Chapter 4

Competition in the Agricultural Seeds Sector: Patents and Competition at a Cross-roads?

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Introduction

In a developed capitalist economy markets and competition are supposed to allocate resources to best satisfy the needs and requirements of consumers. Where a firm gains market power there is the potential to abuse that power and undermine the positive operation of markets and competition to the detriment of consumers.[1] The development and adoption of GMOs in agriculture is likely to be a significant node of problematic competition because of the tensions between patent law and antitrust law. Patent law was expanded in *Diamond v. Chakrabarty* to include GMOs in 1980[2] and then in 2001 in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* (confirming the decision in *Ex parte Hibberd*)[3] to include traditionally bred non-genetically modified plants.[4] This raises the possibility that many of the practices using plants that are now conducted in the gaze of patents were earlier only regulated by competition laws. The effect of these decisions has been to extend the scope of utility patents and eliminate some of the previously pro-competition limitations – like farmer saved seeds, research exemptions and exhaustion provisions – that were available without patents. Add to this the increasing involvement of the for-profit private sector taking over from the public sector in developing new plants,[5] the consolidation of the seed

1 In the agricultural context see, for example, Domina, D. and Taylor, R. 2010. The debilitating effects of concentration markets affecting agriculture. *Drake Journal of Agricultural Law*, 15(1), 61–108, 62–3.

2 *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

3 *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Board of Patent Appeals, 1985).

4 *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 148 (2001).

5 See, for example, Fernandez-Cornejo, J. 2004. *The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development*, Agriculture Information Bulletin No. AIB-786. Washington: USDA, 42–6 (showing a 1,300 per cent real increase in private sector R&D plant breeding expenditures between 1960 and 1996 while, during the same period, public sector R&D plant breeding 'changed very little in real terms'). See also Heisey, P., King, J. and Day Rubenstein, K. 2005. Patterns of public-sector and private-sector patenting in agricultural biotechnology. *Ag Bio Forum*, 8(2–3), 73–82.

industry[6] and the potential for patent holders aggressively to assert their interests, and challenges to competition by firms developing and marketing GMOs can be expected. As a consequence the tension between patent laws and competition laws is likely to play out in the various markets involving GMOs.

The sub-markets for GMOs can conveniently be considered to be an innovation market for the discovery and development of novel and useful genetic traits, an innovation market for the discovery and development of novel and useful germplasm (plant breeding), a genetic traits market for the traits that can be placed into useful plant germplasm, a germplasm market for the germplasm that can have the traits inserted and a traited seeds market for the GMOs that can be planted and grown. Market power in each of these sub-markets and across these sub-markets enables firms exercising that power to foreclose competition by slowing innovation, raising prices, affecting quality, affecting choice and dulling the benefits of competition for producers (such as farmers) and the ultimate consumers of agricultural outputs. Of particular concern is the potential for patents to restrict consumer practices.

Resolving these patent and competition issues is important because developed economy agriculture depends on access to new technologies to improve agricultural production and yields. Perhaps significantly, market prices for agricultural outputs are generally set according to international benchmarks so that the likely effects of limiting competition will be a re-allocation of value within the market (principally through less profit for farmers)[7] and fewer choices for the ultimate consumers of agricultural production. The pricing of agricultural GMOs and the vast differential between GMOs and conventional seeds signals that patents and competition are an issue for GMOs. The US General Accounting Office, for example, concluded:

> Monsanto's US patents for Roundup Ready soybean seeds have given it and the companies to whom it has licensed the technology greater control over seed prices and has enabled them to restrict the availability and use of seeds ... These factors do not have the same impact on Bt corn seed prices. Bt corn is genetically modified hybrid corn, and hybrid corn cannot be easily reproduced from seed. Thus, farmers and others cannot readily reproduce Bt corn seed for use on their farms.[8]

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6 Hayenga, M. 1998. Structural change in the biotech seed and chemical industrial complex. *Ag Bio Forum*, 1(2), 43–55.

7 See, for example, Fernandez-Cornejo, above n 5, 9 (showing an increase from 1.6 per cent of total farm expenditures in 1960 to 3.7 per cent in 1997 or an increasing expenditure on seeds from US$1.95 billion in 1960 to US$ 4.81 billion in 1997, in 1989 dollars).

8 US General Accounting Office. 2000. *Report to the Chairman, Subcommittee on Risk Management, Research, and Specialty Crops, Committee on Agriculture, House of Representatives – Information on Prices of Genetically Modified Seeds in the United States and Argentina*, GAO/RCED/NSIAD-00-55. Washington DC: GAO, 12.

This article addresses some of these likely problems as they are now emerging. The article is structured as follows: an examination of the ways anticompetitive behaviours can restrict access to patent protected materials; an examination of limiting consumer uses through restrictive licensing practices; an examination of the competition effects of post patent regulatory approvals; an examination of the competition effects of post patent access to materials; an examination of customer and product shifting or switching and, finally, a discussion and some conclusions. The analysis in this chapter demonstrates that there are real competition concerns in the ways that patents have been deployed and used with GMOs. The various disputes, however, show that the parties themselves are generally able to find resolutions, albeit resolutions that may raise some concerns and are most likely to maintain the existing market power of key players in the markets for GMOs.

Accessing Patent Protected Materials

Perhaps the biggest patent and competition challenge posed by GMOs has been the lack of competition within and between rival GMO trait platforms. The Monsanto Corporation is really the only firm in the market that has a full suite of traits (see, for example, Table 4.1 showing the GMOs commercially available in Australia). This essentially means that Monsanto has a dominant position in the market for traits and their patents protect that competitive advantage. The following recent Monsanto and DuPont/Pioneer litigation highlights this competition problem.

Monsanto and DuPont/Pioneer entered into a non-exclusive licensing agreement whereby Monsanto licensed DuPont/Pioneer to use the events '40-3-2' and the 'NK603' involving both soybean and corn respectively.[9] The '40-3-2' and the 'NK603' events were the names given to the particular genetic modifications that resulted from inserting the novel DNA into the host plant. The re-issued US Patent 5,633,435 (from US Patent US RE 39,247E) with the priority date 13 September 1994 covers both events.[10] DuPont/Pioneer incorporated the '40-3-2' and 'NK603' events in their products and sold them, paying Monsanto a royalty.[11] After attempting to generate their own varieties to compete with

9 *Monsanto Company v. EI DuPont de Nemours & Co, Complaint (Redacted)*, 4:09-cv-00686 (Eastern District of Missouri, 2009), 3–4 ([7]–[9]); *Monsanto Company v. EI DuPont de Nemours & Co, Defendants Answers and Counterclaim (Redacted)*, 4:09-cv-00686 (Eastern District of Missouri, 2009), 2–3 ([7]–[9]).

10 *Monsanto Company v. EI DuPont de Nemours & Co, Complaint (Redacted)*, ibid., 3 ([7]). See also Gerard Barry, Ganesh Kishore, Stephen Padgette and William Stallings, *Glyphosate Tolerant 5-Enolpyruvylshikimate-3-Phosphate Synthase*, US Patent 5,633,435 (1997), Claim 1.

11 *Monsanto Company v. EI DuPont de Nemours & Co, Complaint (Redacted)*, ibid., 4 ([9]).

the '40-3-2' and 'NK603' events DuPont/Pioneer announced that they were combining their variety with these events.[12] As a consequence of combining the '40-3-2' and 'NK603' events with the DuPont/Pioneer events Monsanto alleged that DuPont/Pioneer had materially breached the licensing agreement[13] and infringed Monsanto's patent.[14] In response DuPont/Pioneer counterclaimed and, among other matters,[15] raised various anti-trusts defences.[16] The essence of their claim was:

> ... to arrest a new anticompetitive campaign by Monsanto designed to maintain and extend its unlawful monopolies into developing markets involving combinations ('stack') of input and output traits that confer multiple and more effective forms of herbicide tolerance or insect resistance or valuable end-use qualities. The chief means by which Monsanto has implemented this strategy has been either to directly deny competitors the ability to stack their traits with Monsanto's unlawfully acquired monopoly traits or to achieve the same result indirectly, by foreclosing competitors from access to the market by denying such stacking rights to independent seed companies. Monsanto has abused its unlawfully-acquired monopoly power to block competitors, thwart innovation and extract from farmers unjustified price increases of over 100 per cent in recent years.[17]

DuPont/Pioneer detailed four components to the scheme: stifling emerging competition to Monsanto's stacked multi-herbicide tolerant product (like competition from the DuPont/Pioneer Optimum GAT product) and shifting independent seed companies and farmers to another patented glyphosate resistant product (for example Roundup Ready 2, based on the 'MON89788' event); preventing independent seed companies from developing and selling products incorporating Monsanto's and others traits through restrictive licensing arrangements that exclude Monsanto's likely competitors and preventing stacking traits; entering anticompetitive agreements with trait developers that give Monsanto veto powers over sublicensing those traits to others, including likely competitors; and limiting access to germplasm into which traits can be placed and the traits that can be placed into germplasm.[18] DuPont/Pioneer identified the relevant markets

12 Ibid., 5 ([12]).
13 Ibid., 5 ([14]) and 16–22 ([76]–[103] and [110]–[122]).
14 Ibid., 5 ([14]) and 14–16 ([61]–[75]).
15 See *Monsanto Company v. EI DuPont de Nemours & Co, Defendants Answers and Counterclaim (Redacted)*, above n 9, 14–17 ([131]).
16 Ibid., 17 ([131]).
17 Ibid., 18–19 ([2]).
18 Ibid., 19–23 ([4]–[10]).

in the US[19] as the markets for 'herbicide-tolerant traits in soybeans',[20] 'herbicide-tolerant traits in corn.'[21] and 'stacked herbicide-tolerant and insect-resistant traits',[22] with Monsanto having the predominant market share (99.7 per cent for glyphosate resistant soybean,[23] 80.8 per cent for glyphosate resistant corn,[24] 74.9 per cent for corn rootworm resistance,[25] and 65.2 per cent for European corn borer resistance).[26] Moreover, DuPont/Pioneer suggested that:

> A small, but significant, non-transitory increase in licensing fees above the competitive levels for herbicide-tolerant traits in [the identified markets] would not cause seed companies or other customers to switch a significant enough quantity of purchases to another product so as to make the price increase unprofitable for a firm with monopoly power.[27]

DuPont/Pioneer also identified the emerging US markets for multiple modes of herbicide and insect resistance in corn,[28] stacked input and output traits in soybean,[29] and stacked input and output traits in corn[30] that Monsanto might also seek to restrict with its alleged anticompetitive activities.[31]

The other significant anticompetitive indications identified by DuPont/Pioneer were the significant barriers to entering the market against Monsanto[32] and the alleged demonstrated use of Monsanto's market power to increase seed prices.[33] DuPont/Pioneer identified two barriers to entering the market: first, time and costs of developing a new trait and second, resistance to getting that new trait to market because of Monsanto's exclusionary licensing of independent seed companies and farmers foreclosing their participation in taking up a new trait. On this second barrier, DuPont/Pioneer noted, '[t]he effect of such foreclosure will be to protect the monopoly power of Monsanto in both existing and emerging markets to the substantial detriment of competition and consumers'.[34]

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19 Ibid., 33 ([55]).
20 Ibid., 26 ([21]).
21 Ibid., 26 ([27]).
22 Ibid., 28 ([32]).
23 Ibid., 26 ([24]).
24 Ibid., 27 ([29]).
25 Ibid., 28 ([34]).
26 Ibid., 28 ([34]).
27 Ibid., 26, 27 and 28–9 ([23], [28] and [36]).
28 Ibid., 29 ([40]).
29 Ibid., 30 ([44]).
30 Ibid., 32 ([50]).
31 See Ibid., 29–32 ([40]–[54]).
32 Ibid., 33–34 ([56]–[57]).
33 Ibid., 34 ([58]).
34 Ibid., 33–34 ([57]).

DuPont/Pioneer set out several factual examples of Monsanto's anticompetitive behaviour:

a. Product shifting – using market power to shift farmers from one product to another for the benefit of Monsanto and not the farmers – Monsanto's patent for the EPSPS gene is based on a claim for the isolated sequence.[35] This patent expires on 13 September 2014.[36] DuPont/Pioneer alleged that to extend its monopoly Monsanto is shifting (or switching) farmers to the Roundup Ready 2 varieties including entering into new licensing agreements with independent seed companies.[37] The Roundup Ready 2 has the same EPSPS gene except that the gene uses a different promoter and the construct of the promoter and the EPSPS gene is subject to a different patent that expires on 15 December 2020.[38] In effect the allegation is that Monsanto is extending its monopoly powers through intellectual property and contracting.[39] The contract is significant as, with its market power, Monsanto can demand that the independent seed companies convert their seeds lines to the Roundup Ready 2, and failing this Monsanto can terminate the license and require all the existing germplasm be destroyed.[40]
b. Restrictive licensing – using market power to exclude Monsanto's competitors – Monsanto is developing varieties of soybean stacked with resistance to glyphosate and other herbicides and insect resistance: 'SmartStax combines multiple insect-resistant traits operating by multiple modes of action and herbicide tolerant traits to multiple herbicides.'[41] DuPont/Pioneer assert that it co-developed the insect-resistant traits with Dow but requires Dow's permission to use the insect-resistant traits in seeds produced by independent seed companies.[42] DuPont/Pioneer also asserts that Dow has entered into an agreement with Monsanto to use the insect-resistant traits in the Monsanto SmartStax product and alleges that Monsanto's agreement includes an anticompetitive arrangement that

35 Barry *et al.*, above n 10, Claim 1.

36 This is 20 years after the priority date of 13 September 1994: ibid., 1.

37 *Monsanto Company v. EI DuPont de Nemours & Co, Defendants Answers and Counterclaim (Redacted)*, above n 10, 37–38 ([67]–[72]).

38 This is 20 years after the filing date of 15 December 2000: Fincher, K., Flasinski, S. and Wilkinson, J. 2003. *Plant Expression Constructs*, US Patent 6,660,911. Washington DC: USPTO, 1.

39 See *Monsanto Company v. EI DuPont de Nemours & Co, Defendants Answers and Counterclaim (Redacted)*, above n 10, 67–8 ([183]).

40 See ibid., 57–66 ([139]–[175]). See also Stumo, M. 2010. Anticompetitive tactics in ag biotech could stifle entrance of generic traits. *Drake Journal of Agricultural Law*, 15(1), 137–48, 138, 141–3 and the references therein.

41 *Monsanto Company v. EI DuPont de Nemours & Co, Defendants Answers and Counterclaim (Redacted)*, above n 10, 38 ([73]–[74]).

42 Ibid., 39 ([75]).

prohibits or penalises Dow for giving DuPont/Pioneer permission to sublicense the traits.[43] DuPont/Pioneer assert that this forecloses them from competing in the market for stacked herbicide and insect resistant products.[44]

This litigation was resolved with Monsanto and DuPont reaching a cross-license agreement allowing DuPont to stack Monsanto's Roundup Ready 2 with its materials.[45] The precise outcome of the settlement remains unclear. There are concerns that the cross-licensing arrangements might limit extending licensing rights to outside parties, creating more anti-competitive barriers. What this case starkly demonstrates is the broader scope of likely competition issues. Some of these are now addressed in more detail.

Limiting Consumer Uses Through Restrictive Licensing

The late expansion of patent law to include GMOs in 1980[46] and traditionally bred non-genetically modified plants in 2001[47] meant that plant and seed markets in agriculture had to rely on private ordering through contracts.[48] The result has been that plants and seeds are no longer sold but instead they are licensed, with the contract setting out the restrictive terms and conditions.[49] When combined with patents, the terms and conditions of such licenses attract the strict liability standard (including treble damages) and apply to innocent infringers through patent infringement rather than breach of contract. The decision of the US Supreme Court in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* illustrates the kinds of accepted terms and conditions that restrict the purchaser:

> Pioneer sells its patented hybrid seeds under a limited label license that provides: 'License is granted solely to produce grain and/or forage' ... The license 'does not extend to the use of seed from such crop or the progeny thereof for

43 Ibid., 39 and 64–6 ([75] and [167]–[175]).

44 Ibid., 39 ([75]).

45 See Chao, B. and Gray, J. 2013. A $1 billion parable. *Denver University Law Review*, 90(1), 185–91.

46 *Diamond v. Chakrabarty*, above n 2, 305.

47 *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, above n 4, 148.

48 See also Winston, E. 2012. A patent misperception. *Lewis and Clark Law Review*, 16(1), 289–335, 294–300 (arguing that the private ordering in agriculture is being allowed to expand on the patent bargain because of a misperception that patents are immune from antitrusts – '[i]t is anti-antitrusts to allow the abuse to continue'); Lawson, C. 2011. Juridifying the self-replicating to commodify the biological nature future: Patents, contracts and seeds, *Griffith Law Review*, 20(4), 851–82, 853–9 (arguing that the use of contracts and the recent interpretation of exhaustion provisions has expanded the reach of exclusivity).

49 See Winston, E. 2006. Why sell what you can license: Contracting around statutory protection of intellectual property. *George Mason Law Review*, 14(1), 93–133.

> propagation or seed multiplication' ... It strictly prohibits 'the use of such seed or the progeny thereof for propagation or seed multiplication or for production or development of a hybrid or different variety of seed'.[50]

How these contracts became so important and powerful for GMOs reflects an interesting choice made by the US courts in deciding the bounds of exhaustion. In three notorious cases farmers obtained GMOs in slightly different circumstances and then relied on the GMO traits without abiding by the patent holder's private ordering arrangements. The outcome has been that the courts have favoured the private ordering arrangements in crafting their resolutions to the disputes.

In *Monsanto Company v. McFarling* in the US Court of Appeals McFarling had purchased some of Monsanto's patent protected Roundup Ready soybean seeds under a 'Technology Agreement' and paid a license fee.[51] The terms of the 'Technology Agreement' included that the seeds would be used 'for planting a commercial crop only in a single season' and that the licensee would not 'save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting'.[52] McFarling did save some seeds from his crop and then used those seeds the following cropping season and repeated this activity in subsequent cropping seasons.[53] McFarling did not pay Monsanto any fees for the saved seeds and their subsequent use in cropping.[54]

McFarling argued, in part, that the 'Technology Agreement' required him to purchase new seed each season from Monsanto and that this unreasonably broadened the patent grant as he was well able to produce his own seed from his existing purchases of Monsanto's patent protected seeds.[55] The majority, Judges Newman and Bryson, rejected this proposition finding that other seeds were available to McFarling and that Monsanto's 'Technology Agreement' applied to 'the purchased seed for the purpose of growing crops and not for the purpose of producing new seed'.[56] Thus:

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50 *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, above n 4, 128.

51 *Monsanto Company v. McFarling*, 302 F.3d 1291, 1293 (2002).

52 Ibid., 1293.

53 Ibid.

54 Ibid.

55 Ibid., 1297.

56 Ibid., 1298. This patent has been extensively litigated, leading to finding that planting seeds containing the invented sequences is an infringement: see *Monsanto Company v. David*, 516 F.3d 1009 (2008); *Monsanto Company v. Parr*, 545 F.Supp.2d 836 (2008); *Monsanto Company v. Vanderhoof*, 2007 WL 1240258 (2007); *Monsanto Company v. Strickland*, 2007 WL 3046700 (2007); *Monsanto Company v. Good*, 2004 WL 1664013 (2003); *Monsanto Company v. Trantham*, 156 F.Supp.2d (2001); *Monsanto Company v. Dawson*, 2000 WL 33953542 (2000); and so on.

> A purchaser's desire to buy a superior product does not require benevolent behaviour by the purveyor of the superior product. Nor does an inventor of new technology violate the antitrust laws merely because its patented product is favoured by consumers.[57]

McFarling's challenge was also, in part, that the 'Technology Agreement' violated the doctrines of patent exhaustion (or first-sale), and the proposition that 'when a patented product has been sold the purchaser acquires "the right to use and sell it, and the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold".'[58] As a consequence McFarling asserted that Monsanto's sale of the patent protected seeds to McFarling exhausted the 'exclusive rights' over the seeds and products and that this could not be restricted by the 'Technology Agreement'.[59] The majority accepted Monsanto's response that the seeds were not sold. Under the 'Technology Agreement' Monsanto sold use rights but not the rights to construct new seeds.[60] The majority relied on the earlier Federal Circuit decision in *Mallinckrodt, Inc. v. Medipart, Inc.* for the proposition that 'use of a patented product "in violation of a valid restriction may be remedied under the patent law, provided that no other law prevents enforcement of the patent".'[61] The conclusion was that Monsanto's authorised sale of the patent protected seeds with the 'Technology Agreement' restriction did not exhaust the 'exclusive rights' but instead was a limited permission to use the seeds for specific purposes according to contract laws that might be remedied under patent law.[62]

In *Monsanto Company v. Scruggs* in the US Court of Appeals, Scruggs bought seeds containing Monsanto's patent protected invention (in this case also including insect resistance in addition to herbicide resistance). Scruggs planted his purchased seeds, saved seeds from the harvest and planted subsequent generations.[63] The important difference was that Scruggs did not sign the 'Technology Agreement'.[64] The seed company from which Scruggs bought the seed was not Monsanto but rather a company licensed to sell the Monsanto seeds, including the requirement to sell them with the signed 'Technology Agreement'.[65] Monsanto filed an infringement suit and was awarded a permanent injunction.[66] Scruggs lodged an appeal arguing, in part, that Monsanto's patent was exhausted because Scruggs had

57 Ibid., 1298.
58 Ibid., citing *United States v. Univis Lens Co*, 316 US 241, 249 (1942).
59 *Monsanto Company v. McFarling*, Ibid., 1298.
60 Ibid., 1298–9.
61 Ibid., 1298 citing *Mallinckrodt, Inc. v. Medipart*, Inc., 976 F.2d 700, 701 (1992).
62 Ibid., 1299–1300.
63 *Monsanto Company v. Scruggs*, 459 F.3d 1328, 1333 (2006).
64 Ibid.
65 Ibid.
66 Ibid.

purchased the Monsanto seeds in an unrestricted sale.[67] Scruggs' argument was that because his purchase was an unrestricted sale the patent exhausted on sale.[68] Despite this argument, Circuit Judge Mayer, with Circuit Judge Dyk concurring on this issue,[69] rejected his proposition:

> The doctrine of patent exhaustion is inapplicable in this case. There was no unrestricted sale because the use of the seeds by seed growers was conditioned on obtaining a license from Monsanto. Furthermore, the "'first sale" doctrine of exhaustion of the patent right is not implicated, as the new seeds grown from the original batch had never been sold' ... Without the actual sale of the second generation seed to Scruggs, there can be no patent exhaustion. The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder.[70]

More recently in *Monsanto Company v. Bowman* a farmer bought seeds from a grain elevator (where seeds are delivered as a commodity after harvest for transport to markets) for the purposes of planting and harvesting a second season crop.[71] Specifically Bowman conformed with Monsanto's licensing arrangements for the first season crop, but then planted a second season crop using mixed seeds, some of which contained Monsanto's patented technology that he had obtained from a grain elevator without the 'Technology Agreement'.[72] Bowman also saved some of the seed from the second season crop for planting in subsequent seasons' second season crop.[73] Monsanto alleged patent infringement.[74] Bowman argued:

> that when the soybeans from a licensed Roundup Ready crop are harvested and sold to a grain elevator or dealer, they are sold without restriction, mixed with all other soybean crops in from the area and, therefore, when purchased and used by farmers to plant as seed (commodity soybeans) for another crop, they are not protected by patent.[75]

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67 Ibid., 1335.

68 Ibid., 1335–6 citing *Mallinckrodt, Inc. v. Medipart*, Inc., 976 F.2d 700, 701 (1992). Notably the decision also refers to the decision in *LG Electronics, Inc. v. Bizcom Electronics, Inc.* 453 F. 3d 1364 (2006) that was expressly overruled on appeal in the Supreme Court in *Quanta Computer, Inc. v. LG Electrics, Inc.*, 553 US 617, 638 (2008).

69 Ibid., 1342.

70 Ibid., 1336 citing *Monsanto v. McFarling*, above n 52, 1299.

71 *Monsanto Company v. Bowman* 686 F.Supp.2d 834, 835 (2009).

72 Ibid., 835–6.

73 Ibid., 836.

74 Ibid., 836.

75 Ibid.

The District Court followed the earlier decisions in *McFarling* and *Scruggs* and found that Bowman had infringed Monsanto's patent because the seeds from the grain elevator containing the patented invention were expressly excluded by agreement from being sold for planting – 'No unconditional sale of the Roundup Ready trait occurred because the farmers could not convey to the grain dealers what they did not possess themselves.'[76] The District Court concluded:

> Unless Monsanto receives the patent protection it is trying to enforce in this case ... there would be nothing stopping all farmers from buying commodity soybeans for planting ... thereby allowing such farmers to receive the benefit of the Roundup Ready genetic modification without compensating Monsanto for its research and development work.[77]

The US Court of Appeals affirmed this decision, reasoning that patent exhaustion did not occur because Bowman had 'created a newly infringing article'.[78] The decision was again affirmed in the US Supreme Court.[79] Essentially the dilemma for the court was that patent exhaustion allows a purchaser in an unrestricted sale to use the invention without restriction but not to remake or replicate the invention – 'That is because the patent holder has "received his reward" only for the actual article sold, and not for subsequent recreations of it.'[80] Seeds, however, contain their own means of reproduction and by using the seed as intended the seed reproduces itself as a crop – 'he is merely using them in the normal way farmers do'.[81] The court concluded:

> Unfortunately for Bowman, that principle decides this case against him. Under the patent exhaustion doctrine, Bowman could resell the patented soybeans he purchased from the grain elevator; so too he could consume the beans himself or feed them to his animals. Monsanto, although the patent holder, would have no business interfering in those uses of Roundup Ready beans. But the exhaustion doctrine does not enable Bowman to make additional patented soybeans without Monsanto's permission (either express or implied). And that is precisely what Bowman did. He took the soybeans he purchased home; planted them in his fields at the time he thought best; applied glyphosate to kill weeds (as well as any soy plants lacking the Roundup Ready trait); and finally harvested more (many more) beans than he started with. That is how 'to

76 Ibid., 839 citing *Monsanto Company v. Scruggs*, 459 F.3d 1328, 1336 (2006).
77 *Monsanto Company v. Bowman*, 657 F.3d 1341, 1348 (2011).
78 Ibid.
79 *Bowman v. Monsanto Company*, 133 S.Ct. 1761 (2013).
80 See *Bowman v. Monsanto Company*, ibid., 1766 citing *United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942).
81 Ibid.

> "make" a new product', to use Bowman's words, when the original product is a seed ... Because Bowman thus reproduced Monsanto's patented invention, the exhaustion doctrine does not protect him.[82]

The Supreme Court justified this perspective, arguing that if there were exhaustion on first sale then Monsanto would only ever '"receive its reward" for the first seeds it sells'[83] and:

> in short order, other seed companies could reproduce the product and market it to growers, thus depriving Monsanto of its monopoly. And farmers themselves need only buy the seed once, whether from Monsanto, a competitor, or (as here) a grain elevator. The grower could multiply his initial purchase, and then multiply that new creation, ad infinitum – each time profiting from the patented seed without compensating its inventor. Bowman's late-season plantings offer a prime illustration. After buying beans for a single harvest, Bowman saved enough seed each year to reduce or eliminate the need for additional purchases. Monsanto still held its patent, but received no gain from Bowman's annual production and sale of Roundup Ready soybeans.[84]

While the court was careful to say that this decision was not the final statement on self-replicating technologies,[85] the effect is to favour Monsanto's private ordering according to its particular terms and conditions. In effect the patent issue of exhaustion has been decided in favour of the patent holder and becomes a mere question about making the invention.

Post-patent Regulatory Approvals

Most nations require GMOs to be approved by a governmental agency for growing and selling. These nations have either adopted specific regulations directed to GMOs or have applied their existing general regulations (with some amendments) to accommodate GMOs. For example, in the US the existing general regulations are applied by the US Department of Agriculture (USDA), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). The particular agency responsible for overseeing the regulation of any given GMO depends on its intended use.[86] The FDA regulates food uses through a voluntary consultation process, the EPA regulates potential

82 Ibid., 1766–7.

83 Ibid., 1767 citing *United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942).

84 *Bowman v. Monsanto Company*, ibid., 1767.

85 Ibid., 1769. See also Sheff, J. 2013. Self-replicating technologies. *Stanford Technology Law Review*, 16(2), 229–56.

86 See *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23,302.

pesticide harms to the environment through the *Federal Insecticide, Fungicide and Rodenticide Act*,[87] and the USDA regulates plant pests and noxious weeds through the *Plant Protection Act*,[88] albeit that other laws may also have some application.[89] The effect of governmental regulation is that GMOs require regulatory approval (generally in the form of a licence) to be grown, distributed, sold or consumed in the market.[90] The regulatory approvals are generally time limited and expire, and require some kind of involvement of the registrant to provide testing data held by the original applicant. These kinds of schemes apply in most markets around the world, meaning that to import and use GMOs requires regulatory approvals.[91]

The requirements for regulatory approval raise competition issues about who will maintain the regulatory approval following the patent term where the patent holder (and their licensees or assignees) ceases to maintain that approval. Theoretically when a patent expires the subject matter of the patent becomes available to the broader market and generic competition is then possible (increasing access and lowering the prices). Where a patent protected product or process also requires other regulatory approval then that approval may become a barrier to competition. These might be considered as two separate competition problems in: (1) regulatory approval in the domestic market for GMOs and their products and (2) regulatory approval in export markets and destinations for GMOs and their products. A patent holder may choose not to maintain regulatory approval with the effect that

87 7 U.S.C. 6. *The Federal Insecticide, Fungicide and Rodenticide Act* gives the EPA authority to limit the sale and distribution of pesticides: 7 U.S.C. § 136 et seq.; 40 C.F.R. §§ 152 and 174.

88 7 U.S.C. 104. *The Plant Protection Act* gives the USDA authority to 'prohibit ore restrict ... any plant ... if [the Secretary of Agriculture] determines that the prohibition or restriction is necessary to prevent ... the dissemination of a plant pest or noxious weed within the United States': 7 U.S.C. § 7712(a). The term 'plant pest' has been broadly interpreted to give the USDA authority (delegated to the Animal and Plant Health Inspection Service): see 7 C.F.R. § 340.

89 See, for examples: FDA – *Food, Drug and Cosmetics Act*, 21 U.S.C. 9; Public Health Service Act, 42 U.S.C. 6A; EPA – *National Environmental Protection Act*, 42 U.S.C. 55; *Toxic Substances Control Act*, 15 U.S.C. 53; *Food, Drug and Cosmetics Act*, 21 U.S.C. 9; USDA – *Virus Serum Toxin Act*, 21 U.S.C. 5; *Meat Inspection Act*, 21 U.S.C. 12; *Poultry Products Inspection Act*, 21 U.S.C. 10; *Egg Products Inspection Act*, 21 U.S.C. § 15 and so on.

90 For an overview of this complex regulatory thicket in the US see McHughen, A. 2006. *Plant Genetic Engineering and Regulation in the United States*, Agricultural Biotechnology in California Series, Publication 8179. [Online]. Available at: http://anrcatalog.ucdavis.edu/pdf/8179.pdf [accessed 3 February 2014].

91 For a general, partisan perspective see Conko, G. 2012. *Is There a Future for Generic Biotech Crops? Regulatory Reform is Needed for a Viable Post-Patent Industry*, Issue Analysis 2012 No 7, 4–10. [Online]. Available at: http://cei.org/sites/default/files/Greg%20Conko%20-%20Is%20There%20a%20Future%20for%20Generic%20Biotech%20Crops.pdf [accessed 3 February 2014].

patent term expiry removes the GMO from the market because there is no longer a regulatory approval to grow, distribute, sell and consume the GMO in the market.[92]

That this is likely to be a problem was well illustrated in the *In re Genetically Modified Rice Litigation*.[93] In this case Bayer CropScience was advised that the rice variety LLRice601 (which was unapproved in the US and Europe and still experimental) was found in the 2005 long grain rice harvest. Damages were awarded against Bayer, partly recognising the economic impact of failing to have regulatory approval in export markets:

> Numerous Bayer documents show that Bayer knew the LL601 had to be kept isolated, could not enter the food chain, and could not enter foreign markets. Bayer employees referred to Europe's 'zero tolerance' policies. They discussed the effects of such an event on the market for rice, recognizing that there could be serious economic impacts. One 2000 memorandum even correctly forecast that if GM rice was found to have spread to conventional varieties, 'We could make any national newscast … and the rice industry would be quite affected to say the least …'[94]

The imminent expiry of the Monsanto patent over Roundup Ready 1 on 13 September 2014[95] (and another 22 biotech traits over the next decade)[96] demonstrated the likely competition problems and how they have been addressed in anticipation of that event. The particular concern here is that, now Monsanto has regulatory approval for its patent protected Roundup Ready 2, the company will have little interest in maintaining regulatory approval for Roundup Ready 1 when it comes off patent. The immediate concern about Monsanto Roundup Ready 1 has probably been put off, at least for soybeans, as Monsanto has committed to 'continue global regulatory approvals through 2021 for RR 1 soybeans'.[97] To address this concern five major seed companies have agreed to a binding legal contract covering the expiry of single gene patents. The *Generic Event Marketability and Access*

92 See generally McEowen, R. 2011. *Expiration of Biotech Crop Patents – Issues For Growers*, Iowa State University Center for Agricultural Law and Taxation Issue Brief, 8 April 2011. [Online]. Available at: http://www.calt.iastate.edu/briefs/CALT%20Legal%20Brief%20-%20Expiration%20of%20Biotech%20Crop%20Patents%20-%20Issues%20for%20Growers.pdf [accessed 3 February 2014].

93 In *re Genetically Modified Rice Litigation* 666 F.Supp.2d 1004, 1014–15 (Eastern District of Missouri, 2009).

94 Ibid., 1031.

95 This is 20 years after the priority date of 13 September 1994: Barry *et al.*, above n 10, 1.

96 See Conko, above n 91, 1.

97 See Jones, P. 2012. *Both Expiring and Healthy Patents Breed Challenges for Ag Biotech*, ISB News Report. [Online]. Available at: http://www.isb.vt.edu/news/2012/feb/jones-1.pdf [accessed 3 February 2014]. See also Redick, T. and Hawker, N. 2010. Legal issues arising from generic biotech crops. *Aglaw Update*, 27(3), 2–6.

Agreement[98] and the *Data Use and Compensation Agreement* are the relevant agreements. The *Generic Event Marketability and Access Agreement* sets out agreements about accessing patent protected products and any regulatory data and authorisations. The *Data Use and Compensation Agreement* sets out agreement to encourage signatories to share or transition responsibility for regulatory maintenance, stewardship and liability.[99]

In overview the *Generic Event Marketability and Access Agreement* provides that the signatories agree:

To 'negotiate in good faith to grant access' to the single event patent protected product and any regulatory data and authorisations.[100]

To make the single event patent protected product available to all signatories after patent expiry in non-proprietary germplasm.[101]

To provide notice to the other signatories of the imminent expiry of a single event patent.[102]

To indicate whether the regulatory approval will be maintained, shared or discontinued by the patent holder.[103]

To establish an administration entity to operate and administer the agreement.[104]

Under the *Generic Event Marketability and Access Agreement* so far there have been two notifications of patent expiry: the Monsanto patent for event MON 810 Corn and the 40-3-2 Soybean.[105] Monsanto has committed to maintain the authorisations necessary for cultivation and sale of seed products and grain in the US and 'to permit undisrupted trade' in materials containing these events.[106]

While the *Generic Event Marketability and Access Agreement* and the *Data Use and Compensation Agreement* are an attempt to address the competition problems of regulatory approval stifling access and use of post-patent products,

98 *Generic Event Marketability and Access Agreement.* [Online]. Available at: http://www.agaccord.org/include/gemaa_firstamendedMay9.pdf [accessed 3 February 2014].

99 Ibid., cl 6.

100 Ibid., cl 4.

101 Ibid., cl 5.

102 Ibid., cl 6.

103 Ibid., cls 6, 7 (maintain), 8 (share) and 9 (discontinue).

104 Ibid., cl 26 and Appendix A.

105 Generic Event Marketability and Access Agreement, *Notice of Patent Expiry – Mon 810 Corn* and *Notice of Patent Expiry – 40-3-2 Soybean.* [Online]. Available at: http://www.agaccord.org/?p=notices [accessed 3 February 2014].

106 Ibid.

it is still too early to determine whether this will be sufficient. Notably the agreements really only deal with the other signatories and, at this stage, the process of dealing with shared or discontinued regulatory approval and multiple event traits (stacked traits) is uncertain. The positive outcome for competition, though, is that Monsanto has committed to maintain existing regulatory approval for its two expiring traits that should enable a generic adoption of the patented traits to be exploited after patent term expiry.[107]

Post-patent Access to Materials

A closely related issue is whether at the expiration of a patent the protected product or process becomes available for generic competition. Underpinning the justification of intellectual property schemes is a period of exclusivity, after which the intellectual property protected material becomes available to the broader public. The *Agreement of Trade-related Aspects of Intellectual Property* (TRIPS) minimum standard provides that the period of exclusivity is 20 years from the filing date.[108] The patent application itself requires a description that discloses the invention in a way that a person skilled in the art might carry out the invention.[109] The contents of the description include a specification setting out details about the invention and how it might be performed.[110] For complex materials, such as DNA constructs, plants, seeds and so on, depositing the materials with a suitable repository can satisfy the description requirements.[111] This overcomes the problem of dealing with materials that might otherwise defy description (such as plants, cells, seeds and the like). The depositor (the patent applicant and/or holder) however, only has obligations to ensure the deposit remains viable during the term of the patent and there are no obligations on the repository either to maintain the materials or to make them available after the patent term expires. Similarly, TRIPS and other intellectual property agreements do not require that materials deposited to satisfy the description requirements are made available after the patent term expires. The result is that patented materials may not be accessible after the patent term expires.

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107 See Sauer, K. 2014. *Roundup Ready® Soybean Post-Patent Regulatory Commitment Extended through 2021.* [Online]. Available at: at http://www.monsanto.com/newsviews/pages/roundup-ready-soybean-post-patent-commitment-extended-through-2021.aspx [accessed 3 February 2014].

108 *Agreement of Trade-related Aspects of Intellectual Property*, Article 33. See also *Canada – Term of Patent Protection* (2000) WT/DS170/AB/R, [95].

109 *Agreement of Trade-related Aspects of Intellectual Property*, Article 29(1).

110 See *Patent Cooperation Treaty*, Article 5; *Regulations under the Patent Cooperation Treaty*, Article 5.

111 *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure*, Article 3.

The *Generic Event Marketability and Access Agreement* addresses this issue by providing that the signatories agree to make the single event patent protected product available to all signatories after patent expiry in the form of non-proprietary germplasm.[112] While this is a solution for the signatories, this is not a solution for non-signatories and their disadvantage may be exacerbated by existing practices where patent protected products are made available under a license that restricts seed saving and compels destruction of existing seed stocks.

Customer/Product Shifting or Switching

Patent holders are often motivated to maintain their intellectual property exclusivity by shifting or switching the market (also called product hopping and ever-greening) in favor of their intellectual property protected product. This has been a well-documented phenomenon in the pharmaceutical industry where, just before patent expiry, the patent holder adopts counter measures to extend their favoured position by shifting or switching customers to another substituted product that is patent protected.[113] Two recent examples demonstrate the kinds of competition issues that arise when a patent holder actively seeks to secure an advantage through switching or shifting. Both involve Monsanto attempting to avoid generic competition by moving customers: (1) from a less robustly protected product to a more robustly protected product and (2) from an unprotected product to a protected product. In the latter case Monsanto has made a number of concessions, almost certainly to avoid competition (antitrust) concerns.

The first example involved alleged attempts by Monsanto to shift or switch customers from the GA21 event to the NK603 event. In essence Monsanto's patent entitlements over the GA21 event were successfully challenged so that Monsanto no longer retained exclusivity.[114] Monsanto did, however, have exclusive patent entitlements over the NK603 event.[115] In a patent spat between Monsanto and Syngenta concerning the event GA21,[116] Syngenta Seed responded in the US District Court in Delaware, alleging Monsanto:

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112 *Generic Event Marketability and Access Agreement*, above n 98, cl 5.

113 For examples, see Westin, J. 2011. Product switching in the pharmaceutical sector – An abuse or legitimate commercial consideration. *European Competition Law Review*, 32(12), 595–601.

114 See *Rhone-Poulenc Agro, S.A. v. Dekalb Genetics Corporation*, 272 F.3d 1335 (2001).

115 See Behr, C., Heck, G., Hironaka, C. and You, J. 2004. *Corn Plants Comprising Event PV-ZMGT32 (nk603)*, US Patent 6,825,400. Washington DC: USPTO.

116 See Jones, P. 2005. *Patent Challenges to AgBiotech Technologies in 2004*, ISB News Report. [Online]. Available at: http://www.isb.vt.edu/news/2005/artspdf/feb0504.pdf [accessed 3 February 2014]; Market Scope Europe Ltd. 2004. *European News And Markets – Crop Protection Monthly*, Issue No 176, 3. [Online]. Available at: www.crop-protection-monthly.co.uk/Archives/CPMJuly2004.doc [accessed 3 February 2014].

> to have: (1) bundled commercial incentives across several products sold to corn growers to create a barrier to plaintiff and other competitors ... (2) enforced exclusive dealing contracts to prevent plaintiff or other competitors from entering markets ... (3) filed the 'baseless' [patent infringement litigation] against plaintiff ... (4) filed separate 'baseless' patent case in Illinois concerning two other glyphosate-tolerant trait patents ... (5) misrepresented plaintiff's ability to commercialize glyphosate-tolerant traits to discourage seed companies from dealing with plaintiff ... (6) demanded destruction of all GA21 production to impair plaintiff's entry into the glyphosate-tolerant traits market ... (7) intimidated seed companies not to do business with plaintiff ... and (8) denied plaintiff access to foundation seeds and pressured foundation seed companies not to deal with plaintiff.[117]

Syngenta and Monsanto eventually settled all their litigation and entered into a licensing arrangement.[118]

The second example is Monsanto's shifting or switching of customers from the patent expiring Roundup Ready 1 to the patent protected Roundup Ready 2. Roundup Ready 2 has the same glyphosate resistance gene linked to a different promoter to activate that gene and the patent expires on 15 December 2020.[119] Monsanto now appears to be slowly shifting its existing uses of Roundup Ready 1 to Roundup Ready 2 and requiring its licensed independent seed sellers to switch to Roundup Ready 2, according to their contractual arrangements:

> Notwithstanding that [Roundup Ready] and [Roundup Ready 2] are virtually identical, it is widely known in the seed industry that Monsanto recently informed independent seed companies ... that they must begin to convert all of their soybean seed lines from [Roundup Ready] to [Roundup Ready 2] within three years if they wish to continue licensing [Roundup Ready]. Otherwise, Monsanto will terminate the [independent seed companies'] license for [Roundup Ready] soybeans and require the [independent seed company] to destroy all of its [Roundup Ready] soybean germplasm. Because many farmers today will not purchase soybean seeds without a glyphosate-tolerant trait, [independent seed companies] face the prospect of losing their Monsanto license and being driven from the soybean seed market unless they agree to switch to [Roundup Ready 2] completely.[120]

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117 *Syngenta Seed, Inc. v. Monsanto Company*, 2005 WL 678855, 2 (D.Del.).

118 See Zuhn, D. 2008. *Monsanto and Syngenta Settle All Litigation Between the Companies*. [Online]. Available at: http://www.patentdocs.org/2008/05/monsanto-and-sy.html [accessed 3 February 2014].

119 This is 20 years after the filing date of 15 December 2000: Fincher et al., above n 38, 1.

120 Stumo, above n 40, 141–2.

If Monsanto can shift to Roundup Ready 2 then it will be able to avoid generic competition and, in particular, competition from farmers saving their seeds from earlier crops to grow again. Switching to Roundup Ready 2 also allows Monsanto to maintain control over growers through the threat of patent infringement rather than just through contracts and protections of IP exclusivity.

Discussion and Conclusions

Central to appreciating the patent and competition issues for GMOs is an appreciation of the specific and limited nature of genetic traits and their limited substitutability. For example, three basic strategies have been used to develop glyphosate tolerance in crop species: over-expression of EPSP synthase, expression of an insensitive EPSP synthase and detoxification of the N-phosphonomethylglycine molecule.[121] Neither over-expression of EPSP synthase nor detoxification of the N-phosphonomethylglycine molecule has proved viable because of the secondary effects of overexpression and insufficient tolerance to glyphosate.[122] This means that over-expression of EPSP synthase is really the only viable alternative with no other substitutes. This is because of an inherent limitation in biology: common evolutionary ancestry means that the same biological mechanisms are broadly distributed across living organisms. Nature has used the same tricks many times over. As a generalisation, therefore, GMOs pose particular competition problems because their traits are generally not substitutable. This raises particular competition problems as patents deliver exclusivity to the rights holder that can be expertly protected and exploited through careful contracting arrangements. The exploitation of GMOs is an exemplar of how patents can best be exploited, and directly challenges the boundary between patent laws and competition laws.

The analysis in this chapter posits that there is a problem of market concentration in agriculture that is being enabled by intellectual property, and particularly patents, over agriculturally significant traits. The main competition problems might be characterised as:

A limited number of technology platforms – only one firm, Monsanto, has a full suite of traits that can be stacked into a final product. They also own many of the key transformational technologies, including the agrobacterium co-transformation method and the anti-biotic genes under the control of a plant promoter. Moreover, there is a limited stock of elite germplasm that is increasingly owned by a private sector that provides limited access to competitors.

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121 Dill, G. 2005. Glyphosate-resistant crops: History, status and future. *Pest Management Science*, 61(3), 219–24, 219 and the references therein.

122 See *Monsanto Company v. EI DuPont de Nemours & Co, Complaint (Redacted)*, above n 10, 13–14 ([57]–[58]).

A limited rivalry between platforms – Monsanto has not allowed its traits to be broadly adopted by competitors. One result of this restricted access is a concentration of the market share across a range of crops in Monsanto's hands. In effect, a single player has managed to integrate its traits across platforms limiting the potential of competition between platforms.

Mergers and acquisitions – competing firms are often acquired by the bigger players so that their technology and knowledge is being concentrated into a few very large firms.

High barriers to entry – the relatively high costs of research and development that are required to participate in this market act as a barrier to entry for new participants. The merger and acquisition by bigger players of any potential competitors exacerbates this problem.

Vertical integration – firms such as Monsanto control downstream players by forcing them to sign restrictive agreements. In the case of agriculture this includes restrictive agreements with germplasm providers, seed sellers and farmers.

The consequences of these competition problems are likely to be lower quality innovation occurring at a reduced frequency. The imperative on maintaining existing power shifts innovative focus in the sector away from producing new inventions and towards protecting existing inventions and existing market arrangements, higher seed prices and fewer product choices. The analysis in this chapter demonstrates that these are real competition concerns, arising from the ways that patents have been deployed and used with GMOs. The various disputes between GMO developers and sellers show that the parties themselves are generally able to find resolutions, albeit that those resolutions may raise competition concerns and maintain the existing market power of the key players in the various markets for GMOs. Most importantly, the likely consequence of reduced competition is a price squeeze on farmers as they offset higher seed prices against fairly stable global commodity market prices. In making this trade-off farmers are accepting that they are the weakest bargainers in the chain and will continue to receive a reduced share of the profits created by GMOs.

Table 4.1 **Commercial uncontrolled released GMOs in Australia up to 2013. This table is compiled from the licenses granted for the uncontrolled release of GMOs into the environment by the Gene Technology Regulator under the *Gene Technology Act 2000* (Cth)**

Plant	Owner	Branding	Event	Description
Cotton (Gossypium hirsutum L.)	Monsanto Australia Ltd	INGARD (Bollgard)	MON531	Insecticide – cry1Ac gene from Bacillus thuringiensis
		Roundup Ready	MON1445	Glyphosate tolerance –cp4 epsps gene from Agrobacterium species CP4
		Roundup Ready/ INGARD	MON1445 x MON531	Insecticide – cry1Ac gene from Bacillus thuringiensis Glyphosate tolerance –cp4 epsps gene from Agrobacterium species CP4
		Bollgard II	MON15985	Insecticide – cry1Ac and cry2Ab genes from Bacillus thuringiensis
		Bollgard II/ Roundup Ready	MON15985 x MON1445	Insecticide – cry1Ac and cry2Ab genes from Bacillus thuringiensis Glyphosate tolerance –cp4 epsps gene from Agrobacterium species CP4
		Roundup Ready Flex	MON88913	Glyphosate tolerance – two modified cp4 epsps genes from Agrobacterium species CP4
		Roundup Ready Flex/ Bollgard II	MON88913 x MON15985	Insecticide – cry1Ac and cry2Ab genes from Bacillus thuringiensis Glyphosate tolerance – two cp4 epsps genes from Agrobacterium species CP4
	Bayer CropScience Pty Ltd	Liberty Link	LLCotton25	Glufosinate ammonium tolerance – bar gene from Streptomyces hygroscopicus
	Dow AgroSciences Australia Pty Ltd	WideStrike	281-24-236 x 3006-21-23	Insecticide – synthetic cry1Ac(synpro) and cry1F(synpro) genes and from Bacillus thuringiensis
Canola (Brassica napus L.)	Monsanto Australia Ltd	Roundup Ready	GT73	Glyphosate tolerance – cp4 epsps gene from Agrobacterium species CP4
	Bayer CropScience Pty Ltd	InVigor	MS8 RF3	Glufosinate ammonium tolerance – bar gene from Streptomyces hygroscopicus Fertility – barnase (male sterility; MS8) and barstar (fertility restorer; RF3) genes Bacillus amyloliquefaciens

Table 4.1 ***Continued***

Plant	Owner	Branding	Event	Description
Canola (Brassica napus L.)	Bayer CropScience Pty Ltd	InVigor	T45	Glufosinate ammonium tolerance – pat gene from Streptomyces hygroscopicus
			Topas 19/2	Glufosinate ammonium tolerance – pat gene from Streptomyces hygroscopicus
			MS1	Glufosinate ammonium tolerance – bar gene from Streptomyces hygroscopicus Fertility – barnase (male sterility) gene from Bacillus amyloliquefaciens
			RF1 and RF2	Glufosinate ammonium tolerance – bar gene from Streptomyces hygroscopicus Fertility – barstar (fertility restorer) gene from Bacillus amyloliquefaciens
			MS8	Glufosinate ammonium tolerance – bar gene from Streptomyces hygroscopicus Fertility – barnase (male sterility) gene from Bacillus amyloliquefaciens
			RF3	Glufosinate ammonium tolerance – bar gene from Streptomyces hygroscopicus Fertility – barstar (fertility restorer) gene from Bacillus amyloliquefaciens
		InVigor x Roundup Ready	MS8/RF3 x GT73	Glufosinate ammonium tolerance – bar gene from Streptomyces hygroscopicus Fertility – barnase (male sterility; MS8) and barstar (fertility restorer; RF3) genes from Bacillus amyloliquefaciens Glyphosate tolerance –cp4 epsps gene from Agrobacterium species CP4 and the goxv247 gene from Ochrobactrum anthropi
Rose (Rosa X hybrida)	Florigene Pty Ltd	GM Hybrid Tea	WKS82/130-4-1	Purple/blue flower colour – Flavonoid 3'5'-hydroxylase gene from Viola x wittrockiana and the Anthocyanin 5-acyltransferase gene from Torenia x hybrida