THE KILLING FIELDS: INTELLECTUAL PROPERTY AND GENETIC USE RESTRICTION TECHNOLOGIES

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I INTRODUCTION

One of the defining characteristics of biological materials is that they have the innate ability to reproduce themselves. As well as making it easier for third parties to appropriate botanical innovations, this has also created problems where the traditional rules of patent infringement, notably the concept of strict liability, have been applied to biological inventions. Another defining characteristic of biological materials is that they are dynamic, volatile and subject to change. In the early part of the 20th century, this led policy makers to develop sui generis legal regimes to protect new varieties of plants.[1] It also created problems for patent owners trying to determine whether their rights had been infringed. While the animate nature of biological materials has created a number of problems for intellectual property law, these problems are not necessarily restricted to biological inventions. For example, the question of whether patents for chemical processes and new use patents have been infringed has been a long-standing problem both for intellectual property owners and for policy makers attempting to protect owners' interests. What sets biological inventions apart from these inventions, however, is the way these problems have been resolved. In particular, while the problems that have arisen when determining whether chemical inventions and new use patents have been infringed were primarily resolved by legal means – for instance, by reversing the onus of proof for patent infringement[2] – there has been a tendency to resort to biological solutions to resolve similar problems when they have arisen in relation to biological materials. The latest example of this, which is the focus of this paper, is 'genetic use restriction technologies' ('GURTs'), which is the name that has been given to

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1 See Margaret Llewelyn, 'From GATT to G.A.T.T.: Fifty Years of European Bio-IP: Part 1' (2003/4) 6(3) *Bio-Science Law Review* 167.

2 A recent example is found in the *Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C*, opened for signature 15 April 1994, 1869 UNTS 299, art 34 (entered into force 1 January 1995).

a range of biotechnologies that enable scientists to manipulate and control many facets of plant production, including when and how plants are reproduced.

GURTs are usually grouped into two general categories.[3] The first relates to technologies that control the expression of a gene associated with a particular trait, such as drought tolerance or salt resistance. With these technologies, which are called 'trait-specific genetic use restriction technologies' ('T-GURTs'), a specific genetically-engineered trait, such as drought or disease resistance, will not be expressed in a plant unless the crop is exposed to an external agent, such as a chemical.[4] The second group of technologies, which are known as 'variety-level genetic use restriction technologies' ('V-GURTs'), control the expression of genes that play a vital role in plant reproduction. By controlling the situations in which plants are able to replicate themselves, these inventions turn Dawkins' conception of organisms as passive survival machines for their genes on its head. Instead, with GURTs, modified genes transform plants into suicide machines for those who control the technology.

To date, over 50 patents for GURTs have been granted worldwide.[5] The most well-known of these was jointly developed by scientists at the United States Department of Agriculture ('USDA') and Delta and Pine Land Company ('DeltaPine'), the largest supplier of cotton seed in the United States. This invention, officially referred to as the 'Technology Protection System' but more commonly known as 'Terminator Technology', consists of a method of genetically modifying plants so that they produce sterile seed.[6] The idea for this novel technology arose as a result of informal discussions that took place in 1993 between representatives from DeltaPine and scientists at the USDA. According to Mel Oliver, who is named as principal inventor in the patent, the USDA approached DeltaPine to see whether they were interested in developing hybrid cotton. DeltaPine declined, primarily because they believed that cotton hybrids did not provide enough of a yield advantage to make them commercially viable.[7] DeltaPine did, however, express an interest in developing genetically-modified plants that produce sterile seed.[8] By mid-1995, the two groups had successfully transformed tobacco plants so that the seeds they produced were sterile. On 7

3 While the research to date has focused on broad-acre crops, there are plans to extend the application of GURTs to aquaculture, trees, and livestock.

4 T-GURTs have the potential to modify plants to make them resistant to drought, insects, and disease, to change growth habit and yield, and to alter the colour, quality, taste or appearance of flowers and fruits. See US Patent No 5,723,765 (issued 3 March 1998) (control of plant gene expression), 8.

5 Cullen Pendleton, 'The Peculiar Case of "Terminator" Technology: Agricultural Biotechnology and Intellectual Property Protection at the Crossroads of the Third Green Revolution' (2004) 23 *Biotechnology Law Report* 1, 6.

6 US Patent No 5,723,765, (issued 3 March 1998) (control of plant gene expression). The term 'terminator technology' was coined by Pat Mooney of the Canadian NGO, Rural Advancement Foundation International, now known as the Action Group on Erosion, Technology and Concentration ('ETC').

7 AgJournal.com, Interview with Dr Mel Oliver, (AgProfile Interview, 19 July 2005) <http://www.agjournal.com/agprofile.cfm?person_id= 27> at 15 April 2005.

8 Ibid.

June 1995 the USDA and DeltaPine applied for a United States patent entitled 'Control of Plant Gene Expression'. The patent was granted on 3 March 1998.[9]

Like many of the GURTs, the USDA-DeltaPine invention was designed to perform a number of different, apparently conflicting roles. One of the primary goals was to develop a non-legal mechanism that would limit the ability of third parties to reproduce biological materials. In particular, the inventors wanted to develop a technical mechanism that would allow them to prevent the unauthorised propagation of new varieties of cotton without having to go to the expense of obtaining patent or plant breeders' rights protection. To this end, the inventors decided to genetically modify plants so that the seeds they produced were sterile. In particular, the inventors introduced a gene taken from the seed of the *Saponaria officinalis* plant (commonly known as 'Soapwort' or 'Bouncing Bet'). This gene is referred to as a 'lethal gene' in the patent because it produces a protein that kills the cells in which it is produced. It is perhaps more accurately described as a 'sterility gene' because it is only produced in the plant seed and does not otherwise affect the health of the plant. When the lethal gene is inserted into cotton plants, the seed that is produced by the plant is sterile. As well as providing a way of controlling reproduction, this also offers a way of circumventing the right to save seed that is granted to farmers under plant breeders' rights legislation in many countries. In this sense GURTs not only represent the embodiment of the Baconian fantasy of mind over matter, they also offer a way of fulfilling the desire, long held by breeders and those who invest in the breeding process, to control the process of reproduction.[10]

While the primary goal of the USDA-DeltaPine invention was to develop a biological means of controlling reproduction, the inventors were faced with two other important considerations. First, since the valuable oils and fibres in cotton plants do not develop until the plants are fully grown, the inventors needed to ensure that the modified plants were able to reach maturity, otherwise the plants would have had no value to farmers. This meant that they needed to develop a mechanism to ensure the resulting seeds were sterile, but which would not inhibit the 'normal' growth cycle of cotton plants. To resolve this problem, the inventors coupled the sterility gene with a gene switch (or promoter) that controls when

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9 US Patent No 5,723,765 (issued 3 March 1998) (control of plant gene expression). The patent contains a number of broad claims, including a method for making a genetically modified plant, a method for producing seed that is incapable of germination, and a method of producing non-viable seed. The patent also claims a number of products obtained by the use of these methods.

10 The ability to control reproduction is also said to have a number of agricultural benefits. These include the prevention of: pre-harvest sprouting of wheat (thus making crops less susceptible to disease); growth during storage (thus extending the shelf and storage life of roots, tubers and many ornamentals); and volunteer plants (a major pest problem where rotation is not practiced). The ability to control the life-cycle of plants also means that crops can be standardised. This is particularly important for large scale mechanised farming, which requires uniform plants that fit with machines. Another potential use of V-GURTs is golf-courses where it is desirable to maintain turf grasses for a long time without seed production. See Harry Collins, 'Promoting Technology and Encouraging Investment' (2001) 21 *Seed Info: Official Newsletter of the WANA Seed Network* 1.

and where the sterility gene is activated.[11] Importantly, the specific promoter that was chosen does not switch on its associated gene until late in seed development after most other fruit and seed structures have formed.[12] At this stage the seed is fully-grown, has accumulated most of its storage oils and proteins, and is drying down in preparation for the dormant period between leaving the parent plant and germination.[13] By fusing the promoter to the sterility gene, the inventors ensured that the sterility gene was only activated when the plant had reached maturity. As a result, the resulting seed is normal, except for the fact that it will not germinate. While farmers who purchase seed that incorporates this technology will initially be able to generate a viable crop, they will not be able to use seed produced from that crop to generate further crops. Instead, they will have to return to the supplier each year to purchase new seed.

The inventors were also faced with the further problem that to be in a position where they could generate seed to sell to farmers, they needed to be able to allow a number of growers to propagate successive generations of plants. In practical terms this meant that they needed to develop a mechanism that would allow them to switch the promoter off. At the same time, however, to ensure that farmers were unable to use any seed they might have saved to plant new crops, the inventors also needed to be able to switch the promoter on prior to the point of sale. To solve this problem, the inventors introduced further genes into the cotton plants that enabled them to control the circumstances in which the genetically modified plants produce the protein that sterilises second generation seed. In particular, the inventors modified the plants so that the process that leads to sterilisation was only initiated when the seed (or plant) was exposed to an external agent: the example given in the patent is the chemical tetracycline. The application of tetracycline acts as a catalyst that triggers a chain reaction. The ultimate result is the sterility of the subsequent generation of seed. In the absence of tetracycline, the transformed seed only has a latent potential for sterility. As such, it will grow in the same way as unmodified seed. By making the process of seed sterilisation subject to an external trigger (tetracycline), the inventors ensured that seed companies could produce enough seed to supply growers. At the same time, however, by treating seed with tetracycline before it was sold to farmers, the inventors also ensured that farmers would not be able to use the subsequent generation of seed to replant new crops.

One of the curious features of genetic use restriction technologies is that the policy debates have largely preceded the application of the science. While there

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11 This aspect of the invention builds upon the fact that most genes are not used by cells all of the time. Rather, they are switched on and off when needed. However, genes do not do this by themselves: they do so with the help of other genes, known as promoters. See generally Matt Ridley, *Nature via Nurture* (2003) 31–7.

12 The particular promoter used was the 'late embryogenesis abundant' ('LEA') promoter that is found in the seed of a particular variety of cotton. As its name suggests, this promoter does not switch on its associated gene until late in seed development (during embryogenesis), after most other fruit and seed structures have formed. See Mel Oliver et al, US Patent No 5,723,765 (Issued 3 March 1998) (Control of Plant Gene Expression), 6.

13 Martha Crouch, *How the Terminator Terminates* (1998) An Occasional Paper of the Edmunds Institute <http://www.edmonds-institute.org/crouch.html> at 15 April 2005.

have been one or two instances where field trials have been reported,[14] the commercial implementation of the technology is still some way off. One of the main problems is that to be commercially viable, the technology needs to be coupled with traits that improve the economic value of the target crop, for example genes conferring drought or frost tolerance, enhanced photosynthesis, more efficient use of nitrogen, or increased yield.[15] So far, however, the search for value-added traits has met with mixed results.[16] There are a number of other technical hurdles that need to be overcome before the technology can be implemented. Prime amongst these is the fact that it is difficult to ensure that transformed plants are stable, particularly where a number of genes are introduced into the target plant.[17] In particular, it is not possible to predict or control where the introduced genes will be located in the recipient genome or how many of the genes will be inserted in the plant.[18] Despite these uncertainties, there has been a lot of discussion in recent years about the relative merits of the technology. While these debates have touched on a range of issues, a key consideration has been the impact that genetic use restriction technologies are likely to have on the intellectual property regimes that protect plant genetic resources, as well as the consequential impact that this will have on users of genetic resources. In this paper, we wish to evaluate these arguments, focusing in particular on the claims that have been made about the impact that the technology is likely to have on the creation and circulation of plant genetic resources.

II USING BIOLOGY TO IMPROVE INTELLECTUAL PROPERTY PROTECTION

There is a growing belief, particularly amongst those who invest in the development of new and improved plant varieties, that there are problems with the legal regimes used to protect botanical innovation. One common complaint relates to the time and cost of obtaining intellectual property protection. Owners have also complained about the difficulty of enforcing intellectual property rights and the related problem of 'seed piracy' that is said to be widespread both in developing countries and in developed countries such as Australia and the United

14 Terminator trees have reportedly been 'tested extensively in large open plots'. See Joe Cummins and Mae-Wan Ho, 'Terminator Trees' (Isis Press Release, 1 March 2005).

15 In relation to hybrid crops, it is often said that farmers are prepared to purchase hybrid seed each year because the cost of purchasing new seed is offset by the economic benefits arising from the improved yield associated with hybrid crops. The situation is much the same with GURTs.

16 The exceptions to this is the introduction of agronomic traits such as herbicide and insect resistance in crops such as corn, cotton, rapeseed, rice and soybean, and the introduction of value-enhanced traits such as altered flower colour in carnations and increased oil content in rapeseed and soybean. For a summary of current and future developments in this field, see Robbin Shoemaker et al, 'Economic Issues in Agricultural Biotechnology', *Economic Research Service Agriculture Information Bulletin No 762, United States Department of Agriculture* (2001) 16–22.

17 Ibid 42.

18 David Murray, *Seeds of Concern: The Genetic Manipulation of Plants* (2003) 33.

States.[19] Many organisations are also highly critical of the scope and nature of intellectual property protection, particularly in so far as it allows farmers and breeders to use botanical innovations without having to compensate the intellectual property owner. Indeed, the practice of using farm-saved seed to plant new crops, which is permitted under plant breeders' rights laws in many countries, is increasingly being condemned by agricultural companies as an act of piracy which undermines investment in crop research. Similar complaints are also made about the breeders' exemption which allows competitors to develop new varieties.[20]

Over time, organisations investing in botanical research have adopted a number of different techniques to overcome what they perceive to be the problem of third parties using but not paying for botanical innovations that they have developed. One response has seen companies move away from using plant breeders' rights and towards patents as a way of protecting new varieties.[21] In part this has been motivated by the fact the exceptions to the scope of protection are more limited under patent law than under plant breeders' rights law. Another response has seen the increased use of end point royalties, rather than seed royalties, as the basis for calculating the remuneration payable for permission to use a protected variety. Where end point royalties are included in seed contracts, farmers pay a percentage of the income on the crop grown rather than a royalty on the seed purchased. As well as shifting the risk of crop failure between farmers and breeders (in much the same way as authors and publishers share the risk of the success of a book), end point royalties also enable right owners to circumvent the farm-saved seed exception. This occurs because farmers pay a royalty irrespective of whether the seed used to plant a crop comes from saved seed, is brought from a legitimate retailer, or a neighbour. Intellectual property owners have also made use of restrictive covenants in patent and plant breeders' rights license agreements to limit the ability of farmers to save and reuse seed. For example, a notification is printed on the bags of Monsanto's 'Roundup Ready' soybean seeds that are sold in the United States stating that the seeds may be protected under one or more patents. It then goes on to provide that:

> The purchase of these seeds conveys no licence under said patents to use these seeds or perform any of the methods covered by these patents. A licence must first be obtained before these seeds can be used in any way. See your seed dealer to sign

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19 See John Breusch, 'Farmers Sowing the Seeds of Suspicion', *Financial Review* (Sydney), 22 November 2004, 63; Monsanto, *Seed Piracy Update* (2003) <http://www.monsanto.com/monsanto/us_ag/content/stewardship/training/course/SeedPiracyUpdate.pdf> at 15 April 2005.

20 See, eg, *International Convention for the Protection of New Varieties of Plants,* opened for signature 2 December 1961, as revised on 23 October 1978 and 19 March 1991, 815 UNTS 89, art 15(1)(ii)(iii) (entered into force 24 April 1968); *Plant Varieties Act 1997* (UK) s 8(b)(c).

21 See, eg, US Patent No 2,050,010,970 (Issued 13 January 2005) (Cotton Cultivar DP 579 BG II).

a Monsanto Technology/Stewardship Agreement. Progeny of these seeds cannot be saved and used for planting or transferred to others for planting.[22]

Ironically, Monsanto advocates the use of these restrictions as part of its 'seed stewardship' program.[23] A farmer is a 'good steward' if he or she signs the Technology/Stewardship Agreement, complies with all agronomic and marketing guidelines, and agrees that they will only plant the purchased seed for a single commercial crop.[24] A 'good steward' also notifies Monsanto of individuals who do not comply with these standards. According to Monsanto, good stewardship 'insures investment in research and development so that new technologies can be brought to market that provide growers and consumers benefits'.[25] Despite the inclusion of contractual terms that restrict the use of saved seed, there is still the problem, by no means peculiar to biological inventions, of having to identify and prosecute 'bad stewards' who fail to comply with these terms. If the person alleged to have infringed the patent acquired the seed from someone other than an authorised licensee (that is, 'brown-bagging') and, as is likely, that person was unaware of these restrictions, then the right holder may be unable to sustain a claim for infringement against that person.

While the tactics adopted by intellectual property owners in recent years have restricted the use that third parties have been able to make of plant genetic resources, nonetheless many organisations are still unhappy with the degree of leakage that occurs under the existing legal regimes. This, so the argument goes, has made companies cautious of investing in research to develop improved non-hybrid, self-pollinating varieties. In part, it was this dissatisfaction that led the USDA and DeltaPine, along with many other agricultural companies, to develop genetic use restriction technologies in the first place. As Mel Oliver said, as well as wanting 'to stop foreign interests from stealing the technology', one of the motivations for developing the technology was '[t]o come up with a system that allowed you to self-police your technology, other than trying to put on laws and legal barriers to farmers saving seed'.[26]

22 Monsanto, *2004 Technology Use Guide* (2004) <http://www.monsanto.com/monsanto/us_ag/content/stewardship/tug/tug2004.pdf> at 15 April 2005. Monsanto's *Technology/Stewardship Agreement*', which must be signed by prospective purchasers before the seed can be purchased, contains a number of other restrictions on the use of saved seed. For example, Monsanto's 2004 US Technology/Stewardship Agreement provides purchasers with a limited license to purchase and plant seed containing Monsanto technologies. In particular, the seed may only be used for planting a single commercial crop. In addition, the purchaser covenants not to: supply any of this seed to any other person or entity; save any crop produced from this seed for planting or supply seed to anyone for planting; use or allow others to use seed for crop breeding, research, generation of herbicide registration data, or seed production (unless the grower has entered into a valid, written production agreement with a licensed seed company).

23 'Most growers understand property protection and know how to be good stewards of the land. In the same manner, Monsanto patents seed traits to protect the value of its property. When growers purchase patented seed, they agree to respect the property rights held by the seed and trait providers': Monsanto, above n 19, 1.

24 Monsanto, above n 22.

25 Ibid 23.

26 Quoted in Leora Broydo, *A Seedy Business* (1998) MotherJones.com <http://www.motherjones.com> at 15 April 2005. See also Rob Edwards, 'End of the Germ Line' (1998) 2127 *New Scientist* 22: 'Our system is a way of self-policing the unauthorised use of American technology … It's similar to copyright protection'.

In so far as genetic use restriction technologies prevent farmers, breeders and other users from reproducing protected plants, it provides in-built biological protection against the unauthorised reproduction both of the seed and any value-added traits that are introduced into plants.[27] By providing a potential solution to the situation whereby third parties use but do not pay for biological resources, GURTs make it more attractive for private organisations (as well as those public sector agencies who have adopted a more commercial approach to research) to invest in agricultural research and development.[28] More specifically, by preventing the use of saved seed, advocates of the technology have argued that it will provide:

> an incentive to conduct breeding research in crop species and geographies which have received little or no research attention in the past, because there was no economic incentive to conduct costly research with no prospect of economic return. Increased breeding research and the subsequent production of new, improved varieties is obviously an advantage to the farmers to which these varieties become available.[29]

In other words, with the aid of GURTs, parties who invest in plant innovation can do so safe in the knowledge that their investment will not be diluted by nature's tendency to proliferate or by the 'bad stewards' who save and reuse this seed.[30] It will also be important where companies that invest in the breeding of new varieties are unhappy with the level or nature of intellectual property protection.[31]

To the extent that genetic use restriction technologies encourage additional funding for agricultural research, proponents of the technology claim that it will stimulate breeding, increase innovation in plant breeding, and ultimately lead to the development of improved varieties. It has also been suggested that GURTs will encourage investment in smaller, currently neglected areas of research and in so doing promote genetic diversity and provide farmers with greater choice. As a representative of DeltaPine said, 'if a technology does not bring benefits and increased prosperity to our customers, the farmers, they will not purchase the

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27 Richard Jefferson et al, 'Genetic Use Restriction Technologies', Annex to Convention on Biological Diversity Subsidiary Body on Scientific, Technical and Technological Advice, *Consequences of the Use of the New Technology for the Control of Plant Gene Expression for the Conservation and Sustainable Use of Biological Diversity*, UNEP/CBD/SBSTTA/4/9/Rev 1 (17 May 1999) 13.

28 Timo Goeschi and Timothy Swanson, 'The Development Impact of Genetic Use Restriction Technologies: A Forecast Based on the Hybrid Crop Experience' (2003) 8 *Environment and Development Economics* 149, 151.

29 Harry Collins and Roger Krueger, 'Potential Impact of GURTs on Smallholder Farmers, Indigenous and Local Communities and Farmers Rights' (Paper presented to the Convention on Biological Diversity Ad Hoc Technical Expert Group on the Impact of Genetic Use Restriction Technologies on Smallholder Farmers, Indigenous People, and Local Communities, 19–21 February 2003) 1 <http://www.etcgroup.org/documents/ collins_kreugerISF.pdf> at 15 April 2005. This paper represents the official position of the International Seed Federation.

30 The ability of GURTs to act as a copy-protection system will be particularly important where hybrid technologies or other natural control mechanisms are not well developed. See the International Seed Federation, '*Position Paper of the International Seed Federation on Genetic Use Restriction Technologies*', adopted at Bangalore, India (2003) International Seed Federation <http://www.worldseed.org/Position_papers/Pos_GURTs.htm> at 15 April 2005.

31 Collins, above n 10, 2.

technology. It is in everyone's interest that more choices be available to all of the world's farmers, and [GURTs] is a means of achieving this goal'.[32]

To date, in extolling the virtues of the GURTs, proponents of the technology have focused on the role it might play in promoting investment in research. Another claim that might be made for the technology, which has important ramifications for legal debates in the area, relates to the controversial claim that the technology offers a potential solution to the problem of genetic pollution.[33] In particular, it has been suggested that because genetic use restriction technologies are able to bring about second generation sterility, if pollen from activated plants pollinate flowers of a wild related species, this means that the resulting seed will be non-viable. As a result, GURTs will prevent the spread of transgenic plants beyond the first generation, because the subsequent generation will be unable to germinate.[34] This has important consequences for a number of legal issues associated with genetically modified crops.

One area where this may be relevant is in relation to the problem of passive infringement that occurs where a person, through no fault of their own, finds that they have infringed a patented biological invention. This problem, which was highlighted by the Canadian Supreme Court in *Monsanto v Schmeiser*,[35] might occur, for example, when wind-born pollen from a patented plant is blown onto a farmer's property where it cross-pollinates their crops. As patent infringement occurs irrespective of the intention of the defendant, in this situation the farmer would be liable for patent infringement even if they were unaware that the patented plant was growing on their property.[36] The fact that a farmer can passively infringe a patented biological invention has important ramifications for the traditional practice whereby seeds saved from one year's harvest are used to sow crops in the following year. It also has wider implications for current debates about the release of genetically modified crops and the acceptable limits of gene patents. In the same way in which it has been suggested that genetic use restriction technologies may be used to minimise unwanted gene flow, it is possible to imagine an argument being made that the technology provides a solution to the problem of passive infringement.

It is possible to imagine similar claims being made about the role that the technology might play in reducing the legal risks that arise where genetically

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32 Ibid 3.

33 There is ongoing debate about whether genetic use restriction technologies are useful as an environmental control mechanism for genetically modified crops. See, eg, Steve Tally, '*Purdue Biotech Experts Say Genetic Plant Sterilisation Technology Is Needed*' (2002) Ascribe Newswire <http://www.biotech-info.net/sterilization.html> at 15 April 2005; Stuart Smyth, George Khachatourians, and Peter Phillips, 'Liabilities and Economics of Transgenic Crops' (2002) 20 *Nature Biotechnology* 537; Henry Daniell, 'Molecular Strategies for Gene Containment in Transgenic Crops' (2002) 20 *Nature Biotechnology* 581.

34 Report of the Panel of Eminent Experts on Ethics in Food and Agriculture, (FAO, Rome, 2001). Cited in FAO, 'Potential Impacts of Genetic Use Restriction Technologies (GURTs) on Agricultural Biodiversity and Agricultural Production Systems' CGRFA-9/02/17, (14–18 October 2002) 1.

35 *Monsanto Canada Inc v Schmeiser* [2004] 1 SCR 902.

36 Brad Sherman, 'Biological Inventions and the Problem of Passive Infringement' (2002) 13 *Australian Intellectual Property Journal* 146.

modified crops escape from a farmer's property onto neighbouring fields.[37] The uncertainty about the legal liability of farmers in this situation, combined with the reluctance of insurance companies to underwrite the associated risks of agricultural nuisance, is one of the reasons why some farmers have been reluctant to plant genetically modified crops. Given that GURTs could, at least in theory, prevent the spread of genetically modified crops, it would decrease the risk confronting farmers if they were to plant genetically modified crops. As such, it is possible to imagine the technology being presented as a way of overcoming one of the barriers to the planting of genetically modified crops.

While the proponents of GURTs believe that the ability to control biological reproduction means that it will provide a number of long-term benefits, critics have been more sceptical. In particular, critics have said that if GURTs are adopted they will render the existing repertoire of intellectual property rights 'largely redundant as property would be embedded in the material itself'.[38] If this occurs biological protection systems would effectively remove the policy control that governments have exercised when designing intellectual property laws. To the extent that intellectual property laws are replaced by biological protection systems, a complex and sensitive set of issues would be determined by technical fiat rather than by institutional negotiation.[39] One of the main concerns is that while limits are imposed on the scope and duration of intellectual property protection, these do not exist in relation to genetic use restriction technologies. For example, while limits are placed upon the types of subject matter protected by intellectual property law, there will be no limits on the subject matter able to be protected by genetic use restriction technologies. As such, it is possible that the protection offered by genetic use restriction technologies will be broader than is provided by intellectual property law. Another concern is that the period of protection will be much longer with GURTs than is the case with intellectual property protection. This is because while patent and plants breeders' rights law are of limited duration the new technology is theoretically able to provide perpetual protection.[40]

Another problem that has been raised is that GURTs have the potential to undermine the defences and exceptions that currently exist in intellectual property law. Of particular concern is the possibility that GURTs will undermine the farmers' rights to save seed.[41] As a result, the technology threatens the practice whereby farmers save grain from one year's crop to sow in subsequent

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37 It should be noted that while this issue has been highlighted by the increased use of genetically modified crops, similar issues arise with non-GM crops.

38 Jefferson et al, above n 27, 37.

39 Alain Pottage, Untitled Paper (manuscript on file with authors) (2004), 1.

40 Convention on Biological Diversity, Subsidiary Body on Scientific, Technical and Technological Advice, 'Note by the Executive Secretary', *Consequences of the Use of the New Technology for the Control of Plant Gene Expression for the Conservation and Sustainable Use of Biological Diversity*, UNEP/CBD/SBSTTA/4/9/Rev 1 (17 May 1999) 9.

41 See, eg, *International Convention for the Protection of New Varieties of Plants,* opened for signature 2 December 1961, as revised on 23 October 1978 and 19 March 1991, 815 UNTS 89, art 15(2) (entered into force 24 April 1968); *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, art 11.

years. If this occurs, farmers would become dependent upon seed manufacturers for the supply of seed and thus their livelihood.[42] As the Nuffield Council on Bioethics said, GURTs are 'only the latest in a long line of more or less efficient ways of compelling farmers to buy seeds from the companies that have developed them'.[43] As well as undermining the farmers' right to save seed, GURTs also have the potential to undermine the exemption in plant breeders' rights law that ensures that varieties are available for further breeding and the research exemption in patent law (where it exists in any meaningful form).[44]

To date there has been little or no discussion about the possibility of GURTs being used to resolve the problems of passive infringement or to minimise the legal risks associated with the agricultural nuisance.[45] However, it is likely that these arguments would be met with the same hostile response that greeted the claims made about the supposed environmental benefits of GURTs.[46]

III BIOLOGICAL PROTECTION SYSTEMS

Many of these arguments will be familiar to intellectual property lawyers. For example, the claims that private sector organisations will only invest in agricultural research if they are able to control the ability of third parties to reproduce the products of that research are similar to the arguments used to justify the grant of patents, designs, copyright and plant breeders' rights. In turn, the fear that biological protection systems will replace intellectual property protection has a number of parallels with the growing debate about the use of technological protection systems to control access to digital works protected by copyright. Claims by the proponents of GURTs that criticisms of the technology are not supported by factual or empirical evidence are similar to the arguments often used to counter ethical objections to the patenting of living inventions.[47]

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42 Jefferson et al, above n 27, 18.

43 Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical and Social Issues* (1999) 77.

44 Food and Agriculture Organisation Commission on Genetic Resources for Food and Agriculture, 'Potential Impacts of Genetic Use Restriction Technologies (GURTs) on Agricultural Biodiversity and Agricultural Production Systems: Technical Study', CGRFA-9/02/17, Annex (14–18 October 2002) 13.

45 A number of other concerns have been raised about the impact of GURTs. See, eg, Hope Shand, 'NGO Statement on Terminator Technologies', presented to UNEP/CBD/COP6 (10 April 2002).

46 For example, it has been said that 'the promotion of terminator seeds as a "green" solution to pollution by genetically modified ('GM') crops is the Trojan Horse of biotechnology. If terminator wins market acceptance under the guise of bio-safety, it will be used as a monopoly tool to prevent farmers from saving and reusing seed'. Hope Shand, 'Terminator No Solution to Gene Flow' (2002) 20 *Nature Biotechnology* 775. Commentators have also raised concerns that if the sterility trait spreads beyond the confines of a field where the GURTs are planted it could produce a 'suicide-plant pandemic' that wipes out an entire species. Jerry Mander, 'Machine Logic: Industrialising Nature and Agriculture' in Andy Kimbrell (ed), *The Fatal Harvest Reader: The Tragedy of Industrial Agriculture* (2002) 87, 90. For a response to arguments of this nature see Collins, above n 10, 2.

47 'Proposal of the United States of America Regarding Procedural and Substantive Issues on the GURTS Memorandum Submitted by the Office of the Union to the Convention on Biological Diversity', UPOV CAJ/47/7 (31 March 2003) Annex II, 5.

In so far as genetic use restriction technologies provide a system of genetic copy protection, there are obvious and useful parallels to the technological protection systems used in relation to digital technologies.[48] There are also parallels with earlier biological mechanisms that were used to control reproduction in plants and animals. These include the intentional infestation of sheep with liver fluke to render them infertile,[49] and sterilisation procedures (known as 'triploidy') used in aquaculture where ovulated eggs are exposed to either heat, cold, pressure or chemical shocks shortly after fertilisation. Perhaps the most well-known biological protection system, and an obvious starting point when thinking about the potential impact that GURTs might have on the circulation and use of plant genetic resources, is provided by hybrid seed.

The process of hybridisation, which has been available for commercial seed since the 1920s, occurs when two highly inbred types are genetically crossed. While the hybrid system is not viable in all crops, over time hybridisation has been used in many cross-pollinated crops including maize, sorghum, sunflower and canola. One of the most important consequences of hybridisation is that it leads to 'heterosis' or 'hybrid vigour'. That is, it leads to increased yield and to more standardised crops. Another notable feature of hybridisation is that while it increases the yield in first generation crops, the quality and quantity of subsequent crops deteriorates, and continues to deteriorate, with each replanting.[50] While farmers are able to use saved seed to replant subsequent crops, the benefits in yield are not realised in subsequent generations. One of the consequences of this is that hybridisation operates as a de facto technological protection system and thus as a way of controlling the way that plant genetic resources are used.[51] While farmers are technically able to use hybrid seed to re-sow new crops, hybrid seed is seldom saved for replanting in developed countries due to 'differences from the parent seed in the produced generation and resulting reduction in performance'.[52] So long as the inbred parent lines that were used to develop the hybrid crop are not disclosed to the public, farmers need to purchase seed annually.[53]

A number of claims have been made about hybridisation and the impact that it had, and continues to have, on the circulation and use of plant genetic resources. For example, it has been suggested that the protection offered by hybridisation encouraged private firms to invest in research and development. Indeed, it has been argued that a primary motivation for the creation of hybrid cultivars was that it enhanced the scope for appropriating rents from research and

48 Dan Burk, 'DNA Rules: Legal and Conceptual Implications of Biological Lock-Out Systems' (2004) 92 *California Law Review* 1553.

49 Harriet Ritvo, 'Possessing Mother Nature: Genetic Capital in Eighteenth-Century Britain' in John Brewer and Susan Staves (eds), *Early Modern Conceptions of Property* (1995) 413.

50 Jefferson et al, above n 27, 21; Food and Agriculture Organisation Commission on Genetic Resources for Food and Agriculture, 'Potential Impacts of Genetic Use Restriction Technologies (GURTS) on Agricultural Biodiversity and Agricultural Production Systems: Technical Study', CGRFA-9/02/17, Annex (14–18 October 2002) 1.

51 Collins, above n 10.

52 Ibid.

53 With hybrids, elite parents are typically not available to breeders.

development.[54] Whether or not this is the case, it is clear that private companies have been more willing to invest in hybrid crop innovations because they are able to control how the resulting varieties are used. Conversely, it has been suggested that private companies have been more reluctant to invest in self-pollinated species that have been difficult to hybridise, such as soybeans, wheat, rice and cotton.[55] The private investment in research facilitated by hybridisation is said to have a number of long-term benefits. For example, it is often suggested that the willingness of farmers to buy hybrid seed each year, rather than saving and replanting seeds from their previous crop, 'insures quality while funding continued research that leads to new and improved varieties'.[56]

As many commentators have noted, hybrid crops share a number of features in common with genetic use restriction technologies. In particular, both act as a form of biological use restriction and, in so doing, have the potential to shape the way plant genetic resources are modified and used. For example, on the basis of experience in relation to hybrid-based agriculture, it has been suggested that GURTs will lead to a higher rate of investment by private industry in crop improvement 'motivated by enhanced scope for rent capture'.[57] It has also been argued on the basis of studies looking at the impact of hybrid maize that 'there is good reason to be concerned that the rate of diffusion will be slow with genetic use restriction technologies, as the flow of plant materials and the level of public funding is restricted'.[58]

While there are obvious parallels between hybridisation and genetic use restriction technologies, we must be careful about the conclusions we draw from this. In part, this is because genetic use restriction technologies potentially provide a much more effective and widespread system of use restriction.[59] In particular, while hybridisation has only successfully been used in a limited number of crops (it is not used in barley, cotton, millet, rice, soybeans and wheat), it is theoretically possible for GURTs to be applied to all seed-bearing crops.[60] Another difference is that while farmers obtain some benefits from the replanting of farm-saved hybrid seed, the replanting of seed protected by GURTs is expected to result in a 100% yield loss.

Another reason why we should be careful about the conclusions we draw from the experience in relation to hybridisation is because the environment that GURTs operate in today is markedly different from that which existed when hybridisation was first adopted in the 1920s. One of the notable differences relates to the important role that intellectual property law now plays in the

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54 Timothy Swanson and Timo Goeschi, 'Genetic Use Restriction Technologies (GURTs): Impacts on Developing Countries' (2000) 2 *International Journal of Biotechnology* 56, 74; Ricarda Steinbrecher and Pat Mooney, 'Terminator Technology: The Threat to World Food Security' (1998) 28 *Ecologist* 276.

55 Collins, above n 10.

56 Ibid.

57 Goeschi and Swanson, above n 28, 162.

58 Swanson and Goeschi, above n 54, 67–8.

59 GURTs are said to be 'radically different in mechanism, scope and implications': Jefferson et al, above n 27, 17.

60 GURTs are likely to have greater impact on those crops 'for which hybridisation has not been carried out on a significant scale, such as wheat and rice': Goeschi and Swanson, above n 28, 152.

creation, circulation, and use of plant genetic resources. In the time since modern intellectual property law came into existence in the middle of the 19th century, it has had little impact on agricultural practices: protection was either non-existent or under utilised. Over the last 20 or so years, however, there has been a dramatic change in the impact that intellectual property law has on botanical innovation.[61] For example, for most of the 18th and 19th centuries, intellectual property protection played, at best, a minimal role in the protection of new plant varieties. The situation began to change in the early part of the 20th century as legislation to protect plant breeding was introduced initially in the United States and then in other common law countries.[62] However, while the registration systems were in place, they were under utilised by most sectors of the agriculture industry. As a result, for most of the 20th century plant breeders' rights did not have much of an impact on many areas of agricultural practice. The situation began to change, however, in the 1960s with the reduction in government funding for public breeding programs. While the timeline differed from country to country, the result was the same: the decline in public funding led to a rapid uptake in plant breeders' rights protection for new varieties.[63] As a result, we have moved from a situation where plant breeders' rights protection had little impact on agricultural practices, to a situation where it now plays a much more prominent role in the creation, circulation, and use of plant genetic resources. For example, 10 years ago most of the wheat grown across Australia was developed by public sector agencies and made freely available to growers. By 2006, however, most of the varieties of wheat grown in Australia will be protected by plant breeders' rights. A similar situation exists in many other developed countries.[64]

The impact that plant breeders' rights has on genetic resources has increased in some jurisdictions as a result of recent amendments that expanded the scope of protection. This occurred when the right was changed from merely being a right over propagating material to become a more general right that now also includes harvested materials (grain) and in some instances products derived from those materials (flour, bread).[65] As a result, the potential reach of intellectual property rights now extends beyond breeders and growers to include bulk handlers, processors and manufacturers. The reach of plant breeders' rights protection was also broadened with the decision to extend the scope of protection beyond the registered variety to also include 'dependent varieties' and 'essentially derived varieties'.[66]

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61 To a large extent, this coincides with the adoption of biotechnology in agriculture.

62 This is now required by *Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C*, opened for signature 15 April 1994, 1869 UNTS 299, art 27(3)(b) (entered into force 1 January 1995).

63 For the position in the UK, see Paolo Palladino, *Plants, Patents and the Historian* (2002) 34–68.

64 The situation is similar with many other broad acre crops.

65 See, eg, *International Convention for the Protection of New Varieties of Plants*, opened for signature 2 December 1961, as revised on 23 October 1978 and 19 March 1991, 815 UNTS 89, art 14(2)(3) (entered into force 24 April 1968); *Plant Varieties Act 1997* (UK) s 6(3)(4).

66 See, eg, *International Convention for the Protection of New Varieties of Plants,* opened for signature 2 December 1961, as revised on 23 October 1978 and 19 March 1991, 815 UNTS 89, art 14(5) (entered into force 24 April 1968); *Plant Varieties Act 1997* (UK), s 7(1)–(4).

Another reason why intellectual property is playing a more important role in the regulation of plant genetic resources is as a result of an increase in patent activity in the field. While patents have not had as much of an impact on agricultural practices as plant breeders' rights (outside of the United States), this is likely to change in the immediate future. Indeed, recent figures show that agricultural patents are the fastest growing area of patent activity in the United States.[67] Similar developments also seem to be taking place in Europe, Australia and Canada. As many commentators have noted, this is largely due to the proliferation of biotechnology-related patents that have been granted over the last 15 or so years. Many of these, including the growing number of patents over genes, gene fragments, markers, research tools and so on, are increasingly having an impact on both agricultural research and on-farm practices. Interestingly a growing number of patents are also being granted over new plant varieties developed by traditional breeding methods. If recent experience in the United States is anything to go by, the increase in patent activity will be accompanied both by more litigation and by more legalistic and technical contracts.[68] Another consequence of the increased use of patents for biological inventions is that a single plant may be now protected by a range of different intellectual property rights. For example, much of the cotton planted in Australia, the United States and a number of other countries is protected by a series of patents (both over the genes incorporated into the cotton plants as well as the research tools used in the isolation of the gene and the genetic modification of the plant); by plant breeders' rights protection (over the specific variety of cotton that hosts the genes); and trade mark protection (over the names Bollgard II and Roundup Ready). As a result, cotton growers are now faced with an agreement to use the protected plant variety and a technology user agreement to use the patented genes that are incorporated into the cotton plant. The interconnected nature of these rights, which may be owned and cross-licensed between a range of different companies, has further entrenched the hold that intellectual property law has over biological resources.

The ongoing juridification of plant genetic resources has been exacerbated by the increased use of grower agreements that attempt to control the way farmers deal with plant materials, particularly in relation to the saving of seed. The increased use of material transfer agreements that are used regulate the transfer of germplasm are also having an impact on agricultural research. While many of these agreements provide that the material in question is not to be protected by intellectual property, the mere fact that this is put into contractual form further juridifies the process. These developments have been reinforced by the growing interest in the commercialisation of agricultural research undertaken by public sector research programs that has occurred in many countries since the 1980s.

A number of changes have also taken place at the international level that have reinforced the growing reach that the law has over biological materials. For

67 John King and Paul Heisey, '*Ag Biotech Patents: Who is Doing What?*' (November 2003) Economics Research Service of the US Department of Agriculture <http://www.ers.usda.gov/AmberWaves/November03/pdf/agbiotech.pdf> at 15 April 2005.

68 See Centre for Food Safety, *Monsanto vs. US Farmers* (2004).

example, the 1993 *Convention on Biological Diversity*[69] ('*CBD*') which introduced the idea of national sovereignty over genetic resources into international law, set into play a number of changes that altered the way plant genetic resources are used. Anecdotal evidence suggests that the *CBD* has slowed down and, in some cases, stopped the exchange of germplasm between countries who are still deciding how the Convention should be implemented domestically. While few countries have implemented the *CBD*, the introduction of benefit-sharing agreements and prior informed consent as techniques to regulate bioprospecting are likely to influence the way that plant genetic resources are used. They are also likely to add to the costs of plant innovation. The *International Treaty on Plant Genetic Resources*,[70] which came into force in June 2004, also has the potential to add to the role the law plays in relation to plant genetic resources. To some extent this will depend on the details of the Material Transfer Agreements to be developed under the Treaty, and the extent to which they allow recipients to take out intellectual property protection over inventions that are derived from plant genetic resources covered by the Treaty.

The process of juridification which has taken place over the last twenty or so years has had an important and ongoing impact on the circulation and consumption of plant genetic resources. One of the consequences of this is that we must be careful about the lessons we draw from the past (such as the experience in relation to hybridisation). Another important but overlooked consequence of the juridification of plant genetic resources is that it will play an important role in mediating the impact that genetic use restriction technologies have when and if they are released commercially. In particular, it means that it is highly unlikely that GURTs will replace intellectual property protection. In part, this is because the existing laws and practices are complex and interwoven. They also often act as substitutes for each other. This is reinforced by the fact that GURTs only provide a means of controlling reproduction: they do not deal with the important issue of how owners are to be renumerated for use of the intellectual property right, nor the way the rights are to be exploited.[71] One of the lessons from other areas of intellectual property is that gaining control of the reproductive process is only ever the first step in a longer process. In developing effective and efficient mechanisms to deal with the way biological innovations are exploited, parties who rely upon GURTs to protect their innovations will inevitably have to rely upon structures, networks and institutions which are themselves either created by, or increasingly subject to, the law.

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69 *Convention on Biological Diversity,* opened for signature 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993).

70 *International Treaty on Plant Genetic Resources for Food and Agriculture*, opened for signature 3 November 2001, [2002] ATNIF 14 (entered into force 29 June 2004).

71 Neither do they deal with the issue of free-riding of the technology by imitators. As has been noted, the use of GURTs does not protect:

> by itself the imitation of a certain product by other companies or entities that may possess the technical capabilities to reverse-engineer or otherwise duplicate the 'technically protected' seed. Hence, patents, PBRs and trade secrets protection would continue to be important tools to secure control over certain materials in the relationship between the innovator and eventual imitators.

Jefferson et al, above n 27, 37.

Ultimately, the impact that GURTs have upon plant genetic resources will vary depending on whether the practical difficulties with the technology are overcome, whether the technology is commercially viable, the nature of the existing farming systems (such as the type of crop, the availability of hybrids, and reliance on local landraces), the level of mechanisation, the geographic region in question, and the extent to which farmers habitually save seed to re-sow annual crops. In many ways the same is true of the impact that the technology is likely to have on the practices and ideals that are protected by intellectual property law. While it is unlikely that GURTs will replace intellectual property law, this does not mean that they will not play an important role in shaping the way intellectual property law develops in the future. In particular, it is likely that breeders and those who invest in plant innovation will use GURTs as a strategic bargaining device to help them influence the shape and direction of intellectual property law. For example, in developing countries, particularly those countries who have to implement Article 27(3)(b) of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*[72] ('*TRIPS*'), GURTs may be used to place pressure on policy makers to ensure that new legislation does not contain exemptions for farmers or breeders.[73] In developed countries GURTs may be used as a way of pressuring policy makers to alter or sideline existing defences. This is in effect what the Seed Federation of Australia has been doing in its campaign to have the innovation patent (which has fewer defences than plant breeders rights) extended to include plant and animal subject matter. There is also a possibility that GURTs will be used to shape the manner and level of remuneration payable where copy-protected genetic material is used. It is also likely that genetic use restriction technologies will act as a catalyst for the further juridification of plant genetic resources. This has already happened, to some extent, as we start to see the first wave of responses to GURTs. For example, a Bill introduced in the United States Congress in 2003 proposes to impose a prohibition on non-fertile plant seeds. In particular, it provides that 'a person may not manufacture, distribute, sell, plant, or otherwise use any seed that is genetically engineered to produce a plant whose seeds are not fertile or are rendered infertile by the application of an external chemical inducer'.[74] In India, laws have been enacted that attempt to limit the scope and operation of GURTs.[75] The juridification of germplasm has been reinforced by the decision of the International Agricultural Research Centres that they will 'not incorporate into their breeding materials any genetic systems designed to prevent seed

72 *Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C*, opened for signature 15 April 1994, 1869 UNTS 299 (entered into force 1 January 1995).

73 International Seed Federation, 'Position Paper of the International Seed Federation on Genetic Use Restriction Technologies', adopted at Bangalore, India, (June 2003) International Seed Federation <http://www.worldseed.org/Position_papers/Pos_GURTs.htm> at 15 April 2005.

74 *Genetically Engineered Crop and Animal Farmer Protection Act of 2003*, HR 2918 § 9, (2003). The Bill was referred to the Committee on Agriculture, Subcommittee on Conservation, Credit, Rural Development and Research.

75 *Protection of Plant Variety and Farmers' Rights Act, 2001* (India).

germination'.[76] In so far as the exclusion of GURTs needs to be monitored by legal means, it will entrench the role that the law plays in regulating the circulation of plant genetic resources.

IV CONCLUSION

As Derrida reminds us, 'an invention always pre-supposes some illegality, the breaking of an implicit contract; it inserts a disorder into the peaceful ordering of things, it disregards the proprieties'.[77] GURTs follow this logic, but potentially do so in a much more violent way than that to which we are accustomed. While GURTs disrupt the natural order of things, it remains to be seen what impact they will have upon existing legal and agricultural practices. Although these technologies have not yet been successfully transplanted from the laboratory to the field, they, and the debates that have crystallised around them, have raised a number of important issues. In terms of intellectual property law, they reinforce the fact that biological subject matter is very different from the subject matter of mechanical and chemical inventions, not only in terms of the grant of property rights but also, and perhaps more importantly, in terms of the use and exploitation of these rights. As such, they remind us of the folly of the idea of technological neutrality in patent law. They also remind us that many of the concepts, ideas and techniques used in intellectual property law were developed to deal with mechanical and, to a lesser extent, chemical inventions. Thinking through the possible impact that genetic use restrictions may have for plant genetic resources also highlights the fact that there has been very little research that focuses on the relationship between intellectual property and agriculture. Before we are in a position to understand the impact that GURTs might have upon plant genetic resources, we first need to understand a lot more about the role that intellectual property plays in the creation, distribution and use of plant genetic resources. Importantly, this includes an understanding of the history of this interaction, as well as a better understanding of the way this has changed over time. Given the increasingly important role that intellectual property is likely to play in the regulation of plant genetic resources and the potentially important role that GURTs might play in changing the way that plant genetic resources are used and consumed, this is an urgent and pressing task.

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76 Consultative Group on International Agricultural Research (December 1998) *CGIAR News* 3 <http://www. worldbank.org/html/cgiar/newsletter/dec98/dec98.pdf> at 15 April 2005.

77 Jacques Derrida, 'Psyche: Inventions of the Other' in Lindsay Waters and Wlad Godzich (eds), *Reading de Man Reading* (1989) 25.