TERMINATOR TECHNOLOGY: PROTECTION OF PATENTS OR A THREAT TO THE PATENT SYSTEM?

SINA MUSCATI*

I. INTRODUCTION

Terminator technology (TT) is a form of genetic engineering that inactivates a plant's ability to reproduce by rendering its seeds infertile. The technology, officially named the "Technology Protection System" when first developed in the late 1990s, prevents farmers from planting seeds from an earlier year's harvest and ensures a constant source of buyers for the seed company.[1] When TT was first publicized in 1998, a huge public backlash followed. Various groups leveled criticism at TT, ranging from advocates of farmers' rights who feared that TT threatened to destroy a millennia-old culture of seed-saving among farmers, to environmentalists threatened by the environmental risks posed by yet another form of genetic engineering.[2] In response to this backlash, Monsanto (then at the forefront of TT research) made a public commitment in 1999 not to commercialize the technology until the completion of studies that would examine its environmental, economic and social effects.[3]

* LLM 2005 (Harvard); Barrister-and-Solicitor 2004 (Ontario); LLB 2003 (Ottawa).

1 Jeremy P. Oczek, *In the Aftermath of the "Terminator" Technology Controversy: IP Protections for Genetically Engineered Seeds and the Right to Save and Replant Seed*, 41 B.C. L. Rev. 627, 628 (2000); *see* U.S. Pat. No. 5,723,765; ETC Group, *Biotech Activists Oppose the Terminator Technology*, ETC News Release (Mar. 13, 1998). "Terminator" is actually a term coined by critics of the technology to emphasize its seed destruction aspects.

2 A good collection of statements and news releases by groups opposed to TT can be found on the website of the Action Group on Erosion, Technology and Concentration (ETC group) available at www.etcgroup.org.

3 *See Gene Protection Technologies: A Monsanto Background Statement*, Perspectives on New Crops and New Uses 1, 2 (J. Janick ed., ASHS Press 1999) [hereinafter *Monsanto*]. The Monsanto statement read as follows:

> Until a thorough, independent examination of gene protection systems has been conducted and all points of view considered, we will not attempt to

Other gene giants, however, continue to seek new patents on TT and have advocated in favor of certain uses of TT.[4] Even Monsanto has reserved the right to use TT in the future. In fact in April 2003, scientists from Monsanto published a paper that lauded TT's intellectual property (IP) protection aspects and claimed TT would help spur seed innovation and prevent biocontamination.[5] It is the IP aspects of TT that are likely to be of greatest interest to seed companies. The protections that TT may offer, however, are much broader than what a normal patent provides. For example, terminator seeds are not time-limited, have no user exemption for farmers, researchers or breeders, and cannot be subject to compulsory licensing.

This paper will analyze these IP aspects of TT and the potential legal bases upon which TT can be restricted. After briefly introducing the science and history of TT, the paper will assess some of the patent law issues it raises. These include whether TT (1) constitutes an impermissible extension of patent rights; (2) has any antitrust implications; (3) violates any farmers' exemption to save seeds; or (4) can be restricted on public policy grounds. The paper will also consider some potential benefits of TT, and end with some brief proposals as to how TT may be accommodated within the existing patent regime.

II. TERMINATOR TECHNOLOGY

A. What is It?

An appreciation of the social and legal implications of TT requires understanding the basic science and history behind the invention. Serious research on TT began in the 1990s and was actually partly funded by the

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> commercialize these technologies. Moreover, in considering whether to commercialize such technologies, we will respond publicly and fully to the conclusions, opinions and arguments that are raised.

Id.

4 *See e.g.* Harry B. Collins & Roger W. Krueger, *Potential Impact of GURTs on Smallholder Farmers, Indigenous & Local Communities and Farmers Rights: The Benefits of GURTs*, http://www.hort.purdue.edu/newcrop/proceedings1999/pdf/v4-127.pdf (accessed May 11, 2005).

5 *See id.* This paper was actually a position paper released by the International Seed Federation but co-authored by Monsanto's R.W. Krueger, and Delta & Pine Land's H.B. Collins. The paper was presented as the official position paper of the International Seed Federation. The paper was made available to the Convention on Biological Diversity's Ad Hoc Technical Expert Group on the Impact of GURTs on Smallholder Farmers, Indigenous People and Local Communities, February 19-21, 2003.

U.S. government through the U.S. Department of Agriculture (USDA), which sought to protect U.S. technology, including U.S. research in genetically modified seeds.[6] The first patent related to TT was awarded in March of 1998 to Delta and Pine Land Company (later to be purchased by Monsanto), in collaboration with the USDA.[7] This patent covers many applications, most notably a method of engineering crops to render their own seeds sterile in the second generation, thereby preventing farmers from saving and replanting seeds.[8] Soon thereafter, a second patent on TT was issued to another seed company, AstraZeneca, in September of 1998.[9] Since then, many other seed multinationals have patented their own variations of TT.[10]

Initially, the sterility produced by TT was irreversible.[11] More recent types of TT allow for the sterility trait to be overcome chemically.[12] For example, one of Monsanto's latest TTs works by inserting an inhibitor gene that stops seeds from producing ACOX, an enzyme necessary for germination.[13] The inhibitor gene can be overridden with another gene that is also inserted through genetic engineering, but that can only be activated by an external chemical trigger.[14] Hence, any seed saved by a farmer would germinate only if the farmer had access to the chemical activator. A second TT, this time developed by Zeneca, involves the insertion of a gene in the plant that works with a promoter to produce a compound (barnase) that destroys cells.[15] The promoter is active only during germination and plant growth, thereby leaving grown plants unaffected but rendering their seeds sterile.[16] The gene can be overcome by a pair of disruptor genes that are,

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6 Martha L. Crouch, *How the Terminator Terminates: An Explanation for the Non-scientist of a Remarkable Patent for Killing Second Generation Seeds of Crop Plants*, ETC News Release (Jan. 1, 1998).

7 *See* U.S. Pat. No. 5,723,765.

8 Crouch, *supra* n. 6.

9 *See* U.S. Pat. No. 5,808,034.

10 *See e.g.* U.S. Pat. No. 5,859,328; U.S. Pat. No. 5,859,341; U.S. Pat. No. 5,880,333; U.S. Pat. No. 5,925,808; U.S. Pat. No. 5,977,441; U.S. Pat. No. 6,057,490.

11 *See e.g.* U.S. Pat. No. 5,723,765 (one of the first patents on a form of TT).

12 *See e.g.* U.S. Pat. No. 5,808,034.

13 ETC Group, *Traitor Technology: How Suicide Seeds Work/Where They are Being Patented*, ETC Group Communiqué (Jan. 30, 1999) (dubbed the "Terminator II" by the ETC Group).

14 *Id.*

15 *Id.*

16 *Id.*

again, activated by prolonged exposure to a chemical.[17] Yet another TT, developed by Novartis, works by genetic engineering that deactivates the essential natural resistance functions of plants, leading to their imminent demise unless that resistance is reactivated by external chemical regulators.[18]

While the variant TTs may work in different ways, the net effect of all is to produce sterile seeds and thereby give the seed owner control over the seeds' germination qualities. Some TTs have even been extended to insects, and there is a potential for analogous TT to be developed for farm animals.[19] In fact, the chemically activated TTs are really one subset of genetic use restriction technologies (GURTs), a broad term that refers to any use of an external chemical inducer to control the expression of any genetic trait of a plant, including sterility.[20] GURTs that control the trait for sterility, thereby restricting that variety of the plant, are known as V-GURTs (V for variety); those that control for any other specific trait, such as color, texture, ripening, etc., are known as T-GURTs (T for trait).[21] The significance of the distinction between T-GURTs and V-GURTs will be discussed later in the paper.

17 *Id.*

18 *See id.* Critics describe such plants as "drug addicted" because they are entirely dependent on external chemicals for their survival. *See* U.S. Pat. No. 5,804,693 (describing genetically modified "universal disease susceptible" plants which produce reduced levels of salicylic acid—a key mediator of plant resistance to a wide variety of pathogens (bacteria, fungi, viruses)); *see also* U.S. Pat. 6,057,490. Held by Syngenta, the patent specifically describes the protection and use of non-immunity mutants—plants that are modified *not* to express systemic acquired resistance genes; *see* ETC Group, *2001: A Seed Odyssey: RAFI's Annual Update on Terminator and Traitor Technology*, ETC Group Communiqué (Jan. 30, 1999) [hereinafter *A Seed Odyssey*].

19 *See* Working Group on Plant Genetic Resources for Food & Agriculture, *Potential Impacts of Genetic Use Restriction Technologies (GURTs) on Agricultural Biodiversity and Agricultural Production Systems*, Commn. on Genetic Resources for Food & Agric. 1, 3 (Mar. 2001) [hereinafter *Potential Impacts*]. This paper was presented at the Conference of the Parties to the Convention on Biological Diversity, 6th meeting, Agenda item 16, The Hague, April 7-19, 2002. One TT for mammals involves developing pairs of gene constructs that induce sex-linked sterility, with compensating elements that can restore fertility in the initial breeding animals. Control of the process to overcome infertility remains with the breeder.

20 ETC Group, *Terminator Technology—Five Years Later*, ETC Group Communiqué (May/June 2003) [hereinafter *Five Years Later*].

21 *Id.*

B. Why is Terminator Technology Sought?

TTs offer seed companies a method of protecting their IP more effectively than any other method. The easily reproducible nature of seeds has always posed a problem to seed researchers seeking to protect their IP interests. This is because millions of dollars and years of research are involved in developing genetically engineered seeds that offer superior value to growers.[22] For research and investment in biotech research to continue, companies need the incentive of being able to share in the profit created by these crops.[23] Therefore, in theory at least, allowing growers to save, reuse, and/or replant patented seed removes this incentive, along with the future availability of innovative biotechnology for all.[24]

Traditionally, seed researchers have relied on IP laws that make it illegal for farmers to re-use or sell harvested seed.[25] The first legislation in the U.S. to grant IP rights to plant breeders was the Townsend-Purnell Patent Act, better known as the Plant Protection Act (PPA), enacted by Congress in 1930.[26] The PPA protects only asexual varieties of plants, i.e. plants reproduced through propagation or grafting.[27] It does not apply to genetically engineered seeds, which are produced from sexual varieties of plants.[28] In 1970, Congress enacted the Plant Variety Protection Act (PVPA), which encompasses sexual plant varieties as well.[29] The PVPA is therefore one possible method of IP protection for genetically engineered seeds.[30]

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22 Crouch, *supra* n. 6.

23 *Id.*

24 *Id.*

25 *Id.*

26 35 U.S.C. §§ 161-64 (2000).

27 *Id.* at § 163.

28 *Id.*

29 7 U.S.C. § 2481 (2000).

30 The PVPA is administered by the Plant Variety Protection Office, which is operated through the USDA. *Id.* at §§ 2321, 2323. The PVPO is charged with the task of issuing certificates of protection to breeder applicants. *Id.* at § 2481. The certificate grants the breeder "the right, during the term of the plant variety protection, to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom." *Id.* at § 2483(a)(1). Anyone violating the rights granted by the PVPA certificate can be sued for infringement. *Id.* at § 2541. The protection provided by a PVPA certificate lasts for a period of twenty years. *Id.* at § 2483(b); *see* Oczek, *supra* n. 1.

Regular utility patents under the Patent Act provide another means of IP protection for genetically engineered seeds.[31] Such patent protection for living things was first recognized in 1980 in the landmark case of *Diamond v. Chakrabarty*, where the U.S. Supreme Court held that living bacteria were patentable subject matter.[32] Then in 1985, in *Ex Parte Hibberd*, the Board of Appeals of the U.S. Patent and Trademark Office ruled that the principles of *Chakrabarty* could be extended to the patenting of genetically engineered plants, seeds and plant tissue.[33]

Licensing agreements provide another means of IP protection for genetically engineered seeds. For example, it is now standard practice in the seed industry for a farmer purchasing genetically engineered seeds to sign a contract (typically known as a "Technology Use Agreement") with the seed provider that contains a clause whereby the farmer relinquishes rights to seeds produced by the crop.[34] This clause is meant to prevent farmers from saving and reselling or reusing patented seed, and has even been described as a "terminator clause" given that it seeks to achieve essentially the same effect as TT.[35]

Traditional IP protection mechanisms for genetically engineered seeds, however, have a number of shortcomings. Monitoring for cases of patent infringement or breaches of a licensing agreement is difficult and expensive, especially in developing countries. Additionally, when a case of infringement is found, the litigation that follows is expensive, time-consuming and unpredictable. IP laws can also be politically unpredictable and are subject to potential legislative change, especially in a field as politically contentious as biotechnology patenting. An alternative form of IP protection such as TT bypasses these problems. With TT, no seed is created, and there is simply nothing for farmers to save, reuse or resell. As one commentator has put it, TT creates seeds that come "with a built-in biological patent enforcement mechanism."[36] TT offers a stronger and more far-reaching monopoly than IP, one unlimited in time, with no exemptions, and without a need for lawyers.

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[31] 35 U.S.C § 101.

[32] 447 U.S. 303, 318 (1980).

[33] 227 U.S.P.Q. 443, 443, 447-48 (B.P.A.I. 1985).

[34] Oczek, *supra* n. 1, at 643.

[35] Samantha M. Ohlgart, *The Terminator Gene: IP Rights vs. The Farmers' Common Law Right to Save Seed*, 7 Drake J. Agric. L. 473 (2002).

[36] Kojo Yelpaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 32 McGeorge L. Rev. 111, 172 (2000).

C. What are the Ethical Concerns?

This all-encompassing nature of TT, while attractive to the industry, is also a reason why it is ethically controversial. There are many public policy interests at play in establishing a system of creating IP. Rewarding an inventor's innovation is only one of those interests. The current legislative system for protecting IP has some flexibility to address these various interests. For example, patents create monopolies limited to 20 years that are restricted to specific claims and can in some cases be subjected to compulsory licensing of the underlying invention. With TT, however, there is no such flexibility. It is a consequence of the technology that the monopoly will be absolute and indefinite.

There are other ethical reasons why many oppose TTs. Some fear that it could extinguish farmer expertise in selecting seed and developing locally-adapted strains, thereby threatening food security and agricultural biodiversity, especially for the poor.[37] This threat is especially true for developing countries, which typically rely on more traditional methods of farming, and where most patent infringement occurs and therefore where TTs will most likely be targeted. More broadly, there is a fear of "bioserfdom," or the complete commercialization of agriculture.[38] GURTs will allow companies to load various commercial characteristics, including sterility, onto a plant variety, which the company may then activate or de-activate at or after the point of sale.[39] This turns farming into a completely commercial and proprietary venture, one where farmers purchase seeds with or without certain "value-added" accessories, depending on what farmers can afford, yet again impacting the poorer developing countries the most. Indeed, the very act of substituting fertile seed with sterile seed, whereby companies artificially create demand and disrupt the age-old cycle of agricultural practice for mere profit, can be seen as ethically problematic.[40]

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37 *See* Crouch, *supra* n. 6.

38 *Five Years Later*, *supra* n. 20, at 4.

39 *See* Crouch, *supra* n. 6.

40 Cullen N. Pendleton, *The Peculiar Case of "Terminator" Technology: Agricultural Biotechnology and IP Protection at the Crossroads of the Third Green Revolution*, 23 Biotechnology L. Rep. 1, n. 122 (Feb. 2004).

III. GROUNDS FOR REGULATING TERMINATOR TECHNOLOGY

A. Patent Misuse

Given the many problems with TT introduced above, is there any legal basis for banning or restricting this technology? One possible basis may be to argue that TTs unlawfully extend patent rights in the seed. Related to this idea is a whole doctrine of law known as "patent misuse."[41] According to the U.S. Supreme Court, the patent misuse affirmative defense was created to deny relief against patent infringement to a patentee "if he has attempted illegally to extend the scope of his patent monopoly."[42] Below is an analysis of how the patent misuse doctrine may apply.

1. Illegal Extension of the Term of a Patent

a. *Brulotte v. Thys Co.*

Perhaps the closest analogy between TTs and patent misuse is the prohibition against extending the term of a patent. This prohibition was strongly affirmed by the U.S. Supreme Court in *Brulotte v. Thys Co.*[43] In that case, Brulotte had sold a number of hop-picking machines to the defendants and licensed their use.[44] The licenses included a fixed royalty payment per season of use.[45] The terms of the licenses were not limited to the terms of the patents, such that the payment of royalties extended beyond the expiration of the patents.[46]

The Court held that such licenses are invalid, finding that post-expiration royalties accruing for post-expiration use of a patent expanded the monopoly power of the patentee beyond that rightfully conveyed by the patent.[47] In the words of the Court,

> a patentee's use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*. If that device were available to

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41 *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 180 (1980).

42 *Id.*

43 379 U.S. 29, 33 (1964).

44 *Id.* at 29.

45 *Id.*

46 *Id.* at 30.

47 *Id.* at 32.

> patentees, the free market visualized for the post-expiration period would be subject to monopoly influences that have no proper place there.[48]

The *Brulotte* ruling cited the U.S. Supreme Court decision, *Scott Paper Co. v. Marcalus Manufacturing Co.*, and stated "any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws."[49] *Brulotte* has subsequently been followed in a number of cases.[50] How the principles of *Brulotte* might apply to the case of TTs is unclear. Are seed companies who use TT employing "a legal device" of the type suggested in *Scott Paper Co.* to extend a patent? Perhaps not, especially given that the monopoly extension resulting from the technology is one that seed companies do not actively create once the seeds are sold, and one that researchers may not even have any control over, depending on the type of TT used. There may not even be a patent involved, because seed companies can sell the seed without patenting it. In such a case, there is no patent monopoly to be extended per se, only a patent-like monopoly that is indefinite and is an inevitable outcome of the technology.

b. The Aftermath of *Brulotte*

It is important to point out that the *Brulotte* decision has faced severe criticism by legal commentators in the years since it was decided.[51] The main criticism has been that post-expiration royalties do not constitute an extension of a patent monopoly insofar as the rates of those royalties are changed accordingly.[52] The economic theory behind this is that licensees presumably know that a patent will expire after 20 years; therefore, if an agreement calls for payments beyond the patent term, those payments will be based on the licensees' assessment of the value of the license during the

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48 *Id.*

49 *Id.* at 31 (quoting *Scott Paper Co. v. Marcalus Mfg. Co.*, 826 U.S. 249, 256 (1945)).

50 *See e.g. Meehan v. PPG Indus., Inc.*, 802 F.2d 881, 883 (7th Cir. 1986) (holding that post-expiration royalties are not allowed); *see also Phillips Screw Co. v. Amtel, Inc.*, 465 F. Supp. 3, 5 (D. Mass. 1978); *GAF Corp. v. Eastman Kodak Co.*, 519 F. Supp. 1203, 1236 (S.D.N.Y. 1981); *Duplan Corp. v. Deering Milliken, Inc.*, 444 F. Supp. 648, 671 (D.S.C. 1971).

51 *See generally* Harold See & Frank M. Caprio, *The Trouble with Brulotte: The Patent Royalty Term and Patent Monopoly Extension*, 1990 Utah L. Rev. 813 (1990).

52 *See e.g. Bayer AG v. Housey Pharms., Inc.*, 228 F. Supp. 2d 467, 472 (D. Del. 2002) (holding that "[c]ollecting royalties after the patent has expired is not per se patent misuse").

patent period.[53] Licensees also incur their greatest costs in the early stages of the development and marketing of an invention.[54] Thus, post-expiration royalty payments that spread out costs over time serve as a convenient payment method for users.[55] They can also have pro-competitive benefits by allowing companies to charge more competitive prices and thereby attract customers from competing technologies in the pre-expiration market.[56]

Some of the strongest criticisms of *Brulotte* have come from courts themselves. In *Scheiber v. Dolby Laboratories Inc.* (*Scheiber*),[57] for example, the Seventh Circuit noted how *Brulotte* had been "severely" and "justly" criticized by both the dissent in that case and in many subsequent law review articles.[58] The court commented as follows:

> The Supreme Court's majority opinion reasoned that by extracting a promise to continue paying royalties after expiration of the patent, the patentee extends the patent beyond the term fixed in the patent statute and therefore in violation of the law. That is not true. After the patent expires, anyone can make the patented process or product without being guilty of patent infringement. . . . For a licensee in accordance with a provision in the license agreement to go on paying royalties after the patent expires does not extend the duration of the patent either technically or practically, because, as this case demonstrates, if the licensee agrees to continue paying royalties after the patent expires the royalty rate will be lower. *The duration of the patent fixes the limit of the patentee's power to extract royalties; it is a detail whether he extracts them at a higher rate over a shorter period of time or a lower rate over a longer period of time. . . . . [C]harging royalties beyond the term of the patent does not lengthen the patentee's monopoly; it merely alters the timing of royalty payments.*[59]

The *Scheiber* case involved the payment of post-expiration royalties in an agreement essentially indistinguishable from that in *Brulotte*. While the court declared that precedent dubious, it still followed it, commenting that "we have no authority to overrule a Supreme Court decision no matter how dubious its reasoning strikes us, or even how out of touch with the Supreme Court's current thinking the decision seems."[60] Other courts have

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[53] *Id.*

[54] Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 Mich. L. Rev. 985, 1027 (1999).

[55] C. Layton, *Ten Innovations* 148 (George Allen & Unwin Ltd. 1972).

[56] Kelly Hershey, *Annual Review of Law and Technology: I. Intellectual Property: B. Patent: 3. Patent Misuse: Scheiber v. Dolby Laboratories, Inc.*, 18 Berkeley Tech. L.J. 159, 171 (2003).

[57] 293 F.3d 1014 (7th Cir. 2002).

[58] *Id.* at 1017.

[59] *Id.* at 1017-18 (emphasis added).

[60] *Id.* at 1018.

progressively narrowed the application of *Brulotte*. For example, in *Zenith Radio Corp. v. Hazeltine Research, Inc.*,[61] the U.S. Supreme Court allowed post-expiration royalties if they were based on the use of the subject invention prior to the expiration of the patent.[62] The Court stated that "the patentee could lawfully charge a royalty for practicing a patented invention prior to its expiration date and that the payment of this royalty could be postponed beyond that time."[63] Courts have allowed royalty payments on a patent later found to be invalid if the parties had agreed to those payments beforehand and the licensing of patent applications.[64] It is also important to note that a key factor influencing the *Brulotte* decision was the U.S. doctrine of pre-emption. This doctrine makes it illegal to extend the life of a patent (a federal area of law) by contract, given the federalist structure of the U.S.[65] How the same situation would play out in other countries, however, is far from clear.[66]

How might some of the criticisms of *Brulotte* be relevant to TTs? Much as the court reasoned in *Scheiber*, licensees of Terminator seeds who are made aware of the sterility in the second generation will presumably compare them with traditional seeds and the price of those seeds will thereby be affected accordingly. There is also, arguably, no patent monopoly extension in the sense that anyone is free to produce competing versions of the seed, including non-Terminator versions, after 20 years (or immediately, if there is no patent on the seed). This argument is strongest if there are people or companies that possess the technical expertise to reverse-engineer or otherwise duplicate protected seed. Hence, TT is not completely foolproof and patents and other plant breeders' rights can, for this reason, continue to play important roles in the relationship between the innovator and eventual imitators.[67]

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61 395 U.S. 100 (1969).

62 *Id.* at 136-38.

63 *Id.* at 136.

64 *Aronson v. Quick Point Pencil Co*., 440 U.S. 257, 264, 266 (1979).

65 *See e.g. Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (explaining that state law is pre-empted where it produces a result inconsistent with the objective of a federal statute); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (explaining that state law is pre-empted whenever it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

66 *See generally* Mark A. Lemley, *Beyond Preemption: The Law and Policy of IP Licensing*, 87 Cal. L. Rev. 111 (1999).

67 *Consequences of the Use of the New Technology for the Control of Plant Gene Expression for the Conservation and Sustainable Use of Biological Diversity; Note by the Executive Director,* Convention on Biological Diversity (June 21-25, 1999) [hereinafter *Consequences*].

This situation, however, is not comparable with that faced by seed companies developing traditional genetically modified seed. Traditional seeds can be simply grown and saved by both farmers and competitors with little effort. If significant technical expertise, expensive and sophisticated equipment, and costly facilities are required to reproduce the seed and compete, then there will be fewer potential competitors.[68] This is especially true if the seed innovators have devised effective ways of keeping the genetic benefit of that seed secret.

c. Other Case-Law on Extending the Term of a Patent

There is also a line of legal reasoning that states that patent rights cannot be extended indefinitely post-expiration by other means, such as by trademark law. For example, in *In Re Walker-Gordon Laboratory Co.*,[69] a mark for milk bottles consisting substantially of a silver-colored cap was held to be not registerable.[70] The Federal District Court explained, "to grant registration of a mere functional element, or physical article, standing alone, as a trade-mark, would be almost equivalent, in its effect, to the grant of a perpetual patent."[71] In reaching this decision, the court noted that "it is not conceivable that Congress ever intended that such a result should be accomplished through the trade-mark [sic] registration statute."[72]

In, *Zip Dee, Inc. v. Dometic Corp.*,[73] Zip Dee owned four patents related to RVs and filed suit against Dometic Corporation for patent and trademark infringement arising out of the latter's marketing of a competing brand of RV awning with a slatted metal covering.[74] On a motion for summary judgment, Dometic argued that Zip Dee was precluded from asserting trademark rights in a feature disclosed in several patents and, in any event, that the slatted metal cover was functional in the trademark sense.[75]

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68 Pendleton, *supra* n. 40, at 12. Interestingly, this same reasoning will also make it harder for infringers to copy the seed. At the margins, this could turn a losing venture into a profitable one. The added security to seed companies will promote innovation, and this could actually be a reason to support TT.

69 53 F.2d 548 (C.C.P.A. 1931).

70 *Id.*

71 *Id.*

72 *Id.*

73 931 F. Supp. 602 (N.D. Ill. 1996).

74 *Id.* at 605-06.

75 *Id.* at 606.

The court concluded that "because there is a federal right to copy and use an invention upon expiration of a utility patent, trademark law cannot be used to provide a permanent monopoly on the same invention."[76]

Again, it is unclear how these principles apply to TT. The broader principle arising from these cases appears to be that the granting of indefinite monopolies (as TT would do) is undesirable. Use of these cases in support of this proposition as applied to TT can be problematic because TT is distinguishable in a variety of ways. For example, the issue of statutory interpretation alluded to in *Walker-Gordon* is irrelevant to TT where what is at issue is not the intention of Congress in passing the trademark statute, but simply whether the monopoly resulting from the technology itself can be independently allowed. Additionally, the fact that there was a patent that had expired in *Zip Dee* is, again, irrelevant for Terminator seeds, which create monopolies independent of a patent. Other courts have also rejected the argument that conferring other monopolies such as trademark protection, at least on a product configuration or design, amounts to granting a perpetual patent, given the nature of trademark rights.[77]

2. Other Impermissible Extensions of Patent Rights

In addition to duration, there are other aspects of patent rights that can also be impermissibly extended. One possibility is to extend the monopoly beyond the claims of the patent. For example, under U.S. patent law, the protection of a particular plant trait would not necessarily imply the protection of the full genome of the plant that expresses it; control of the use or commercialization of the plant is allowed only so long as the plant expresses the relevant trait.[78] TT, however, would block the further exploitation of not only the trait or traits intended to be protected, but the whole associated genome.[79] This would be a gross expansion of rights.

Another impermissible extension of patent rights relates to the principle of territoriality whereby patent rights are limited to the country that granted the patent. These territoriality limits are not recognized by TTs, which will behave the same way biologically wherever they are applied. Patent misuse can also occur in various other ways that are not so relevant to the case of TTs. For example, various forms of exclusive dealings, cross-

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76 *Id.* at 608-09.

77 *See Kohler Co. v. Moen Inc.*, 12 F.3d 632 (7th Cir. 1993).

78 *Consequences*, *supra* n. 67.

79 *Id.*

licensing and pooling arrangements, grantbacks, tying arrangements, and resale price maintenance have been found to constitute patent misuse.[80]

It is important to remember, generally, the application of the doctrine of patent misuse to TTs is highly questionable for a number of reasons. The most prominent reason has already been touched upon, in that patent misuse requires the existence of a patent, whereas the monopoly effects of TT operate independently of a patent. Indeed, the doctrine of patent misuse exists as an *affirmative defense* to a claim for patent infringement. There is no independent cause of action for misuse.[81] Hence, patent misuse cannot constitute a basis for suing a seed company to prevent them from producing, selling, or licensing terminator seeds.

Another observation is that almost all cases prohibiting monopoly extensions involve affirmative acts that go beyond passive acts such as a refusal to deal or license. Again, with TTs, the only affirmative act per se is the sale or licensing of a seed variant known to have such a far-reaching monopoly. After that, biology takes over and no further act is required on the part of the licensor. Many patent misuse cases also involve conduct that is independently unlawful or not ordinarily privileged, such as sham litigation, false advertising, or other oppressive conduct.[82] What might constitute such proscribed conduct in the case of TT is not clear. For these reasons, the direct relevance of the doctrine of patent misuse to TT is doubtful, except perhaps for a situation where a seed company using TT has initiated legal action in furtherance of any patent rights it may hold. It is, however, still useful to analyze the doctrine for indirect applications of its principles, given the analogous nature of the monopoly benefits conferred by patented seeds and Terminator seeds.

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80 *See generally Antitrust Guidelines for the Licensing of Intellectual Property* (U.S. Dept. of Just. & Fed. Trade Commn. Apr. 6, 1995) (available at http://www.usdoj.gov/atr/ public/guidelines/ipguide.htm [hereinafter *Antitrust Guidelines*]. A sample of some agreements that courts have disapproved of include the licensing of a package of patents if the licensee was forced to accept unwanted patents, *Duplan Corp. v. Deering Milliken, Inc.*, 444 F. Supp. 648 (D.S.C. 1977), settlement agreements that end patent infringement and patent validity litigation, *Rocform Corp. v. Acitelli-Standard Concrete Wall, Inc.*, 367 F.2d 678 (6th Cir. 1970), and contracts requiring royalty payments on invalid patents, *Grunewald v. Power Swing Partners*, 9 B.R. 512 (Bankr. N.D. Cal. 1980).

81 *See e.g. U.S. Gypsum Co. v. Natl. Gypsum Co.*, 352 U.S. 457, 465 (1957) (affirming that no independent cause of action exists for patent misuse).

82 Richard H. Stern, *IP-related Refusals to Deal*, IEEE 8-11 (Mar./Apr. 2000).

B. Antitrust

1. Interplay Between IP and Antitrust

Given the problems inherent with applying the doctrine of patent misuse to TT, it is important to seek some other legal doctrine by which way it may be possible to regulate TT. One such doctrine might be antitrust law. Whereas patent misuse focuses on whether a patent owner has illegally extended the scope of a patent with an anti-competitive effect, antitrust laws aim to prevent the holders of market power from harming competition through unreasonable conduct.[83] The fundamental text of U.S. antitrust law, as applicable here, is Section 2 of the Sherman Act, which reads:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony.[84]

This provision has been interpreted to include only unreasonable restraints of trade.[85]

To determine the reasonableness of the restraints, courts will consider such factors as specific information about the relevant business, the condition of the business before and after the restraint was imposed, and the history, nature and effect of the restraint.[86] It is also important to note that the Sherman Act applies only to agreements that have a substantial effect in the U.S. Such a requirement may be met by activities that have the effect of restraining other U.S. manufacturers from accessing foreign markets.[87]

It is often said that an inevitable tension exists between the elements of monopoly in IP (and TT, by comparison), and the general idea of free competition advocated by antitrust laws. IP, however, is really based on the idea that more competition will result if enterprises can be motivated to innovate, secure in the knowledge that competitors will not free ride on their accomplishments. In this sense, IP and antitrust laws share a common purpose of promoting innovation and enhancing consumer welfare. Patent laws achieve this purpose by providing incentives for innovation via

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[83] *See generally Windsurfing Intl., Inc. v. AMF, Inc.*, 782 F.2d 995 (Fed. Cir. 1986) (describing the distinction between antitrust laws and patent misuse).

[84] 15 U.S.C. § 2 (2000).

[85] *See e.g. Ariz. v. Maricopa County Med. Socy.*, 457 U.S. 332, 342-43 (1982).

[86] *See generally* Thomas K. Jowalski & Christian M. Smolizza, *Reach-through licensing: A U.S. perspective* (Henry Stewart Publications 2000).

[87] *Hartford Fire Ins. Co. v. Cal.*, 509 U.S. 764, 796 (1993); *see Foreign Trade Antitrust Improvements Act of 1982*, 15 U.S.C. § 6.

enforceable property rights for the creators of new and useful products and processes. Antitrust laws do so by prohibiting certain activity that may harm competition with respect to existing or new ways of serving consumers.[88]

Cases at the intersection of IP and antitrust (as TT might be expected to be) have traditionally been analyzed by examining the impact of IP protection mechanisms on economic incentives to innovate, and balancing these against anti-competitive effects.[89] This is part of the broader antitrust rule of reason, whereby pro-competitive effects are weighed against anti-competitive effects.[90] In subjecting TT to this analysis, a question that might be posed is whether the restraints on competition inflicted by TT (an example of which might be the potentially permanent inability of competitors to create generic versions of the protected seed) are necessary to achieve benefits that outweigh anti-competitive effects. The Federal Circuit has already held generally that a patentee's actions are valid only so long as their anticompetitive effects do not extend beyond the statutory grant.[91] Can this statement apply by analogy to TT, which would extend patent-like protection well beyond any potential statutory grant?

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88 *Antitrust Guidelines*, *supra* n. 80, at § 3.2.3.

89 *Id*. at § 3.4.

90 Jowalski & Smolizza, *supra* n. 86, at ¶ 27.

91 *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327-28 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143 (2001). "Illegal extension" of a patent has been defined as occurring when a patentee has "impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect." *Windsurfing Intl., Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986) (quoting *Blonder-Tongue Laboratories, Inc. v. U. of Ill. Found.*, 402 U.S. 313, 343 (1971)). The Patent Act states that "[n]o patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned." 35 U.S.C. § 271(d).

2. The Need for Balancing

In the broader analysis, it is this limited nature of the statutory grant, coupled with the pro-innovative effects, that is largely the reason why patents are accepted by many legal scholars as being compatible with antitrust principles. For example, by statute, patents are granted only on inventions that are novel and non-obvious, and the nature of the invention must be disclosed in the application. These restrictions are part of the bargain made with the patentee in exchange for the monopoly that a patent provides—a monopoly that is itself limited to 20 years and to the specific claims in the patent. Indeed, this is the compromise that the government has presumably deemed appropriate in establishing the present patent system.

None of the restrictions or limits of the current patent system will apply to the monopoly conferred by TT. In this sense, TT can be viewed as a threat to government prerogative on IP policy, thereby threatening national sovereignty. TTs create a monopoly that goes far beyond what a patent confers, which is unapproved by any governmental body. Moreover, through IP rights, governments are able to fine-tune the application of certain biotechnologies, and allow for certain exemptions to those rights as a situation may require, for example through the use of compulsory licensing. This flexibility is lost with TT.

A related argument is that TT also undermines the patent system by threatening to render obsolete the age-old practice of seed selection and other natural means used to develop new seed varieties. As one commentator states:

> An invention that would preclude the use of natural techniques to improve on the quality, variety, or other characteristics of seeds by large numbers of people seems nefarious and to undermine the very goals sought to be achieved under the patent regime by the Framers [of the Constitution].[92]

3. Anticompetitive Effects of Terminator Technology

How might antitrust-based restrictions on the use of TTs be achieved, at least in the U.S.? It seems that state attorneys general can play a key role. They have been active in multistate antitrust enforcement since the early 1980s. The Hart-Scott-Rodino Antitrust Improvements Act of 1976 provided state attorneys general with the express statutory authority to sue for monetary damages on behalf of natural persons.[93] In 1983, a Task Force was established as a permanent subcommittee of the National Association of

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[92] Yelpaala, *supra* n. 36, at 208-09.

[93] 15 U.S.C. § 15(c).

Attorneys General (NAAG) Antitrust Committee.[94] State attorneys general are now involved in a variety of antitrust enforcement matters.[95]

The Task Force has settled the majority of cases it has pursued without litigation.[96] A large number of the cases it has been involved with are Federal Trade Commission (FTC) allegations of anticompetitive conduct in the pharmaceutical industry involving possibly illegal payments made to generic companies to delay generic drug availability.[97] In these cases, the unlawful extension of the patent allowed patentees to continue to charge monopoly prices for the drug when, had the generic company entered the market when originally intended, they would have had to price the drug more competitively.[98]

Could an analogy be drawn between such anticompetitive behavior and TT? The situation is slightly different in that nothing is stopping generic companies from entering the market of the Terminator seed. When there is no patent and therefore no disclosure, however, it may be much more difficult for generics to produce competing products, either after 20 years or at any time. Further, in the case of patented seeds, farmers would normally be able to start growing the seeds themselves after 20 years. TT, however, would prevent this. Another factor to take note of is that most antitrust cases involve some further anticompetitive action on the part of the patentee. It is still not clear how courts will respond to cases where the anticompetitive result is merely a consequence of the technology, as with TT.

There are a number of other potentially anticompetitive effects of TTs that should be noted for antitrust purposes. The indefinite duration of protection that TTs would provide could lead to the establishment of a concentrated, dominant market position by the seed company that could then be abused. For example, the seed company might non-competitively restrict the output of seeds to enhance prices.[99] It could also select seeds for production based purely on their profitability, rather than the needs of

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94 *Report from Officialdom: 60 Minutes with Robert M. Langer, Assistant Attorney General State of Connecticut, and Chair, NAAG Multistate Antitrust Task Force*, 60 Antitrust L.J. 197, 199 (1991).

95 Patricia A. Conners, *Current Trends and Issues in State Antitrust Enforcement*, 16 Loy. Consumer L. Rev. 37, 38 (2003).

96 *Id.* at 40.

97 For example, all fifty states agreed to settle the case of *New York v. Aventis S.A.*, thereby resolving allegations that Aventis, the branded maker of a certain medication, unlawfully extended its patent for the drug by paying a generic company to delay entry of its generic equivalent. MDL No. 1278, No. 01-CV-71835 (NGE) (E.D. Mich. Jan. 29, 2003).

98 Conners, *supra* n. 95, at 46-47.

99 Yelpaala, *supra* n. 36, at 209.

society.[100] By increasing dependence on seed production and distribution to only a few depersonalized commercial suppliers such as themselves, they may well create risks to seed supply and food security.[101] For example, given the inability of farmers to save seeds, a supplying company that collapses or abolishes the product line could, in extreme circumstances, leave farmers without seed.[102] As one commentator has noted:

> With the extraordinary and unprecedented consolidation of biotechnology intellectual property and the delivery mechanisms of seed companies within a few multinational corporations, it may well be time to explore the option of invoking governmental anti-trust laws.[103]

C. The Farmer's Right to Save Seeds

1. Introduction to Seed Saving

The practice of seed saving mentioned in the last paragraph is of great importance to many farmers. Referred to colloquially as "brown bagging," this practice is viewed by many farmers as a historical and traditional right. Ever since humans became farmers, saving seed for replanting the following year's crop has been a basic tenet of agriculture. Many of the world's farmers routinely save seed from their harvest to replant the following season.

This practice has at various times received some legal recognition. For example, the protections available under the PVPA, discussed earlier, are restricted by a "crop exemption."[104] This exemption permits farmers to save seeds from crops grown from a PVPA protected variety of seed, and to use the seed without compensating the owner of the protected variety.[105] Subsequent case law has somewhat restricted the application of this provision. For example, it has been held that the crop exemption applies only when farmers sell seeds directly to other farmers without third party intervention.[106] Also, the Supreme Court, while recognizing the practice of "brown bagging," has held that a farmer cannot save seed solely for the purpose of selling it and can sell only as much as had been saved for the

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100 See *id.*

101 *Consequences*, *supra* n. 67, at 15.

102 *Potential Impacts*, *supra* n. 19, at 7.

103 *Consequences*, *supra* n. 67, at 50.

104 7 U.S.C. § 2543.

105 *Id.*

106 *Delta & Pine Land Co. v. Peoples Gin Co.*, 694 F.2d 1012, 1016 (5th Cir. 1983).

purpose of replanting his/her own farm.[107] Congress has since restricted the crop exemption provision even further and farmers may now sell seed only "for other than reproductive purposes," which includes selling seed as a food product or animal feed, but not for the planting of new crops.[108]

It is unclear how any farmer's right to save seeds will play out under the Patent Act or other IP legislation. It may be possible to argue a common law property right for farmers to save seed, perhaps based on a farmer's tradition of doing so for thousands of years, in a manner similar to such public property doctrines as adverse possession or prescriptive easements. These doctrines, however, have traditionally been limited in application to cases involving real property.[109] It is therefore doubtful whether, in the U.S. at least, there is any concrete farmer's right to save seed that could be used as a means of challenging the legality of TT.

2. UPOV Convention

The farmer's right to save seeds has received wider recognition internationally. For example, the Convention of the Union for the Protection of New Varieties of Plants (UPOV Convention), to which most developed countries (including the U.S.) are signatories, recognizes certain farmers' rights.[110] In its most recent 1991 revision, the Convention states that private acts for non-commercial purposes are not covered by plant breeders' rights.[111] It also provides for the option of restricting breeders' rights "in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting . . . the protected variety," a right also known as the "farmers' exemption."[112] The Act also protects acts done for experimental purposes (the "research exemption") and for the purpose of breeding other varieties of plant (the "breeders' exemption").[113]

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107 *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 188, 192 (1995).

108 *See Plant Variety Protection Act Amendments of 1994*, Pub. L. No. 103-349, 108 Stat. 3136, 3137 (1994).

109 Oczek, *supra* n. 1, at 652.

110 *See generally International Convention for the Protection of New Varieties of Plants of December 2, 1961*, http://www.upov.int/en/publications/conventions/1991/act1991.htm (accessed April 3, 2005) (as revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991).

111 *Id.* at art. 15(1).

112 *Id.* at art. 15(2).

113 *Id.* at art. 15(1).

Many commentators argue that the protection of acts done privately and for non-commercial purposes is essential for subsistence farmers who use plant varieties for their own food production.[114] Furthermore, the research exemption and the breeders' exemption are important elements in plant variety protection, helping to ensure that all breeders have access to the materials of varieties released by others.[115] The absolute nature of the monopoly created by TT does not allow for any of the exemptions that the UPOV Convention provides for. This could harm subsistence farmers, prevent access to breeding materials, hinder research, and hamper breeding progress and sustainability, thereby limiting benefits to society.

3. Other International Aspects

The national laws and regional regulations of many countries now allow for the farmers' exemption provided under the UPOV Act. For example, Australia's Plant Breeder's Rights Act allows farmers to save seeds from a protected variety for the next year's crop without having to pay a royalty.[116] In Europe, pursuant to the E.U. Biotechnology Inventions Directive on community plant variety rights, small farmers are not required to pay any remuneration to plant variety right holders, although other farmers are still required to pay an "equitable" amount.[117] Also, in Canada, the Canadian Biotechnology Advisory Committee (CBAC) recommended in 2002 that higher life forms (including plants, seeds and non-human animals) be patentable subject to a "farmers' privilege."[118] This privilege specifies that farmers are permitted to save and sow seeds from patented plants or to reproduce patented animals for their own use.[119] These recommendations are currently under consideration by the Canadian government.

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[114] *See e.g. Memorandum Prepared by the Office of UPOV on the Genetic Use Restriction Technologies* (Jan. 10, 2003) (available at http://www.eldis.org/static/DOC11879.htm (accessed May 11, 2005)).

[115] *Id.*

[116] Plant Breeder's Rights Act §§ 16-17 (1994) (Australia).

[117] European Community Council Reg. No. 2100/94 art. 14, O.J. 1.9.94 No. L227/1 (discussing Community plant variety rights).

[118] Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues—Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*, http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00188e .html (Jun. 2002) (accessed Apr. 3, 2005). The CBAC was created in 1999 to provide the Government of Canada with independent advice on policy issues associated with biotechnology.

[119] *Id.*

There are other international treaties dealing with farmers' rights. Most notable among these is the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[120] This treaty creates a positive obligation on the national governments of signatory states to protect certain farmers' rights as set out in Article 9:

> 9.2 In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:
>
> (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
> (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
> (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.
>
> 9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.[121]

This treaty has been ratified and/or signed by most countries, including the U.S. It will come into effect 90 days after the 40th government has ratified it.[122] It makes binding upon national governments the recognition of farmers' rights, including the right to save, use, sell, and exchange farm-saved seeds. Restricting TT is therefore one way for states such as the U.S. to comply with international obligations under the treaties they have signed, such as the ITPGRFA.

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[120] Food and Agriculture Organization of the United Nations, *International Treaty on Plant Genetic Resources in Food and Agriculture*, ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf (accessed May 11, 2005) (hereinafter *ITPGRFA*).

[121] *Id.* at art. 9.2-9.3.

[122] As of January 10, 2005, 33 countries had ratified the treaty. They were Bangladesh, Bhutan, Canada, the Central African Republic, Ivory Coast, Cuba, Cyprus, Denmark, Egypt, El Salvador, Eritrea, Ethiopia, Finland, Ghana, Germany, Greece, India, Ireland, Italy, Jordan, Lebanon, Luxembourg, Malawi, Namibia, Niger, Norway, Spain, Sudan, Sweden, Switzerland, Syria, Tunisia, and the U.K. An up-to-date list of ratifiers can be found through the official FAO website at http://www.fao.org/Legal/TREATIES/033s-e.htm (accessed June 14, 2005).

D. Public Policy Doctrines

1. International Approaches

Another possible basis for restricting TT is to prevent their patenting on the basis of public policy. It is noteworthy that the U.S. Patent Act does not contain an explicit public policy exception. Such an exception, however, may implicitly exist under U.S. patent law. In the 1817 case of *Lowell v. Lewis*, Justice Story was called upon to decide whether a patent was invalid under the Patent Act of 1793 for failing to claim a "useful invention."[123] Relying on the "utility" concept, Justice Story held that a patent would be invalid if it was "frivolous or injurious to the well-being, good policy, or sound morals of society."[124] In 1987, Donald J. Quigg, then Commissioner of the U.S. Patent and Trademark Office (USPTO), issued a press release suggesting that a patent might be denied on public policy grounds under *Lowell*.[125] This suggests the decision may still be good law, and therefore a possible basis for denying patents on inventions involving TT. Some commentators recommend that the U.S. adopt a clearer public policy exemption for patents.[126]

Other countries and jurisdictions have more established public policy provisions in their patent laws. For example, Article 53(a) of the European Patent Convention (EPC) does not permit granting a patent if the publication or exploitation of the invention would be contrary to "ordre public" or morality.[127] Similarly, the U.K. Patents Act of 1977 provides that a patent shall not be granted if the publication or exploitation of the invention would be generally expected to encourage offensive, immoral, or antisocial behavior.[128] The public policy exception is also captured in the European Directive on the Legal Protection of Biotechnological Inventions

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123 *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817).

124 *Id.*

125 Donald J. Quigg, Commissioner of the U.S. Patent and Trademark Office, *Policy Statement on Patentability of Animals* (Apr. 21, 1987) (reported in 1077 Off. Gaz. Patent Office 24).

126 *See e.g.* Yelpaala, *supra* n. 36 (demonstrating that using TT, a patent holder can extent his or her rights beyond the period of the patent monopoly, thus running counter to public policy).

127 European Patent Office, *Convention on the Grant of European Patents* art. 53(a), http://www.european-patent-office.org/legal/epc/ e/ma1.html (accessed May 11, 2005).

128 *Patents Act* ch. 37 § 16(1) (1977) (United Kingdom).

(Biotechnology Directive).[129] Under Article 6 of the Biotechnology Directive, "inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality."[130]

One important public policy provision is found in Article 27(2) of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). That provision states:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which 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.[131]

There is no generally accepted notion of what constitutes "ordre public" as referred to in the provision. Therefore, WTO member countries have considerable flexibility to define what is covered, depending upon their own concepts of protecting public values.[132] Concrete scientific evidence that TT represents a danger to the environment or to human, animal or plant health would be a strong basis for denying patent protection under Article 27(2) of TRIPS.

2. Grounds for Exclusion

Various potential dangers of TT might warrant denying patent protection from a public policy perspective. Some of these have already been addressed, such as the threats TT poses to food security, or to national sovereignty. There are a number of other potential harms that should be considered. One such consideration is the risk of Terminator genetic material contaminating the surrounding environment. For example, cross-pollination of Terminator plants with neighboring plants and adjacent farm plots might lead to the sterility trait spreading far beyond the precursor seeds. How many plants and seeds will be contaminated depends on various factors, such as the degree of cross-pollination, the species of plant, the variety of

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129 European Parliament and Council Directive 98/44/EC, *The Legal Protection of Biotechnological Inventions*, O.J. 30.7.98 No. L213/13, http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf (accessed May 11, 2005).

130 *Id.* at art. 6.

131 World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual Property Rights*, art. 27(2) (1995), http://www.wto.org/english/tratop_e/trips_e/t_agm3_e.htm (accessed April 3, 2005).

132 *Consequences*, *supra* n. 67, at § 115.

crop, weather conditions, and the proximity of adjacent fields.[133] Potentially, however, cross-pollenation with Terminator plants could make seed-saving untenable for adjacent farmers who never intended to employ TT. One commentator has even forecasted terminator genes being used for military purposes, where Terminator seeds could be sold or administered abroad and triggered to intentionally destroy crop generations later.[134]

Contamination can also occur in the food chain. For example, it is unclear how the sterility gene, or the chemical triggers associated with it, will affect birds, insects, fungi and bacteria that eat or infect Terminator seeds.[135] Nor is it clear how such seeds, left in the field, will affect the ecology of soil organisms.[136] There may even be risks to human consumption. Consider, for example, a case where an ornamental sunflower spreads the Terminator gene to an oilseed variety, thereby introducing the toxin into edible oil or sunflower seed meal, without any determination being made as to whether the new, dangerous variety is safe for consumption.[137] That TT is yet to be deployed on a commercial scale means much of the debate on this subject is purely hypothetical. Therefore, researchers must continuously weigh the potential contamination effects of TTs versus the need for them.

Another potential harm of TT and GURTs is the so-called threat of "bioserfdom." For example, in the case of chemically-triggered GURTs, seed companies will have the opportunity to load various commercial characteristics (including fertility) onto a plant variety (or animal breed), which they can then activate or deactivate. In this way, a farmer will buy seed with or without certain properties, much like he/she might buy a tractor or other agricultural equipment. The degree of harm posed to farmers from bioserfdom will vary depending on the nature of the farming system affected. For example, in low-input farming systems (LIFS), farmers continuously breed and improve local seed to maintain adaptive fitness and productivity. Such systems are often characterized by high crop diversity, low soil quality, and few external inputs such as fertilizers or pesticides. Here, Terminator seeds would substitute traditional, locally-adapted varieties. This process could hamper the resilience and long-term productivity of LIFS, especially in

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133 Crouch, *supra* n. 6.

134 Ricarda Steinbrecher & Patrick Mooney, *Terminator Technology: The Threat to World Food Security*, 28 The Ecologist 279 (Sept. 1, 1998).

135 Crouch, *supra* n. 6.

136 *Id.*

137 *Id.*

marginal environments that rely on local varieties particularly responsive to the nuances of extreme conditions.[138] The adverse effects in these small environments occur because companies would develop few or no TT varieties to meet the environmental conditions of these limited seed markets. LIFS are to be contrasted with highly industrialized agricultural systems, characterized by wide scale use of a limited number of plant varieties, fertilizers, pesticides, irrigation and mechanization.[139] These farmers typically have access to finances and credit, and can probably accept TT if quality is reasonably assured in their crops.[140]

TT may also pose a hindrance to public sector research in agriculture. As discussed earlier, the research or experimental use exemptions that promote agricultural research will not exist with TT. The negative impact this would have is likely to be felt more strongly in developing countries, where few private research initiatives are in place. Research on minor crops could also be threatened. Such research is essential in catering to the agricultural needs for certain segments of society. With the shift away from public sector research, however, they are more likely to be substituted by private research on more profitable major crops.[141]

E. Arguments in Favor of Terminator Technology

1. Hybrid Seeds

It is important that any debate on restricting TT also objectively address the possible benefits of TT, as well as potential drawbacks. Some defenders of Terminator seeds draw an analogy to hybrid seeds.[142] Such hybrid seeds are bred to have certain desired characteristics not present in either parent alone. Thus, while the first generation of a hybrid is genetically fairly uniform, the next generation is quite variable due to gene shuffling

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[138] *Potential Impacts*, *supra* n. 19.

[139] *Consequences*, *supra* n. 67, at § 136.

[140] *Id.*

[141] *See generally* Convention on Biological Diversity, *Report of the Ad Hoc Technical Expert Group Meeting on the Potential Impacts of Genetic Use Restriction Technologies on Smallholder Farmers, Indigenous and Local Communities and Farmers' Rights* § 16(b), http://www.biodiv.org/doc/meetings/tk/wg8j-03/information/wg8j-03-inf-02-en.doc (accessed April 4, 2005) [hereinafter *Ad Hoc Meeting*].

[142] *See e.g.* Pendleton, *supra* n. 40, at 20.

resulting from sexual reproduction.[143] Industrial farmers growing hybrid seeds typically purchase new seeds every year.[144] In this way, hybrid seeds already have some measure of biological protection similar to TT.

One illustrative example of the widespread adoption of hybrids is corn. A hybrid variant originally developed in 1908 accounts for nearly 100% of the corn grown in the U.S. today.[145] As one commentator has argued, although hybrid seed corn has to be purchased every year, American corn farmers have not become impoverished, but have instead "abandoned normal corn in favor of a . . . seed that had to be purchased yearly because yield was so much better."[146] Similarly, after hybrid rice seed was introduced in Bangladesh in 1999, farmers are in many cases producing yields over 30% higher than before and are able and "willing to pay for new hybrid seed ever [sic] year."[147] If TT is able to provide similar yield increases, could it not similarly benefit farmers? The protections that hybrid seeds provide has also skewed research and development into these varieties and away from non-hybridized seeds such as wheat and rice for which seed companies have no method of controlling reproduction.[148] Should such a method of protection be created by TT, research and development may become more diversified.

It is important to remember that significant differences still exist between hybrid and Terminator seeds. For example, with hybridization, breeders seeking to use genetic material from the hybrid seeds for research or other purposes could retrieve it from second generation plants.[149] With TT, however, that second generation is killed off entirely.[150] Also, the theory behind hybridization is to create genetic crosses that give plants higher yields and vigor. The commercial non-viability of subsequent generations is really an ancillary effect. The sole purpose of TT, however, is to facilitate monopoly control and increase profits for agribusiness.[151] As such, there is a significant ethical difference between the two procedures.

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143 Crouch, *supra* n. 6.

144 *Id.*

145 Steinbrecher & Mooney, *supra* n. 134, at 276.

146 Pendleton, *supra* n. 40, at 20.

147 *Id.*

148 Oczek, *supra* n. 1, at 632.

149 Crouch, *supra* n. 6.

150 *Id.*

151 *Id.*

2. The Value of Seed Saving

Other commentators have criticized the importance given to the practice of seed-saving, and the argument that TT poses a threat to agricultural self-sufficiency. Consider the following critique:

> Logically, if farmers are self-sufficient with regard to seed, then they are producing all the seed they need for current consumption and subsequent planting or sale: they are not even part of the market for sold seed. If so, they are indifferent to what manner of seed is sold or its price, and likewise the market is indifferent to them, for good or ill, whether they are wealthy or poor.[152]

As Pendleton points out, only the self-sufficiency of farmers who are not self-sufficient is threatened by TT. To be fair, the author instead describes many farmers as "serially self-sufficient," alternating between periods where they have no need to buy seed and periods of market participation.[153]

Monsanto has also encouraged farmers to replace traditional practices of saving seed with ones where they would choose among various seeds in the marketplace:

> Policy objectives should be to increase farmers' income and welfare, not to relegating the farmers to past practices which limit his potential and restrict them to conditions of the past. Not having to purchase seed is not a rewarding goal for farmers. This is an unfortunate case of farmers being asked to restrict their choices, at the expense of the farmers' own economic well being. Farmers' welfare will be improved when the farmers are allowed to make the choices based on economics, not on non-farmers' beliefs about whether farmers should save seed for replanting.[154]

While Monsanto clearly has a commercial interest in offering such advice, the practice of purchasing new seed annually is, from an economic perspective, no different from paying agricultural workers' wages or purchasing farm equipment. All are financial inputs into the whole agricultural process.[155]

More fundamentally, farmers have a choice to accept TT, or reject them and preserve their old way of life. If they feel they will not profit from TT, they may demand normal seed and if this demand persists, there will likely be a company willing to satisfy it. Curiously, Iraq may become an interesting test case as to the implications of overhauling a traditionally seed-saving system. The Food and Agriculture Organization (FAO) estimates that in 2002, 97% of Iraqi farmers relied on saved seed from their own stocks or

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152 Pendleton, *supra* n. 40, at 19.

153 *Id.*

154 Collins & Krueger, *supra* n. 4, at 3.

155 Pendleton, *supra* n. 40, at 20.

purchased from local markets.[156] New legislation from the Iraqi interim government, however, will apparently prevent farmers from saving the seed of "new" plant varieties registered under the law.[157] What implications this will have for Iraqi agriculture should be monitored closely.

3. Procompetitive Effects

Some potential anticompetitive effects of TT were discussed at length earlier in this article. However, TT may also have some potentially procompetitive effects. The assurances of IP protection that TT provides to seed companies can encourage them to further innovate and compete with each other. For example, such assurances can lead to a significant lowering of transaction costs that would otherwise have been necessary to enforce patent protection through legal channels, and may ensure such protection in countries with no IP systems in place.[158] This will likely be a strong incentive for increased research and development investments in those areas. And as discussed earlier, TT could stimulate private sector suppliers to enter other markets, such as those for non-hybrid seed research.

4. Bioprotection

One final argument in favor of TT is its potential as a bioprotection mechanism. This potential arises from the fact that the same trait conferring sterility on Terminator seeds can keep genetically altered material in those seeds from escaping into the environment by ensuring that they do not survive beyond the first generation. This, some proponents have argued, should assuage the fears of those concerned with the unpredictable effects of releasing genetically modified organisms (GMOs) into the ecosystem.[159]

This bioprotection aspect of TTs has been lauded by a number of notable organizations. In April 2000, for example, the National Research Council (NRC) of the U.S. National Academy of Sciences released a report describing TT as an "effective method of confining gene flow," particularly

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[156] GRAIN, Iraq's New Patent Law: A Declaration of War Against Farmers (Oct. 2004), http://www.grain.org/nfg/?id=253 (accessed June 11, 2005).

[157] *Id.*

[158] *Potential Impacts*, *supra* n. 19, at ¶ 44.

[159] *See e.g.* Collins & Krueger, *supra* n. 4.

for reducing wild species invasion.[160] In July later that year, seven national science academies released a report entitled *Transgenic Plants and World Agriculture* that commented as follows with respect to GURTs:

> GURTs potentially have beneficial applications for consumers, growers, and the environment that should not be overlooked in debates over intellectual property rights. For example, GURTs could be used to prevent transgenes from spreading to closely related wild plants by preventing germination of any crossbred seeds. Furthermore, this technology could potentially eliminate the problems of "volunteer" plants that appear from seed left in the field after harvest. Volunteer plants must be eliminated before the next crop is planted because they are hosts for pests and pathogens and can nullify the benefits of crop rotation.[161]

In March 2001, The U.K.'s Advisory Committee on Releases to the Environment (ACRE), which advises the U.K. government on the risks of GMOs, published its annual report. In it, TT was described as "a promising technique for genetic isolation."[162]

Despite these reports there are still doubts as to the effectiveness of any bioprotection application of TT. For example, when batches of seed are treated to incorporate the sterility trait, it is unlikely that every single seed will be rendered sterile. Those unaffected seeds can then germinate and fertilize surrounding areas. Further, the inevitable process of genetic mutation is bound to render some seeds fertile again.[163] There is also a phenomenon known as gene silencing, where introduced genes that were previously active suddenly stop functioning.[164] Were this to occur with the Terminator gene, previously sterile plants could again start to grow and reproduce, possibly for several generations. While it is true that the rate of occurrence of such anomalies is very low, consider that there are now over 150 million acres of genetically-modified (GM) crops covering the U.S.[165]

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[160] Comm. on Genetically Modified Pest-Protected Plants, Bd. on Agric. and Nat. Resources, Natl. Research Council, *Genetically Modified Pest Protected Plants: Science and Regulation* 90 (Natl. Acad. Press 2000).

[161] *Transgenic Plants and World Agriculture* 33-34 (Natl. Acad. Press 2000). The report was prepared under the auspices of the Royal Society of London, the U.S. National Academy of Sciences, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Science Academy, the Mexican Academy of Sciences and the Third World Academy of Sciences. *Id.* (noted on title page).

[162] Department for Environment, Food & Rural Affairs, *Advisory Committee on Releases to the Environment* (United Kingdom) (available at http://www.defra.gov.uk/environment/acre/bestprac/guidance (accessed June 11, 2005)).

[163] Charles Choi, *The Terminator's Back: Controversial Scheme Might Prevent Transgenic Spread*, Sci. Am. 30 (Sept. 2002).

[164] Crouch, *supra* n. 6.

[165] Choi, *supra* n. 163.

Thus, even if the terminator system's failure rate were one in a million, that would still amount to 150 acres of fertile plants.[166] Again, the lack of experimentation or significant field applications of TT renders this debate theoretical. Any argument that TT is effective or ineffective in halting transgene spread will need to be substantiated with field data in different environments and farming systems.[167]

It is also important to be aware of alternative areas of research that can also have bioprotection applications. One of these is research in maternal inheritance technology. This research applies to sexual plant varieties, and causes modified genes to pass down only to the seeds (the maternal line), and not to the pollen (the paternal line).[168] This would substantially reduce the contamination risks of genes being spread through airborne pollen. For example, scientists working with tobacco and potatoes have recently been able to modify the genome of the chloroplast, a cellular organelle that does not transfer genes from pollen, leading some scientists to predict that the new technique will prevent escape of foreign genes through pollen.[169] Clearly, new technologies evolve rapidly and these developments will influence just how dependent bioprotection will be on TT.

F. Possible Responses

1. Absolute Prohibition

In light of the discussion thus far on the possible threats and merits of TT, what response should the government take? One possibility is a complete ban.[170] For example, the patenting of TTs could be banned on some public policy ground, as discussed above. However, prohibiting the patenting of TTs will not be enough to prevent their use. Patents only give a right to exclude others from practicing an invention; they do not affect the

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166 *Id.* The author notes, however, that research is currently underway to reduce TT failure rates to as low as 1 in 10 billion. *Id.*

167 *Consequences*, *supra* n. 67, at Annex ¶ z.

168 Choi, *supra* n. 163. In plant sexual biology, seeds represent the maternal lineage (the equivalent of the mammalian "egg"), and pollen represents the paternal lineage (the equivalent of the mammalian "sperm"). *See e.g.* James D. Mauseth, *Botany: An Introduction to Plant Biology* (3d ed., Jones & Bartlett Publishers 2003).

169 *A Seed Odyssey*, *supra* n. 18, at 5-6.

170 This approach was taken by India, presumably due to perceived threats to its 100 million farmers, 80 percent of whom are dependent on farm-saved seed. *See* ETC Group, *Terminator 2 Years Later: Suicide Seeds on the Fast Track*, ETC Group Communiqué (Feb./Mar. 2000).

right to practice that invention in the first place. In fact, invalidating patents on TTs without simultaneously restricting their use can actually have the opposite of the desired effect, inviting everyone to use TT commercially in an uncontrolled fashion.[171]

Governments may also decide to allow the use of T-GURTs only, and prohibit V-GURTs (including TTs). As explained earlier, T-GURTs control for various traits of a plant, though not sterility. Plants not expressing the controlled trait could still produce seed that can be saved, replanted, researched or experimented on. There is no longer a requirement for repeated seed purchase. As such, the potential impacts of T-GURTs can be less severe than V-GURTs. In this way, T-GURTs may at least partly address the concerns of seed developers to secure a return on their investment, while offering a choice to farmers.[172] The traits can be chemically activated whenever farmers decide, so long as they possess the seed. T-GURTs can also fall more in line with the established patent system. Their chemical activators will presumably also be patented and after 20 years, competitors can start producing and selling the activators to all farmers.

2. Limited Prohibition

Another option is a limited prohibition. For example, the government could condition the use of TT on simultaneously obtaining a patent for that seed, thereby drawing it closer towards the existing patent regime. It might even require companies to create non-Terminator versions of the seed to be distributed to farmers in place of the Terminator seed in the 20th year. Permission to use TT could then be withheld until satisfactory evidence is provided of the creation of a non-sterile equivalent.

3. Compulsory "Non-Sterilization" or "De-Sterilization"

Chemically-activated Terminator seeds could also possibly be accommodated within the current IP system. For example, unactivated versions of such seeds can be provided for use in breeding programs and research, while seed companies can continue to have their IP interests protected elsewhere. And after 20 years, governments can require that such chemical activation cease, to mirror the monopoly term within the existing

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[171] *Consequences*, *supra* n. 67, at Annex ¶ v.

[172] *Id.* at Annex ¶ k.

patent system. The use of chemical triggering may also become significant in another sense. Research is currently being conducted on transgene deletion technology, which would chemically induce the removal of foreign DNA before the crop is harvested.[173]

One potential implication of deletion technology is that it may give farmers the ability to replant nontransgenic seeds harvested from transgenic plants by simply applying an external chemical trigger to their crop. Where the transgene at issue affects the sterility trait, deletion technology may be a way to reverse the effects of TT. If effective, it may be another means by which governments may be able to restrict the monopoly conferred by TT, e.g. by forcing seed companies to provide it to licensees after 20 years, or to exempt researchers. Some critics of TT oppose deletion technology as well, arguing that it may be ineffective and that it shifts the burden of excising offensive transgenes from the biotech industry to the farmer and society at large.[174] Some measure of control over TT, however, is still better than none.

A useful analogy to make at this point is between TT and encryption technology. Like TT, encryption is also meant to address the problems created by relatively easy reproduction of protected materials (namely copyrighted music or software) by large groups of people.[175] Both TT and encryption can be used as an alternative to IP rights. To accommodate "fair use" of copyrighted materials, some jurisdictions allow for the removal of the encryption.[176] Perhaps deletion technology can enable the similar removal of the sterility trait in a way that would allow for "fair use" by farmers, "research use," or use by anyone after 20 years.

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[173] The technology basically works by adding "another gene next to the engineered trait gene. . . . The additional gene would code for an enzyme that cuts DNA at specific sequences. Those specific sequences . . . would be put on either side of the enzyme gene and engineered trait gene. When the enzyme gene was activated, the enzyme produced would cut out the DNA in between the two recognition sequences, thus removing all of the engineered DNA, except for one of the recognition sequences." *Five Years Later*, *supra* n. 20, at 8-9.

[174] *See id.* (asking "[w]hy should society accept a new, unproven technology to fix a defective one?"). Indeed, Maxygen, the company that spearheaded the research on transgene deletion technology, is not currently pursuing this technology, largely due to the negative publicity it has generated.

[175] William W. Fisher, III, *The Impact of "Terminator Gene" Technologies on Developing Countries: A Legal Analysis*, in *Biotechnology, Agriculture and the Developing World: The Distributional Implications of Technological Change* (Timothy Swanson ed., Edward Elgar Publg. 2002).

[176] For more information on the "fair use" exemption in copyright law, *see e.g.* Stephana I. Colbert & Oren R. Griffin, *The Impact of "Fair Use" in the Higher Education Community: A Necessary Exception?*, 62 Alb. L. Rev. 437 (1998); Kristine J. Hoffman, *Fair Use or Fair Game? The Internet, MP3 and Copyright Law*, 11 Alb. L.J. Sci. & Tech. 153 (2000).

IV. CONCLUSION

TT appeals to the seed industry as a cheaper, more effective method of protecting their investments than the traditional patent system. However, it has a number of legal implications that this paper has addressed. One of these involves the doctrine of patent misuse, a doctrine that may be difficult to apply in the case of TT since it serves mainly as a defense to patent infringement, and not as an independent cause of action. TT is probably more likely to have antitrust implications if the absolute monopoly that it confers is deemed to limit competition or threaten the delicate balancing that the government has tried to achieve through the existing patent system. TT would also stop farmers from being able to save seed. While this has not yet been recognized as an explicit right of farmers in the U.S., the practice has received some international legal protection through the UPOV Act and the ITPGRFA and restricting TT could to some extent be an act of compliance with international obligations under these treaties.

Evidence that TT represents a danger to the environment or human, animal or plant health could also be a basis for denying patent protection under Article 27.2 of TRIPS. However, concrete scientific evidence about the effects of TT is seriously lacking at the moment, and needs to become an active study area. This would help give domestic policy a sound basis on which to act. For example, governments may choose to prohibit TT, perhaps opting instead for T-GURT varieties of plants that confer the benefits of trait protection, but are not sterile. Or governments could allow TT but condition its use on the creation of effective non-sterile equivalents by a company, or on their employing effective transgene deletion technology, so as to limit the extent of the monopoly conferred. Deciding on an effective approach will require a good scientific grounding and informed debate among members of the agribusiness, legal and farming communities, a debate that today remains in its preliminary stages.