

# COMPETITION ISSUES ARISING FROM GENERIC BIOTECH CROPS

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## I. INTRODUCTION

With the expiration of the last of the patents protecting Monsanto’s Roundup Ready® (RR) soybean coming in 2015 and other biotech crops soon to follow, the biotech seed industry is taking steps to assess a comprehensive approach for managing the threat of potential trade disruption arising from off-patent biotech crops planted as “generic” versions in the fields of the United States, but which lack overseas approval.<sup>1</sup> These generic crops require a royalty-generating partner crop to join in a “stack,” which will provide a current patent and regulatory data owner with the resources to renew such approvals.<sup>2</sup>

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1. Julie Douglas, *Preparing for Patent Expiration*, SEED WORLD, June 2012, [http://www.seedworld.com/index.php?option=com\\_content&view=article&id=487:preparing-for-patent-expiration-seed-world-june-2012&catid=83](http://www.seedworld.com/index.php?option=com_content&view=article&id=487:preparing-for-patent-expiration-seed-world-june-2012&catid=83).

2. Soybeans and most other row crops may appear as “volunteers” in subsequent seasons. If a farmer saves and plants non-hybrid crops like the RR soybean on occasion, volunteers may continue to come up at low levels for years to come. Richard K. Zollinger & Jerry L. Ries,

All biotech crops currently in commercial use come with a time-limited set of patents (in the United States and elsewhere) and expiring regulatory approvals in key markets overseas (for example, the European Union and China).<sup>3</sup> With products going off patent, but remaining in the commercial grain supply, industry stewardship or other mechanisms must enable the maintenance of regulatory and product responsibilities. In cases where the original registrant has effectively abandoned the product in its commercial line-up, it may be necessary to transfer the registrations to a party who is able and willing to maintain the necessary global regulatory approvals. This could help prevent the disruption of trade that might otherwise result from off-patent biotech crops showing up in shipments to markets where they have become illegal—what could be considered an “unapproved” genetic event. As a practical matter, the new owner who will seek renewal of the generic biotech crop will likely stack this crop with a patented or otherwise proprietary (for example, a plant variety protected) crop that has a potential stream of royalties. While this Article will focus on the first major biotech crop to go off patent, Monsanto’s RR soybean, the legal issues arising from that patent/regulatory approval expiration apply to many other biotech crops now in wide use.<sup>4</sup>

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*Glyphosate-Resistant Volunteer Soybean Control*, in 61 N. CENT. WEED SCI. SOC’Y, RESEARCH REPORT 80 (Bryan Young ed., 2004), available at <http://www.ncwss.org/proceed/2004/ResRep04/80.pdf>.

3. Roger A. McEowen, *Expiration of Biotech Crop Patents - Issues for Growers*, CTR. FOR AGRIC. LAW AND TAXATION, IOWA STATE UNIV., 1 (2011), <http://www.calt.iastate.edu/briefs/CALT%20Legal%20Brief%20-%20Expiration%20of%20Biotech%20Crop%20Patents%20-%20Issues%20for%20Growers.pdf>; see also Nat’l Cotton Council, *U.S. Agriculture Faces GE Patent Expirations*, DELTA FARM PRESS, Nov. 23, 2012, <http://deltafarmpress.com/cotton/us-agriculture-faces-ge-patent-expirations>.

4. This Article expands on earlier discussions of antitrust, intellectual property, and other competition issues. See, e.g., Allison Luxenberg, *Agriculture and Antitrust Enforcement Issues in Our 21st Century Economy: A Summary of the Historic Joint Effort by the USDA and DOJ*, AGRIC. L. UPDATE (Am. Agric. Law Ass’n, Brownsville, Or.), Jan. 2010, at 5; Thomas P. Redick & Norman W. Hawker, *Legal Issues Arising from Generic Biotech Crops*, AGRIC. L. UPDATE (Am. Agric. Law Ass’n, Brownsville, Or.), Dec. 2010, at 2. In particular, it touches on the interwoven issues of patent expiration, expiring regulatory approvals, and liability risks for biotech crops that lack approval overseas.

## II. COMPETITION ISSUES

### A. *Factual Background*

A substantial percentage of the soybeans, cotton, wheat, canola, and subsistence crops are varietal crops that “breed true.”<sup>5</sup> They are commonly produced as non-hybrids that can be saved and replanted.<sup>6</sup> In contrast, corn (maize) and sorghum are generally produced commercially as hybrids in most areas of the world, and the open-pollinated varieties in commercial use are not generally covered by patents.<sup>7</sup>

In a seminal article addressing this issue, Argentine scholars Lema and Lowenstein hail the coming of this generic generation of biotech traits, predicting it will “lower the production costs of agro-commodities in more restrictive countries” where patents are enforced.<sup>8</sup> They caution, however, that such benefits could disappear if the patent holders fail to renew regulatory approval of a biotech trait.<sup>9</sup> This can occur when a patent expires and the patent holder has a new product that would compete with the older generic product.<sup>10</sup>

Monsanto is banking on commercial success of its second-generation glyphosate-resistant biotech soybean, the Genuity™ RR 2 Yield® (RR2Y) product. Monsanto has already placed its RR2Y soybean in commercial production and the product enjoys expanding acreage with each passing year.<sup>11</sup> Monsanto sold this new trait in seventy soybean varieties on 6 million U.S. acres in 2010,<sup>12</sup>

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5. INT’L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, AGRICULTURAL BIOTECHNOLOGY (A LOT MORE THAN JUST GM CROPS) 5 (2010), available at [http://www.isaaa.org/resources/publications/agricultural\\_biotechnology/download/Agricultural\\_Biotechnology.pdf](http://www.isaaa.org/resources/publications/agricultural_biotechnology/download/Agricultural_Biotechnology.pdf) (explaining that seeds “breed true” when several cycles of self-pollination create closely resembled results).

6. See H.D. KUMAR, AGRICULTURAL ECOLOGY 248 (2006).

7. Richard K. Perrin & Lilyan E. Fulginiti, *Pricing and Welfare Impacts of New Crop Traits: The Role of IPRs and Coase’s Conjecture Revisited*, 11 *AGBIOFORUM* 134, 135–36 (2008).

8. Martin A. Lema & Vanesa Lowenstein, *Tit for Tat: Agbiotech Intellectual Property and Corporate Social Responsibility*, 2 *BRIDGES TRADE BIORES REV.* 11, 11–12 (2008) (suggesting biotech companies renew approvals overseas as a matter of “corporate social responsibility” comparable to efforts to manage insect and weed resistance to such crops).

9. *Id.* at 11.

10. *Id.*

11. *Roundup Ready Soybean Patent Expiration*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/roundup-ready-patent-expiration.aspx> (last visited May 10, 2013).

12. Press Release, Dow AgroSciences, Monsanto and Dow AgroSciences Reach New Licensing Agreement on Roundup Ready 2 Yield® Soybean Technology (June 2, 2010), available at <http://www.dowagro.com/newsroom/corporate/2010/20100602a.htm>. Under the agreement:

and expects this number to reach 39–41 million acres in 2013.<sup>13</sup> Monsanto expects its RR2Y soybean to provide better yields than the original RR soybean,<sup>14</sup> which goes to a generic (off-patent) status in 2015.<sup>15</sup> Monsanto's clarification of the expiration date for all patents on this soybean, after widespread confusion as to the expiration year as illustrated by a GAO report in 2000,<sup>16</sup> should ensure that growers are not misled into patent-infringement by various erroneous publications. Monsanto is seeking other seed companies to act as licensees of the RR2Y

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- Dow AgroSciences gains the rights to stack Roundup Ready 2 Yield technology with other biotechnology traits
  - Dow AgroSciences also gains the rights to out license Dow AgroSciences' germplasm containing Roundup Ready 2 Yield technology, alone or in stacks, to third parties that hold Genuity Roundup Ready 2 Yield licenses from Monsanto.

*Id.*

13. *Genuity Roundup Ready 2 Yield Soybeans*, MONSANTO, <http://www.monsanto.com/products/Pages/genuity-roundup-ready-2-yield-soybeans.aspx> (last visited May 10, 2013).

14. *Id.* Monsanto is currently defending itself against consumer allegations in Arkansas and West Virginia where their respective Attorneys General claim the RR2Y soybean is not meeting yield claims. Carey Gillam, *W. Virginia Probing Monsanto Seed Pricing*, REUTERS (June 25, 2010), <http://www.reuters.com/article/2010/06/25/monsanto-investigation-idUSN2515475920100625>; see also Press Release, Dustin McDaniel, Ark. Attorney Gen., Attorney General Launches Monsanto Inquiry (Sept. 2, 2010), available at [http://ag.arkansas.gov/newsroom/index.php?do:newsDetail=1&news\\_id=325](http://ag.arkansas.gov/newsroom/index.php?do:newsDetail=1&news_id=325); Press Release, Monsanto Co., Monsanto Statement on Arkansas Civil Investigative Demand (Sept. 2, 2010), <http://www.monsanto.com/newsviews/Pages/monsanto-statement-on-arkansas-civil-investigative-demand.aspx> (“Test trial plots conducted in Arkansas in 2009 demonstrate that the technology delivered an average of 4 more bushels per acre” and “no Arkansas farmers planted the technology according to a preliminary review of sales data.”).

15. The Monsanto-owned patents expire in 2014. *Roundup Ready Soybean Patent Expiration*, *supra* note 11 (“The world’s most widely adopted biotech trait, Roundup Ready<sup>®</sup> soybeans, is set to go off patent soon in the U.S.—the last applicable Monsanto-owned patent is expected to expire in 2014.”). Monsanto also relies on third party patents, however, including U.S. Patent No. 5,717,084 (filed June 6, 1995) (issued Feb. 10, 1998) and U.S. Patent No. 5,728,925 (filed Apr. 28, 1995) (issued Mar. 17, 1998), that do not expire until 2015. See 35 U.S.C. § 154(c)(1) (2006). Therefore, the RR soybeans do not become a truly generic product until 2015. See Mica Veihman, *Monsanto Plans for Roundup Ready<sup>®</sup> Soybeans Post Patent*, BEYOND THE ROWS, MONSANTO BLOG (Dec. 16, 2009), <http://monsantoblog.com/2009/12/16/plans-for-roundup-ready-soybeans/>; Nick Weber, *An Update on Roundup Ready Patent Expiration*, BEYOND THE ROWS, MONSANTO BLOG (May 2, 2011), <http://monsantoblog.com/2011/05/02/an-update-on-roundup-ready-patent-expiration/>.

16. *Cf.* U.S. GEN. ACCOUNTING OFFICE, GAO/RCED/NSIAD-00-55, BIOTECHNOLOGY: INFORMATION ON PRICES OF GENETICALLY MODIFIED SEEDS IN THE UNITED STATES AND ARGENTINA 13 n.10 (2000) (“The patents on the Roundup Ready soybean technology expire on July 10, 2007.”).

trait, including “stacking” it with other traits, as the recent licensing agreement with Dow Agrosciences on RR2Y illustrates.<sup>17</sup>

In contrast to the relationship with Dow Agrosciences, Monsanto has asserted that DuPont Pioneer lacks the rights to stack the first RR soybean with traits that also confer glyphosate tolerance.<sup>18</sup> There appears, however, to be no dispute between the parties regarding Pioneer’s right to stack RR with its Plenish<sup>®</sup> trait and other genes.<sup>19</sup> Pioneer also developed soybean varieties that include its Optimum<sup>®</sup> GAT<sup>®</sup> trait in combination with RR in its highest-performing soybean lines (second glyphosate tolerance event).<sup>20</sup> Monsanto sued Pioneer in an effort to stop the commercialization of those products.<sup>21</sup> Pioneer asserted contractual and affirmative defenses challenging the validity and infringement of the patent Monsanto is asserting against its Optimum GAT soybeans.<sup>22</sup> Pioneer also asserted certain antitrust counterclaims related to, inter alia, an alleged anticompetitive “switching strategy” that induces independent seed companies to switch from RR1 to RR2Y soybeans during the years leading up to 2015, when the last of the RR soybean patents expire.<sup>23</sup>

It should be noted that in December of 2009, after considerable industry scrutiny of their switching strategy, Monsanto issued a statement indicating that it had extended all RR seed licenses through the patent term expiration so that each licensee can make its own decision on breeding and product offerings with original RR soybeans for its grower customers.<sup>24</sup>

The RR soybean will be found for years to come after expiration of its patents in 2015, however, as companies like DuPont use this trait in combination

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17. See Press Release, Dow AgroSciences, *supra* note 12; *Licensing: The Facts on Monsanto’s Approach to Licensing*, MONSANTO, <http://www.monsanto.com/whoweare/Pages/seed-licensing.aspx> (last visited May 10, 2013) (indicating that Monsanto stands ready to negotiate germplasm licenses with anyone who wants one, though the terms which Monsanto will accept for such licenses remains unknown).

18. *Monsanto Co. v. E.I. Dupont De Nemours & Co.*, No. 4:09CV00686 ERW, 2010 WL 234951, \*\*1–2 (E.D. Mo. Jan. 15, 2010), *vacated in part on reconsideration*, 2010 WL 3039210 (E.D. Mo. July 30, 2010).

19. See *id.* at \*3; *Sorting out the Facts Behind Stacks*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/gene-stacks-facts.aspx> (last visited May 10, 2013).

20. *Monsanto Co.*, 2010 WL 234951, at \*1.

21. *Id.* Monsanto has also publicly stated it has offered Pioneer a license which would provide these rights for an unspecified additional royalty, but that offer apparently has not been accepted. See *id.*

22. *Id.* at \*1, \*4–5.

23. *Id.* at \*1.

24. *Roundup Ready Soybean Patent Expiration*, *supra* note 11; see also Press Release, Monsanto Co., *Monsanto’s Response to the Associated Press Article on Licensing* (Dec. 12, 2009), available at <http://monsanto.mediaroom.com/index.php?s=27632&item=77126> (rebutting various criticisms of its licensing practices).

with others, and growers save a little seed from year to year (with weather causing replanting of crops, some growers use saved seed as a backup in the event they lose part of a crop to flooding).<sup>25</sup> Some commentators have expressed concern over potential trade disruption caused by such voluntary seed-saving in markets like the European Union (EU) that continue to have zero tolerance and testing for unapproved-in-EU varieties and 0.9% for expired-approval varieties, which could, in turn, mean the entire U.S. soybean industry would need to create incentives for soybean seed companies to create RR stacks and file for renewal of approval of the generic biotech crop along with the other traits in the stack.<sup>26</sup> Based on feedback reported from strategy sessions within the seed industry, however, predicted amounts of saved seed could likely be accommodated under an appropriately stated policy allowing “low level presence” (LLP), which takes into account the twenty year history of safe use of crops like the RR soybean.<sup>27</sup>

With antitrust investigations pending, Monsanto engaged in a dialogue with other stakeholders in the soybean industry and issued a press release saying that it had decided to: (1) continue filing for regulatory approval through at least 2021, and (2) refrain from a plan to enforce the seed-retrieval aspects of soybean seed license contracts.<sup>28</sup> This move directly contradicted predictions by some commentators that Monsanto would use the lack of overseas approval—by letting approvals expire—to help promote RR2Y and drive RR soybeans off the market (as if the soybeans could be retrieved from ninety percent of U.S. acres).<sup>29</sup> Monsanto’s leadership on this issue may (or may not) be followed by other members of the Biotechnology Industry Organization, which is engaging relevant stakeholders in a discussion of stewardship for expiring patents and approvals.<sup>30</sup>

### B. Patent Expirations

Patents have a term of twenty years, generally, with staggered expiration in markets around the world, depending upon filing date and enforceability of

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25. See *Roundup Ready Soybean Patent Expiration*, *supra* note 11.

26. Alexander J. Stein & Emilio Rodriguez-Cerezo, *Low-Level Presence of New GM Crops: An Issue on the Rise for Countries Where They Lack Approval*, 13 *AGBIOFORUM* 173, 173–74 (2010).

27. SEED ASS’N OF THE AMERICAS, *SEED MOVEMENT IN THE AMERICAS* 14–16 (2009).

28. Letter from James P. Tobin, Indus. Affairs Lead, Monsanto Co., to Stakeholders (Dec. 15, 2009), available at <http://accordingtomonsanto.files.wordpress.com/2009/12/stakeholder-letter00011.pdf>; Letter from James P. Tobin, Vice President, Indus. Affairs, Monsanto Co., to Steve Censky, CEO, Am. Soybean Ass’n 1 (July 8, 2010) (on file with author).

29. See, e.g., Michael Stumo, *Anticompetitive Tactics in Ag Biotech Could Stifle Entrance of Generic Traits*, 15 *DRAKE J. AGRIC. L.* 137, 140–42 (2010).

30. Letter from James P. Tobin to Steve Censky, *supra* note 28, at 1.

patent rights; similar “plant variety protection” (PVP) rights are layered over the patent rights issue.<sup>31</sup> The other five major biotech seed companies, like Monsanto, will probably have biotech crops that remain competitive and reap PVP license royalties after patent expiration. For example, Bayer Cropsciences’ LibertyLink<sup>®</sup> soybean goes off-patent in 2023, and it will have PVP protection for many of the soybean varieties that incorporate this trait.<sup>32</sup> Similar issues in patent expiration exist for cotton and other crops, including non-hybrid corn.

Most patents associated with biotech crops fall into the twenty year rule. In 1994, Congress amended United States law to conform to the General Agreement on Tariffs and Trade (GATT) after the Uruguay Round.<sup>33</sup> Among other things, Congress extended the term of patents from seventeen years post-grant to twenty years post-filing of the patent application for patents filed after June 8, 1995.<sup>34</sup>

Patent law encourages innovation by insulating inventors from competition for a period of time, after which the invention becomes available to the public for free. Antitrust law encourages competition in the marketplace. Tension between these two important bodies of law is illustrated by Monsanto’s efforts to prepare for the expiration of its RR soybean patents. Diana Moss, vice president of the American Antitrust Institute, suggested Monsanto’s conduct may have stifled competition, especially when viewed in light of new economic learning on competition within and between competing platforms.<sup>35</sup> DuPont echoed Moss in its antitrust litigation filings.<sup>36</sup> Monsanto responded to many of Moss’ concerns, at times making use of proprietary data—seed company contracts and licensing strategies are often considered confidential business information—and Monsanto relied on this data and other arguments to establish the existence of competition.<sup>37</sup>

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31. 35 U.S.C. § 154(a)(2) (2006); Plant Variety Protection Act, 7 U.S.C. § 2483(b)(1) (2006); *see also* U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed., 9th Rev. 2012), *available at* <http://www.uspto.gov/web/offices/pac/mpep/mpep-2700.pdf>.

32. U.S. Patent No. 7,112,665 (filed June 5, 1995) (issued Sept. 26, 2006); *see* 35 U.S.C. § 154(c)(1) (providing for a seventeen year term for patents filed prior to June 8, 1995 when the Uruguay Round Agreements took effect).

33. Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (codified as amended in scattered sections of 19 U.S.C.).

34. 35 U.S.C. § 154(a)(2).

35. DIANA MOSS, AM. ANTITRUST INST., TRANSGENIC SEED PLATFORMS: COMPETITION BETWEEN A ROCK AND A HARD PLACE? 12–13 (2009), *available at* [http://www.antitrustinstitute.org/sites/default/files/AAI\\_Platforms%20and%20Transgenic%20Seed\\_102320091053.pdf](http://www.antitrustinstitute.org/sites/default/files/AAI_Platforms%20and%20Transgenic%20Seed_102320091053.pdf).

36. *See* Answer and Counterclaims at 18–68, Monsanto Co. v. E.I. DuPont De Nemours & Co., No. CIVA 4:09CV00686 ERW (E.D. Mo. June 16, 2010).

37. *See generally* VANDY HOWELL ET AL., MONSANTO CO., COMPETITION AND INNOVATION IN AMERICAN AGRICULTURE: A RESPONSE TO THE AMERICAN ANTITRUST INSTITUTE’S

While Monsanto did not make the data publicly available, the Department of Justice (DOJ) had access to all proprietary data when evaluating DuPont's allegations. At the very least, Moss' analysis and the lack of publicly available information in support of Monsanto's defense leave the question open in academic and public fora.

Patents are not the only relevant intellectual property for biotech crops. Many crops have both patent and (PVP) rights. PVP protection can prevent growers in the United States from saving and replanting or selling seed.<sup>38</sup> Again, it should be noted that Monsanto has also committed to allow growers to save Monsanto-owned RR varieties from the 2015 crop, while other leading soybean companies have not addressed the issue of a generic trait in their protected varieties.<sup>39</sup>

### C. Regulatory Approval Expirations

As noted in the discussion below, the American Soybean Association (ASA) has suggested that some form of data access and compensation mechanism is needed to allow would-be competitors to renew and obtain new regulatory approvals for products incorporating genetic traits in major markets overseas.<sup>40</sup> Approvals in certain overseas markets expire after ten years (EU) and three to five years (China), making the dates for RR soybeans to expire in 2016 and 2011, respectively.<sup>41</sup> Other major soybean exporting nations, such as Argentina, Paraguay, and Brazil are planting the RR soybean and will face similar troubles. Failure to renew regulatory approval in a timely manner could lead to significant global trade disruption.

In some markets, a tolerance is allowed for animal feed only, making it possible to avoid trade disruption if the amount being commingled is low

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"TRANSGENIC SEED PLATFORMS: COMPETITION BETWEEN A ROCK AND A HARD PLACE?" (2009), available at <http://www.corporatecrimereporter.com/documents/monsanto.pdf> (arguing that the AAI paper was misleading and lacked data necessary to form a foundation).

38. INT'L CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS, ACT OF 1991, at art. 14 (1991), available at <http://www.upov.int/export/sites/upov/en/publications/conventions/1991/pdf/act1991.pdf>; see *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 191 (1995) (interpreting the Plant Variety Production Act to mean a farmer could only sell seed that had been retained by the farmer to plant on his own acreage).

39. *Roundup Ready Soybean Patent Expiration*, *supra* note 11.

40. See discussion *infra* Part II.D; see also McEowen, *supra* note 3, at 4 n.15.

41. See *GM Crop Database: MON-89788-1 (MON89788)*, CTR. FOR ENVTL. RISK ASSESSMENT, [http://www.cera-gmc.org/?action=gm\\_crop\\_database&mode=ShowProd&data=MON89788](http://www.cera-gmc.org/?action=gm_crop_database&mode=ShowProd&data=MON89788) (last modified Mar. 1, 2009); Henry I. Miller & Drew L. Kershen, *Innovation Arrested by the Law of Unintended Consequences*, *FORBES*, Mar. 30, 2011, <http://www.forbes.com/sites/henrymiller/2011/03/30/innovation-arrested-by-the-law-of-unintended-consequences/>.

enough.<sup>42</sup> If commingling with expired RR soybeans were to occur at higher levels, then no commodity U.S. soybeans (beyond a trickle of certified non-GMO soybeans) could be exported to any nation that has not renewed approval.<sup>43</sup>

Fortunately, under considerable pressure from a number of industry groups, Monsanto promised in a December 2009 letter that it would maintain RR soybean registrations in overseas markets through at least 2017,<sup>44</sup> and extended their commitment to 2021.<sup>45</sup> The renewed registration of the RR soybean would eliminate the risk of loss of exports of soybeans to the EU and China. Monsanto expects, however, an industry-wide solution to emerge to enable a generic seed company or industry consortium to take responsibility for product stewardship and conditions of registration, and to obtain key major market approval renewals for the RR soybean.<sup>46</sup>

The United States exports over \$10 billion per year in soybeans to the EU and China alone.<sup>47</sup> China is the largest U.S. soybean customer, importing nearly 50% of the dollar value of U.S. soybean and soy product exports.<sup>48</sup> China's soybean imports for the 2011 were 59.2 million tons, rising to 63 million tons in 2012, with expected imports of approximately 65.5 million tons in 2013.<sup>49</sup>

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42. CHRISTINE STROSSMAN, FOREIGN AGRIC. SERV., USDA, GAIN REPORT NO. SZ9002, AGRICULTURAL BIOTECHNOLOGY ANNUAL: SWISS BIOTECHNOLOGY UPDATE 4 (2009), available at [http://gain.fas.usda.gov/Recent%20GAIN%20Publications/AGRICULTURAL%20BIOTECHNOLOGY%20ANNUAL\\_Geneva\\_Switzerland\\_7-23-2009.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/AGRICULTURAL%20BIOTECHNOLOGY%20ANNUAL_Geneva_Switzerland_7-23-2009.pdf). The EU has a 0.9% tolerance for Bt 176 Corn (Syngenta) in feed products for a five-year period after expiration of authorization. *Id.*; *EU Register of Authorised GMOs*, EUR. COMM'N, [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm) (search "Bt 176") (last visited May 10, 2013).

43. Marie Powell, *Monsanto Seed Questions Persist*, CTR. FOR RURAL AFFAIRS (Apr. 6, 2010), <http://www.cfra.org/node/2628>.

44. Letter from James P. Tobin to Stakeholders, *supra* note 28, at 1.

45. K. Sauer, *Roundup Ready<sup>®</sup> Soybean Post-Patent Regulatory Commitment Extended Through 2021*, MONSANTO (July 8, 2010), <http://www.monsanto.com/newsviews/Pages/Roundup-Ready-Soybean-Post-Patent-Commitment-Extended-through-2021.aspx>.

46. *Id.*

47. *Soy Stats 2012: Introduction*, AM. SOYBEAN ASS'N, [http://www.soystats.com/2012/page\\_02.htm](http://www.soystats.com/2012/page_02.htm) (last visited May 10, 2013).

48. *Id.*; see also FOREIGN AGRIC. SERV., USDA, CIRCULAR SERIES FOP 04-13, THE UNITED STATES SEIZES OPPORTUNITY TO EXPAND FOREIGN SOYBEAN MEAL SALES 2 (2013), available at <http://www.fas.usda.gov/psdonline/circulars/oilseeds.pdf> (U.S. export commitments for soy totaled 36.1 million tons globally; exports to China alone accounted for 21.8 million tons).

49. FOREIGN AGRIC. SERV., USDA, CH13005, PEOPLES REPUBLIC OF CHINA OILSEED AND PRODUCTS ANNUAL tbl.4 (2013), available at [http://gain.fas.usda.gov/Recent%20GAIN%20Publications/OILSEEDS%20AND%20PRODUCTS%20ANNUAL\\_Beijing\\_China%20-%20Peoples%20Republic%20of\\_3-6-2013.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/OILSEEDS%20AND%20PRODUCTS%20ANNUAL_Beijing_China%20-%20Peoples%20Republic%20of_3-6-2013.pdf). But see *China Soybean Imports Are Slower in 2012/13 with a Shortfall in South American Trade*, ECON. RESEARCH SERV., USDA (Apr. 12, 2013), <http://www.ers.usda.gov/data-products/chart-gallery/detail.aspx?chartId=34808&ref=collection#UYhyt7WTgeM> (showing fewer imports than projected).

“China’s soybean imports are projected to rise 52 percent to 103 million tons” in 2022–2023 which will account for “more than 90 percent of the projected growth in global soybean imports.”<sup>50</sup> While China needs U.S. soybeans, it also has domestic soybean industry interests that are troubled by cheap U.S. soy imports and a history of selective trade disruption based on various alleged health and safety concerns.<sup>51</sup>

The failure to get approval overseas for such crops can lead to significant trade disruption and resulting liability risks. Several “inadvertent releases” have caused problems in the past<sup>52</sup> and led to the “retiring” of StarLink corn (CBH351) and Bt176 corn (off-patent, off-EU approval).<sup>53</sup> If the industry response to the challenges presented by the generic generation of biotech crops is not adequate, and the LLP proposals noted above do not become the global standard, then trade disruption comparable to past episodes may recur.<sup>54</sup>

Regulatory approval expiration is a proliferating concept as more nations adopt biosafety laws requiring regulatory approval. The Biosafety Protocol’s controversial “precautionary approach” to approval of biotech crops has largely

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50. INTERAGENCY AGRIC. PROJECTIONS COMM., USDA, OCE-2013-1, USDA AGRICULTURAL PROJECTIONS TO 2022, at 31 (2013), available at <http://www.ers.usda.gov/media/1013562/oce131.pdf>.

51. For example, in 2006, Chinese authorities claimed a soybean shipment contained alleged pesticide residue (the red coloring was from pokeberry juice, not a pesticide) and through February 2007, AQSIQ found these alleged treated soybeans in two U.S. shipments. GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMIN., USDA, MEETING SUMMARY: GRAIN INSPECTION ADVISORY COMM. 7 (Dec. 16–17, 2008) [hereinafter MEETING SUMMARY], available at <http://www.gipsa.usda.gov/fgis/advcommittee/ac1208.pdf>.

52. See FED. GRAIN INSPECTION SERV., USDA, 2009 ANNUAL REPORT, at 15 (2009), available at [http://www.gipsa.usda.gov/Publications/fgis/ar/2009\\_fgis\\_AR.pdf](http://www.gipsa.usda.gov/Publications/fgis/ar/2009_fgis_AR.pdf); U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-08-751, GENETICALLY ENGINEERED CROPS: AGENCIES ARE PROPOSING CHANGES TO IMPROVE OVERSIGHT, BUT COULD TAKE ADDITIONAL STEPS TO ENHANCE COORDINATION AND MONITORING 14–24 (2008); MEETING SUMMARY, *supra* note 51, at 7.

53. MEETING SUMMARY, *supra* note 51, at 6; STROSSMAN, *supra* note 42, at 4; *Starlink™ Corn Regulatory Information*, ENVTL. PROT. AGENCY (Apr. 2008), [http://www.epa.gov/opp00001/biopesticides/pips/starlink\\_corn.htm](http://www.epa.gov/opp00001/biopesticides/pips/starlink_corn.htm).

54. One of the most precautionary markets for biotech crops, the EU, has set a tolerance of 0.9% for traces of biotech crops that have yet to renew approval. Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC, 2003 O.J. (L 268) 24; see also Thomas P. Redick & Micheal J. Adrian, *Do European Union Non-Tariff Barriers Create Economic Nuisances in the United States?*, 1 J. FOOD L. & POL’Y 87, 93–94 (2005). This should help to reduce the risk of trade disruption from crops like Bt176 corn, which has not been sold commercially for nearly ten years and presumably would be found at low levels, if at all, in the grain export supplies of major exporters like the United States, Brazil, and Argentina.

driven this trend, which considers long-term health risks to be under review for a very long time period.<sup>55</sup>

One of the key issues with respect to regulatory approval laws for existing biotech crops is the concept of “familiarity” for certain genetic events that have been in widespread use for many years without causing known, or even reasonably, suspected health effects. To some extent, familiarity is recognized in the form of a tolerance for commingling approved and unapproved crops at low levels. Both the EU and Switzerland, for example, allow a 0.9% tolerance for adventitious presence of this event in animal feed products for five years after expiration of regulatory approval.<sup>56</sup> Where a generic biotech crop has brought health or environmental benefits with a decade or more of safe use, a more rapid acceptance based on familiarity should apply. Users of the RR soybean, for example, have reported no ill effects to humans or animals, and major environmental groups and consumer organizations have recognized some of the environmental and social benefits.<sup>57</sup> The compilation of safety data and broader release of this data to the scientific community around the world through mechanisms like the Biosafety Clearing House established under the Cartagena Protocol on Biosafety can enable government regulators to consider eliminating, over time, the requirement of renewed approval for events that have a sufficiently long history of safe use.

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55. See COMM’N OF THE EUR. CMTYS., COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE (2000), available at [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf) (describing use of Precautionary Principle when effects of actions are shrouded in scientific uncertainty).

56. STROSSMAN, *supra* note 42, at 4.

Bt 176 corn (Syngenta) was approved in 1998 and therefore the 10-year authorization expired in 2008. As the company has not requested renewal, the event is no longer authorized. However, in line with EU provisions, there is a 0.9% tolerance for adventitious presence of this event in feed products for a five-year period. Imports of feed products made from corn or soy events approved in the EU . . . will continue to be allowed.

*Id.*

57. See, e.g., GREGORY JAFFE, CENTER FOR SCI. IN THE PUB. INTEREST, STRAIGHT TALK ON GENETICALLY ENGINEERED FOODS: ANSWERS TO FREQUENTLY ASKED QUESTIONS 8 (2012), available at <http://cspinet.org/new/pdf/biotech-faq.pdf> (discussing a range of benefits provided by GE crops); *Soil Erosion & Soy*, WORLD WILDLIFE FUND, [http://wwf.panda.org/what\\_we\\_do/footprint/agriculture/soy/impacts/soil\\_erosion](http://wwf.panda.org/what_we_do/footprint/agriculture/soy/impacts/soil_erosion) (last visited May 10, 2013) (discussing the advantages of modern genetic technology in curbing soil erosion).

D. *Facilitating Global Approvals of Genetic Biotech “Generic Events”*

The solution to sustaining regulatory approval is simple in concept but perhaps complex in implementation. The longstanding pesticide industry practice of shared “data access and compensation” provides one possible solution to avoiding potential trade disruption. U.S. law gives biocide innovators certain rights to “data compensation” and provides a legal remedy and procedure for obtaining compensation.<sup>58</sup> If a few companies interested in marketing generic versions of the genetic event emerge, then these companies can ask the patent owner—Monsanto, in the case of the RR soybean—to sell them rights to proprietary health and safety information held by the patent owner, which is likely the shortest route to ensuring rapid renewal of regulatory approval in major overseas markets for products which include that previously patented technology. Such domestic data compensation currently exists for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), but this pesticide law would need to be expanded via contract or legislative changes to make similar data compensation mandatory for all biotech crops.<sup>59</sup>

The biotech seed industry has shown a remarkable ability to manage its own issues, from Insect Resistance Management using FIFRA permitting<sup>60</sup> to voluntary arbitration of potential harm to biodiversity, which led to the innovative Liability Compact (Compact) under the Biosafety Protocol whereby major biotech seed companies agreed to reimburse nations that prove, in international arbitration proceedings, that biotech crops caused harm to biodiversity.<sup>61</sup> A contractual understanding, similar to the Compact, would allow all contracting members of the voluntary data compensation system to agree to share data and arbitrate disputes in a manner similar to FIFRA arbitration. Such contractual arrangements do not require legislative changes.

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58. Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136a(c)(1)(F) (2006); *see also* Arbitration of Pesticide Data Disputes, 29 C.F.R. § 1440.1 (2012) (providing for arbitration if the parties are unable to come to mutual agreement on appropriate compensation for data sharing).

59. *See* 7 U.S.C. § 136a(c)(1)(F)(iii) (terms of compensation for domestic data).

60. *See EPA’s Regulation of Biotechnology for Use in Pest Management*, ENVTL. PROT. AGENCY (Jan. 2012), [http://www.epa.gov/opp00001/biopesticides/reg\\_of\\_biotech/eparegofbio tech.htm](http://www.epa.gov/opp00001/biopesticides/reg_of_biotech/eparegofbio tech.htm).

61. THE COMPACT: A CONTRACTUAL MECHANISM FOR RESPONSE IN THE EVENT OF DAMAGE TO BIOLOGICAL DIVERSITY CAUSED BY THE RELEASE OF A LIVING MODIFIED ORGANISM (2012), *available at* <http://www.biodiversitycompact.org/wp-content/uploads/Compact-Second-Amended-Text.pdf>. The biotechnology industry is creating a voluntary compensation and arbitration scheme to address harm to biodiversity caused through the fault of a biotech seed company, subject to the customary defenses in negligence law. *The Compact*, CROPLIFE INT’L, [http://www.croplife.org/the\\_compact](http://www.croplife.org/the_compact) (last visited May 10, 2013).

Responding to the potential threat of trade disruption posed by patents that expire and similarly expiring overseas approval, the American Soybean Association's (ASA) 2008 policy resolutions included the following:

ASA supports enabling trait providers and seed companies to access and use the data package of a patented biotech trait through agreements and established procedures for the purpose of preparing to register and commercialize generic versions of the trait after patent expiration. ASA supports efforts by the private sector or, if necessary, the federal government [to] facilitate[] this process.<sup>62</sup>

#### E. Antitrust and Competition Policy Concerns

The impending expiration of Monsanto's RR patent provides an opportunity for a fresh look at the antitrust issues in genetically modified (GM) seed. DOJ launched an investigation of the seed industry in 2010, and concerns about possible anticompetitive practices were expressed at public workshops held by DOJ and USDA.<sup>63</sup> Similarly, DuPont asserted antitrust counterclaims in patent litigation against Monsanto.<sup>64</sup> DOJ concluded its probe of Monsanto without taking any action,<sup>65</sup> and a jury awarded Monsanto \$1 billion on the patent claims against DuPont.<sup>66</sup> DuPont's antitrust claims against Monsanto were expected to

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62. 2013 Resolutions, AM. SOYBEAN ASS'N (Mar. 2, 2013), <http://www.soygrowers.com/resolutions/default.htm>. ASA represents U.S. soybean farmers on domestic and international issues of importance to the soybean industry. See *Vision, Mission, Purpose & Strategic Objectives*, AM. SOYBEAN ASS'N (Mar 5, 2011), <http://www.soygrowers.com/resolutions/vmp.htm>. ASA affirmed this position in its 2013 policy resolutions as well. See 2013 Resolutions, *supra*.

63. U.S. DEP'T OF JUSTICE, COMPETITION AND AGRICULTURE: VOICES FROM THE WORKSHOPS ON AGRICULTURE AND ANTITRUST ENFORCEMENT IN OUR 21ST CENTURY ECONOMY AND THOUGHTS ON THE WAY FORWARD 5-15 (2012) [hereinafter VOICES FROM THE WORKSHOPS], available at <http://www.justice.gov/atr/public/reports/283291.pdf>; see also Press Release, U.S. Dep't of Justice, DOJ and USDA Hold First-Ever Workshop on Competition Issues in Agriculture (Mar. 12, 2010), available at <http://www.justice.gov/opa/pr/2010/March/10-ag-258.html>; Aruna Viswanatha, *DOJ Confirms Seed Industry Probe*, MAIN JUST. (Jan. 14, 2010, 1:23 PM), <http://www.mainjustice.com/2010/01/14/doj-confirms-seed-industry-probe/>.

64. *Monsanto Co. v. E.I. Dupont De Nemours & Co.*, No. 4:09CV00686 ERW, 2010 WL 234951 (E.D. Mo. Jan. 15, 2010), *vacated in part on reconsideration*, 2010 WL 3039210 (E.D. Mo. July 30, 2010).

65. See Tom Philpott, *DOJ Mysteriously Quits Monsanto Antitrust Investigation*, MOTHER JONES, Dec. 1, 2012, <http://www.motherjones.com/tom-philpott/2012/11/dojs-monsantoseed-industry-investigation-ends-thud>.

66. Carey Gillam, *Monsanto Shares Rise After \$1 Billion Award Against DuPont*, REUTERS (Aug. 2, 2012), <http://in.reuters.com/article/2012/08/02/us-monsanto-dupont-lawsuit-idINBRE87101R20120802>.

go to trial in October 2013,<sup>67</sup> but DuPont agreed to drop the claim in exchange for the dismissal of the \$1 billion patent infringement award.<sup>68</sup> These issues, as others have noted, go “beyond the immediate interests of Monsanto and its adversaries” and have important implications to many in the industry.<sup>69</sup>

### 1. *Monsanto’s Antitrust Challenge Under Monopolization Law*

Patent law encourages innovation by insulating inventors from competition for a period of time, and antitrust law encourages competition in the marketplace. Naturally, therefore, a certain amount of tension exists between these two important bodies of law, and this tension appears in the ongoing discussion of Monsanto’s efforts to prepare for the expiration of its RR 1 patent. In October 2009, the American Antitrust Institute released a white paper written by Diana Moss, its vice president and one of its senior fellows, examining the issue.<sup>70</sup>

Moss argued that antitrust analysis should focus on rivalry within seed platforms, intra-platform competition, rather than rivalry between seed platforms, inter-platform competition, because only one firm in the transgenic seed industry has “a full suite of . . . traits suitable for stacking.”<sup>71</sup> To bring new transgenic seed products to market, trait developers need access to traits developed by rivals to stack with their own traits, and they need access to seed germplasm into which they insert their stacked traits.<sup>72</sup> Mergers over the past decade, however, have inhibited intra-platform competition by reducing the number of trait developers, concentrating patent holdings in the hands of a few large firms, and eliminating many of the independent seed companies.<sup>73</sup> Indeed, Monsanto appears to control between seventy-five and ninety-five percent of the market for insect resistance (Bt) and herbicide tolerance (Ht) traits depending on the crop being considered.<sup>74</sup> Monsanto’s acquisition of independent seed companies has enabled it to vertical-

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67. Georgina Gustin, *Justice Department Ends Monsanto Antitrust Probe*, ST. LOUIS POST-DISPATCH, Nov. 19, 2012, [http://www.stltoday.com/business/local/justice-department-ends-monsanto-antitrust-probe/article\\_667ceab6-e568-57c8-a110-3d99efc31c4c.html](http://www.stltoday.com/business/local/justice-department-ends-monsanto-antitrust-probe/article_667ceab6-e568-57c8-a110-3d99efc31c4c.html).

68. Andrew Pollack, *Monsanto and DuPont Settle Fight over Patent Licensing*, N.Y. TIMES, Mar. 26, 2013, [http://www.nytimes.com/2013/03/27/business/monsanto-and-dupont-settle-fight-over-roundup-ready-technology.html?\\_r=0](http://www.nytimes.com/2013/03/27/business/monsanto-and-dupont-settle-fight-over-roundup-ready-technology.html?_r=0).

69. Daryl L. Lim, *Rebooting the Bean*, AGRIC. & FOOD COMM. (Am. Bar Ass’n, Section of Antitrust Law, Chi., Ill.), Fall 2012, at 2, 4.

70. MOSS, *supra* note 35.

71. *Id.* at 12.

72. *Id.*

73. *Id.* at 13.

74. *Id.* (citations omitted).

ly integrate into the downstream markets, and it now has market shares of about sixty-five percent for traited soybeans and forty-five percent for traited cotton.<sup>75</sup>

With consolidation, Moss found evidence of a surge in the quantity and a decline in the quality of innovation that may have resulted from Monsanto's ability to serve "as a gatekeeper for rivals seeking the access [to patented technologies and information] necessary for intra-platform competition."<sup>76</sup> There are a number of ways in which a dominant firm such as Monsanto may use otherwise legitimate patented technology to stifle competition. The use of patents to deny rivals access to research tools and fundamental technologies is one example of anticompetitive licensing restrictions.<sup>77</sup> Ownership of a large suite of patented technologies can also result in a patent "thicket" enabling the patent holder to "hold up" entry by rival innovators who must delay entry into the market while they resolve patent conflicts.<sup>78</sup> Inconsequential changes to existing patented technology can also enable a firm to effectively extend the life of its original patent.<sup>79</sup> While its unusually vigorous use of patent infringement litigation may mean that Monsanto's patents are more valuable to it than its rivals' patents are to their owners, Monsanto could also be seeking to protect or extend its dominance through litigation.

It would appear there is cause for serious concern about the possible anticompetitive effects of Monsanto's conduct. Additional information, especially proprietary data to which Moss did not have access, might alter the picture of the competitive landscape.<sup>80</sup> The lack of public data, however, is an argument for enforcement agencies to use their tools of investigation, not a justification for ignoring an apparent problem. Furthermore, as Moss points out, Monsanto's overall argument rests on outmoded and simplistic notions of the single monopoly profit theory, for example, that a firm cannot gain additional supra-competitive profits by holding a monopoly position in two related markets.<sup>81</sup>

DOJ began an investigation into these concerns in early 2010.<sup>82</sup> After conducting extensive public workshops in conjunction with the USDA on com-

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75. Moss, *supra* note 35, at 13–14 (citations omitted).

76. *Id.* at 19–20.

77. *See id.* at 20–22.

78. *Id.* at 22.

79. *Id.* at 22–23.

80. *See* HOWELL ET AL., *supra* note 37, at 2; DIANA L. MOSS, AM. ANTITRUST INST., TRANSGENIC SEED PLATFORMS: COMPETITION BETWEEN A ROCK AND A HARD PLACE?, ADDENDUM 6 (2010), available at [http://www.antitrustinstitute.org/~antitrust/sites/default/files/Addendum%20to%20AAI%20White%20Paper\\_Transgenic%20Seed.4.5\\_040520101107.pdf](http://www.antitrustinstitute.org/~antitrust/sites/default/files/Addendum%20to%20AAI%20White%20Paper_Transgenic%20Seed.4.5_040520101107.pdf).

81. *See* MOSS ADDENDUM, *supra* note 80, at 4.

82. Bloomberg News, *Antitrust Questions for Monsanto*, N.Y. TIMES, Jan. 14, 2010, <http://www.nytimes.com/2010/01/15/business/15seed.html>.

petition issues in agriculture,<sup>83</sup> DOJ issued a report on these issues in May 2012.<sup>84</sup> DOJ noted that the workshops demonstrated that “antitrust enforcement has a crucial role to play in fostering a healthy and competitive agriculture sector.”<sup>85</sup>

High market concentration, including in the seed industry, provided one of the recurrent themes in the workshops. DOJ specifically found that “many producers lamented a lack of options in buying seeds.”<sup>86</sup> In fact, “[t]he rise of genetically modified seeds generated intense and extensive discussion,” especially with regard to restrictions on their use and the “dearth of choices.”<sup>87</sup> The workshops also included supporters of current industry practices.<sup>88</sup> Consequently, DOJ concluded little other than that the issue “implicates the careful balance of the antitrust laws and the intellectual property laws” and, more generally, that “the increased importance of intellectual property in the agricultural space raises the possibility of anticompetitive licensing practices.”<sup>89</sup>

Monsanto also faced private antitrust litigation, including DuPont’s counterclaims in a lawsuit brought by Monsanto to enforce its patent. DuPont’s counterclaims offered two specific theories of potential liability. First, they argued that Monsanto, perhaps taking a leaf from the pharmaceutical industry, attempted to prevent generic entry into the market by steering independent seed companies away from RR to its more recently patented RR2Y.<sup>90</sup> This “product hopping” may violate antitrust law if the new product consists of trivial changes to the existing product without any real benefits to the consumer, a contention which, not surprisingly, Monsanto disputes.<sup>91</sup>

The DuPont counterclaims also raised the issue of whether RR constitutes an essential facility. The United States Supreme Court has expressed some skepticism about the validity of the doctrine.<sup>92</sup> Furthermore, denial of access is at the heart of an essential facilities claim, and Monsanto licenses RR to competi-

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83. *Agriculture and Antitrust Enforcement Issues in Our 21st Century Economy*, U.S. DEP’T OF JUSTICE, <http://www.justice.gov/atr/public/workshops/ag2010/> (last updated May 16, 2013).

84. See VOICES FROM THE WORKSHOPS, *supra* note 63.

85. *Id.* at 2.

86. *Id.* at 6.

87. *Id.* at 13.

88. See *id.* at 14.

89. *Id.* at 23–24.

90. Answer and Counterclaims, *supra* note 36, at 20; Lim, *supra* note 69, at 9.

91. See Lim, *supra* note 69, at 9; see also Stumo, *supra* note 29, at 140–43, 148–49.

92. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 410–11 (2004). See generally Norman W. Hawker, *Open Windows: The Essential Facilities Doctrine and Microsoft*, 25 OHIO N.U. L. REV. 115, 117–22 (1999) (discussing pre-*Trinko* development of the essential facilities doctrine).

tors, albeit on a restricted basis.<sup>93</sup> Nonetheless, commentators have shown that a potential basis for application of the doctrine may exist in DuPont's case against Monsanto.<sup>94</sup>

Perhaps because of concern about these antitrust issues, in 2010 the Biotechnology Industry Organization (BIO) and the American Seed Trade Association (ASTA) began facilitating discussions aimed at developing a private agreement dealing with the maintenance of post-patent regulatory approval for GM crops.<sup>95</sup> While not directly aimed at the antitrust issues, the result has been two tentative agreements, the Generic Event Marketability and Access Agreement (GEMAA) and the Data Use and Compensation Agreement (DUCA), which could lower the barrier to entry for generic GE crops, including generic equivalents for RR.<sup>96</sup> GEMAA has gone into effect, and its signatories include Monsanto.<sup>97</sup> While the details of these agreements go beyond the scope of this Article, GEMAA is designed to provide a mechanism for the maintenance of regulatory approvals, including transitioning of responsibility for maintenance to new parties, such as generic developers.<sup>98</sup> DUCA seeks to provide access to needed data through a data compensation mechanism, as opposed to maintenance of regulatory approval, and remains under negotiation.<sup>99</sup> Whether these agreements can alleviate the antitrust concerns that have been raised remains to be seen, but GEMAA and DUCA appear to be positive steps. Also encouraging is Monsan-

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93. See *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1132 (7th Cir. 1983) (citations omitted); William Neuman, *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, N.Y. TIMES, Mar. 11, 2010, <http://www.nytimes.com/2010/03/12/business/12seed.html?pagewanted=all&r=0> ("Monsanto says that its licensing shows it is the opposite of a monopolist, encouraging rather than hampering competition.").

94. See Lim, *supra* note 69, at 10–11. See generally Joseph M. Purcell, Jr., Note, *The "Essential Facilities" Doctrine in the Sunlight: Stacking Patented Genetic Traits in Agriculture*, 85 ST. JOHN'S L. REV. 1251 (2011) (arguing that the essential facilities doctrine should be available to courts).

95. J. Thomas Carrato & Brandon W. Neuschafer, *The Accord: A Private Contractual Mechanism for the Transition of Proprietary Biotechnology Events to a Generic Marketplace 1* (Oct. 20, 2012) (unpublished manuscript).

96. *Id.* at 3; see THE ACCORD: GENERIC EVENT MARKETABILITY & ACCESS AGREEMENT (GEMAA), available at <http://www.agaccord.org/include/agreement.pdf>; *About the Accord, ACCORD*, <http://www.agaccord.org/?p=about> (last visited May 10, 2013) ("The DUCA is targeted to be open for signatures the first quarter of 2013.").

97. Press Release, Am. Seed Trade Ass'n & Biotech. Indus. Org., *The Accord: Generic Event Marketability and Access Agreement Is Now Effective* (Nov. 15, 2012), available at <http://www.agaccord.org/include/press11152012.pdf>.

98. Factsheet, Am. Seed Trade Ass'n & Biotech. Indus. Org., *The Accord: Generic Event Marketability and Access Agreement Is Open for Signature* (Oct. 31, 2012), available at <http://www.agaccord.org/include/facts.pdf>.

99. Carrato & Neuschafer, *supra* note 95, at 3.

to's decision in December 2009 to offer to keep filing for regulatory approval through 2021.<sup>100</sup>

Given DOJ's recent acknowledgment of the overall importance of a competitive market place for transgenic seed platforms and the case for the existence of problems, its recent decision to drop its investigation is especially troubling in the absence of any announced findings.<sup>101</sup> Even with the positive steps being made to reduce barrier entries for generic GM seed developers, antitrust enforcement authorities and Congress should pursue the policy implications offered by Moss. Specifically, Congress should consider legislative solutions similar to the Hatch-Waxman Act for agricultural biotechnology industry rather than rely solely on private agreements in the industry.<sup>102</sup> In addition, investigations by antitrust agencies into mergers and other conduct in the industry "should focus on the three tiers that comprise seed platforms—innovation, genetic traits, and trait-ed seed—and the interfaces that link them."<sup>103</sup> Careful consideration must be given to "whether restrictions on the use of technology (e.g., anti-stacking provisions) exceed the scope of the patent[s]."<sup>104</sup>

Special attention must be given to remedies. Divestiture of experimental lines of germplasm, for example, may not ensure competition given the long lead times for development of transgenic seed products. Care must be taken to ensure that purchases of divested assets do not encounter hold-up problems later in the process. Consideration of compulsory licensing may be required. Remedies should not be limited to the creation of effective competing platforms, but should also include the elimination of incentives for seed companies not to distribute rival products that lock farmers into Monsanto's products. After all, as DOJ stated, "antitrust laws stand as 'a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade,' establishing 'a regime of competition as the fundamental principle governing commerce.'"<sup>105</sup>

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100. Sauer, *supra* note 45.

101. See *Department of Justice Drops Monsanto Antitrust Investigation Without Explanation*, NAT'L SUSTAINABLE AGRIC. COAL. (Dec. 5, 2012), <http://sustainableagriculture.net/blog/doj-drops-investigation/>; Philpott, *supra* note 65.

102. See generally *Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act*, Pub. L. No. 98-412, 98 Stat. 1585 (1984) (codified in scattered sections of 21 U.S.C. and 35 U.S.C.).

103. MOSS, *supra* note 35, at 27.

104. *Id.* at 28.

105. VOICES FROM THE WORKSHOPS, *supra* note 63, at 17 (quoting *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958); *City of Lafayette v. La. Power & Light Co.*, 435 U.S. 389, 398 (1978)).

### III. CONCLUSION

A web of potential legal issues has arisen as a result of the upcoming expiration of patents on Monsanto's highly successful RR soybean. If a generic biotech genetic event, like the RR soybean, goes off patent in an exporting nation (like the United States in 2015) and fails to get renewal of approval in an export market (such as China after 2021), then trade disruption could ensue, unless some generic seed provider takes steps to gain regulatory approval. Consideration of a complex set of industry interests—seed companies, grower associations, grain traders, and others—will be required to resolve all the complex issues raised by the coming “generic generation” of biotech crops.