living organism is found not to be contrary to *ordre public* or morality under EPC principles. When considering whether terminator technology is contrary to *ordre public*, countries must employ this utilitarian balancing test.

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grounds" because "private ownership of substances created by nature is wrong, and inimical to cultural values in different parts of the world").

201. TRIPS Agreement, *supra* note 14, art. 27.2.

202. Strauss, *supra* note 20, at 307.

203. Harvard/Onco-mouse, [1992] O.J. E.P.O.R. 588, 593 (Examining Div.).

204. *Id.* at 588.

205. U.S. Patent No. 4,736,866 to Harvard College claiming "a transgenic non-human mammal whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal . . . ."

206. *Bioethics and Patent Law: The Case of the Oncomouse*, WIPO MAGAZINE, Mar. 2006, http://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html.

b. Using the Balancing Test to Determine Whether a Patent is Contrary to Ordre Public

The European Board of Appeal in its earlier *Harvard Oncomouse* decision adopted the balancing exercise, or utilitarian approach.[207] Courts have interpreted "serious prejudice" to include either actual or potential harm, so countries must consider both in attempt to accomplish a holistic review.[208] Whenever an invention involves higher life forms, the question of morality has to be examined and possible detrimental effects and risks have to be weighed against the merits and advantages.[209] When later considering the patent in *Greenpeace*, however, the Board expressly declined to employ the balancing test used in the *Oncomouse* decision, noting that it "was not the only way of assessing patentability" under Article 53(a) but was "just one possible way."[210] In that case, the decision as to whether Article 53(a) was a bar to patenting the plant invention at issue depended mainly on a careful weighing of the suffering of animals and possible risks to the environment on the one hand and the invention's usefulness to mankind on the other.[211]

c. In Comparison to GATT

Examination of case history from GATT Article XX and GATS Article XIV can help determine the scope of Article 27.2 of TRIPS.[212] Because protection of the environment falls under the umbrella term of *ordre public* or morality, the primary analogue to GATT and GATS is best analyzed under the "public morals" exceptions of GATT Article XX(a) and GATS

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207. *See* Harvard/Onco-mouse, [1990] O.J. E.P.O.R 451 (Examining Div.); Harvard/Onco-mouse, [1990] E.P.O.R. 501; Harvard/Onco-mouse, [1990] O.J. E.P.O.R. 490 (TBA); Harvard/Onco-mouse, [1991] E.P.O.R. 525 (Examining Div.).

208. CORREA, *supra* note 164, at 99-101.

209. Harvard/Onco-mouse, [1990] E.P.O.R. 501, 527.

210. Bagley, *supra* note 122, at 523.

211. Plant Cells/Plant Genetic Systems, [1995] O.J. E.P.O.R. 545 (TBA) (Reasons ¶ 9).

212. Byrnes, *supra* note 187, at 254 n.55. GATT Article XX and GATS Article XIV provide important exceptions for public policy, public health, environmental, and public emergency concerns to all of the provisions covered in each of the respective agreements. The ability to apply jurisprudence from an exceptions clause of one agreement to an exceptions clause of another is supported by the notion that each of these agreements is designed with the same economic policy goals in mind. Accordingly, derogation from these economic policy goals can be substantiated under similar lines of reasoning supported by the exceptions clauses of each agreement.

Article XIV(a). These provisions deal with exceptions from patenting necessary to protect public morals or to maintain public order, which extends to protection of human, animal, or plant life or avoidance of serious prejudice to the environment.[213] GATT Article XX(a) and GATS Article XIV(a) cases should be read to include the same concerns under a TRIPS Article 27.2 analysis.[214]

d. In Comparison with the European Patent Commission

In general, the EPO has narrowly construed exceptions to patentability in the EPC, particularly with respect to plant and animal varieties.[215] Similar to Article 27.2 of TRIPS, Article 53(a) of the EPC provides that European patents shall not be granted in "respect of inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."[216] Unlike TRIPS Article 27.2, this provision is mandatory.[217]

Today, inventions that cause serious prejudice to the environment can be considered contrary to *ordre public*, as the European Patent Office Board of Appeal held in *Plant Genetic Systems*.[218] In this decision, the EPO considered the patentability of a plant that had been genetically modified to be resistant to glutamine synthetase inhibitors, a type of herbicide.[219] In the reasons for its decision, the EPO stated that inventions likely to seriously prejudice the environment are contrary to *ordre public* and should be excluded from patentability[220] as long as threat to the environment is sufficiently substantiated at the time the decision is taken by the EPO.[221] There is no specific reference in Article 53(c) to the protection of the environment, likely because this concern had not yet emerged at the

213. Marrakesh Agreement, *supra* note 154, art. XIV(a).

214. Byrnes, *supra* note 187, at 255.

215. Plant Cells/Plant Genetic Systems, [1995] O.J. E.P.O.R. 545 (TBA) (Reasons ¶ 8).

216. Estaelle Derclaye, *Intellectual Property Rights & Global Warming*, 12 INTELL. PROP. L. REV. 263, 273 (2008). *See generally* Convention on the Grant of European Patents art. 53, Oct. 5, 1973, 13 I.L.M. 276, https://treaties.un.org/doc/Publication/UNTS/Volume%201065/volume-1065-I-16208-English.pdf.

217. Derclaye, *supra* note 216.

218. Plant Cells/Plant Genetic Systems, [1995] O.J. E.P.O.R. 545 (TBA) (Reasons ¶ 5).

219. *Id.*

220. *Id.*

221. Plant Cells/Plant Genetic Systems, [1995] O.J. E.P.O.R. 545 (TBA) (Reasons ¶ 18.5).

time the provision was adopted in 1973; the *Plant Genetic Systems* ruling shows that protection of the environment can now be read into its interpretation.[222]

4. And to Avoid "Serious Prejudice to the Environment"

Inventions that prejudice the environment can be considered contrary to *ordre public*, but it is not clear how extensive the prejudice must be before a country can exclude such subject matter from patentability.[223] The text of Article 27.2 requires the prejudice to be serious, but this standard is still imprecise. The seriousness may be actual or potential since Article 27.2 does not distinguish between the two.[224] The "avoiding serious prejudice" provision appears to have emerged out of jurisprudence on exceptions to patentable subject matter under the EPC. This provision deviates from the EPC and European Directive by including the phrases "protecting human, animal or plant life or health" and "avoiding serious prejudice to the environment" as examples of "*ordre public* and morality." This wording takes a meaningful step forward in accounting for environmental factors. It is unquestionable that biological diversity concerns both protecting "human, animal or plant life or health" and "avoiding serious prejudice to the environment."[225]

B. Applying Article 27.2 to Genetically Modified Crops

The fact that the TRIPS Agreement does not expressly address genetically modified products may result in inconsistent application, particularly concerning patents for living organisms, engineered gene materials, or the legal status of genetically modified crops. Moreover, incorporation of intellectual property issues into the trade-oriented TRIPS Agreement has led to ambiguity in interpretation of the treaty norms.[226] The best way to determine whether the *ordre public* benefits of genetically modified crops outweigh the potential prejudice to the environment is to employ the balancing test used by the European Patent Council in the *Harvard Oncomouse* case. When applied, this balancing test results in the conclusion that the benefits of GM crops with terminator technology do not outweigh the burden that the technology puts on society. Even without

222. Derclaye, *supra* note 216.
223. *Id.* at 272.
224. *Id.*
225. Shim, *supra* note 51, at 224-25.
226. Murphy, *supra* note 200, at 68-69.

comprehensive facts outlining the full impact of this technology, the potential consequences are too great to risk.

V. SOLUTIONS

A. Current Dispute Resolution Mechanisms

If a dispute arises regarding a country's decision to exclude an invention from patentability according to TRIPS, the Dispute Settlement Body may scrutinize that decision.[227] In the European Union, Member States may invoke a safeguard provision and temporarily ban a GMO product if it is possibly harmful to human health or the environment.[228] This is not a sufficient solution because other countries that trade with Europe are constantly pressuring the EU to lower its safety standards to allow for easier trade.

B. Proposed Alternate Solutions

Until there is more research on terminator technology to prove that it is safe to use, such technology should be able to be banned by any WTO Member State through universal interpretation of TRIPS Article 27.2. There is a clear trend towards the development of issue-specific legal mechanisms as a preferred means of dealing with environmental problems.[229] The articulation of international legal principles through dispute resolution processes is slow and gradual and cannot address issues of prevention and collective action in the fine-grained way of law-making via treaty.[230] The often-irreversible character of environmental damage, and the limitation of reparation after the fact, means that prevention of this damage is of the utmost importance.[231] Patent law has historically been territorial in nature, with sovereign states granting patents and providing means for patentees to enforce their rights only within their borders.[232] A more international

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227. Ackermann, *supra* note 185, at 493; *see* JAMES CRAWFORD, BROWNLIE'S PRINCIPLES OF PUBLIC INTERNATIONAL LAW 738 (8th ed. 2012).

228. Karky & Perry, *supra* note 38, at 17; *see also* Commission Regulation 258/97, 1997 O.J. (L. 43) (EC) ("Article 12 of Regulation 258/97 allows member states to temporarily ban products if there are 'detailed grounds for considering that the use of a food or a food ingredient . . . endangers human health or the environment"').

229. CRAWFORD, *supra* note 227, at 364.

230. *Id.*

231. *Id.* at 254.

232. Bagley, *supra* note 122, at 493; *see, e.g.,* 35 U.S.C. § 271(a) (2000) (remedy for infringement that occurs within the United States); *see* Margo A.

regime should be implemented in order to protect an environmental space that is not constrained to borders. An effective intellectual property regime must be international in scope.[233]

1. Proposed Solutions

States have a general obligation to ensure that activities within their jurisdiction respect the environment of other states and of areas beyond national control, as affirmed by the International Court of Justice in the *Legality of the Threat of Use of Nuclear Weapons* advisory opinion.[234] Nations have an obligation, expressed in Principle 17 of the Rio Declaration, to conduct an environmental impact assessment for any proposed activities that are likely to have a significant adverse impact on the environment and are subject to a decision of a competent national authority.[235] When it comes to genetically modified technology that spreads rapidly and replicates naturally, individual nations do not have time to undergo this extensive safety assessment. Instead, the WTO should consider this environmental impact assessment within the interpretation of Article 27.2 as applied to genetically modified crops. Generally, compulsory licenses would help improve the environment, so a clear and international standard is necessary.[236] While experts may argue that the grant or denial of patents on microorganisms and other biotechnology is not likely to put an end to genetic research or to its attendant risks, this debate should not prevent Member States from taking concrete steps to prohibit further degradation to the environment.[237]

2. The Precautionary Principle

It is appropriate under Article 27.2 for a nation to presume that certain inventions pose an environmental risk.[238] International law in other areas

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Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 729-30 (2003) (discussing efforts to eliminate the territoriality of U.S. and foreign patent systems); Curtis A. Bradley, *Territorial Intellectual Property Rights in an Age of Globalism*, 37 VA. J. INT'L L. 505, 520-21 (1997) (discussing territoriality of U.S. patent law).

233. Lopez, *supra* note 25, at 369.

234. CRAWFORD, *supra* note 227, at 359.

235. U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I), Principle 17 (Aug. 12, 1992) [hereinafter *Rio Declaration*].

236. Derclaye, *supra* note 216, at 287.

237. Bagley, *supra* note 122, at 535.

238. Harper, *supra* note 17, at 417.

recognizes this possibility through the precautionary principle, one of the best-known principles of environmental protection.[239] This provision has been described as an attempt to codify the concept of precaution in law, where "precaution" refers to a strategy for addressing risk.[240] Principle 15 of the Rio Declaration on Environment and Development states that when there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[241] Annex III of the Cartagena Protocol on Biosafety[242] declared that lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, as absence of risk, or as an acceptable risk.[243] Once a nation has perceived a potential risk to the environment, it should be able to freely act to prohibit this danger. Many times, a nation may act too late. To protect against this risk, a nation should require a pre-market showing from both domestic and foreign producers that an invention is safe.[244] Precautionary regulation, such as that proposed in this Article, is justified when there is no clear evidence about a particular risk scenario, when the risk itself is uncertain, or until the risk is disproved.[245] When it comes to terminator technology, the evidence is clear: this technology can and will damage the environment if released in great quantities.

There is wide agreement that GATT allows any contracting party to adopt appropriate domestic environmental policies by providing countries with very considerable scope to use trade-related policies to protect national environmental resources without calling into question their GATT obligations.[246] Both GATT and other international laws support the precautionary use of Article 27.2.[247] GATT suggests that the interpretation of TRIPS Article 27.2 be approached through a two-step argument: (1)

239. Crawford, *supra* note 227, at 357.
240. *Id.*
241. *Rio Declaration, supra* note 235.
242. "The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003." *The Cartagena Protocol on Biosafety*, CONVENTION ON BIOLOGICAL DIVERSITY, https://perma.cc/HW2Z-F325 (last updated Dec. 21, 2017).
243. *Id.*
244. Harper, *supra* note 17, at 417-18.
245. CRAWFORD, *supra* note 227, at 258.
246. Harper, *supra* note 17, at 418.
247. *Id.* at 384.

GATT creates a rebuttable presumption supporting the use of international industrial standards and (2) the international standards of widest applicability endorse product life cycle management, pollution preventions, and product impact disclosure.[248]

Article 27.2 is not mandatory; members have discretion to prohibit immoral inventions.[249] This provision of the TRIPS Agreement certainly covers the scope of genetically modified plants or foods and the freedom of the Member States to allow or not allow genetically modified products to be brought into its market or environment if the situations warrants.[250] The questions that TRIPS cannot answer include where society should draw the line between protection that will stimulate innovation and progress and the level of protection that will stifle beneficial research or cause other harms.[251]

International intellectual property agreements alone will not provide solutions to the difficult questions regarding gene technologies and self-replicating inventions. TRIPS is driven by a "commodity logic," which aims to maximize profits for intellectual property producers.[252] Given the troubled history that developing countries have experienced with the intellectual property system, marked especially by their historical inability to exercise meaningful sovereignty over intellectual property standards, it is only fair that the exceptions built into TRIPS provide broad latitude for policy objectives.[253]

CONCLUSION

There is a trend towards "upward harmonization" of global intellectual property standards, which was caused in part by underutilization of TRIPS flexibility by all countries.[254] The countries created the TRIPS Agreement

248. *Id.* at 403-04.

249. Derclaye, *supra* note 216, at 272.

250. Karky & Perry, *supra* note 38, at 15; *see, e.g.*, Byrnes, *supra* note 187, at 254 (Bolivia's broad notion of harmony with nature, which is embodied in the indigenous philosophy of *suma qamana*, can be used to justify a ban on the patenting of life under the *ordre public* or morality provisions of Article 27.2.).

251. J. Janewa Osei-Tutu, *Agricultural Biotechnology: Drawing on International Law to Promote Progress*, 2015 MICH. ST. L. REV. 531, 544 (2015).

252. Chidi Oguamanam, *Regime Tension in the Intellectual Property Rights Arena: Farmer's Rights and Post-TRIPS Counter Regime Trends*, 29 DALHOUSIE L.J. 413, 424 (2006) (quoting James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT'L L. 261, 309 (2002)).

253. Byrnes, *supra* note 187, at 265.

254. *Id.* at 265 n.113.

with the main purpose of uniting countries through consistent intellectual property standards, in the hope of making international trade easier. As it stands now, the application of Article 27 is sloppy and varies greatly from Member State to Member State. There is no evidence that any member has ever used Article 27.2 to refuse patenting based on grounds of environmental protection.

As stewards of the Earth, humans have a unique position that comes with a duty to take care of the environment, protecting it for the next generation. Without a clear standard to follow, the protection of the environment becomes complicated and therefore seemingly less of a priority. The interpretation of TRIPS Article 27.2 presented in this Article is necessary to stop the degradation of the environment by crops embedded with terminator technology, for the wellbeing of humans and our planet depends on it.

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