ANTICOMPETITIVE TACTICS IN AG BIOTECH COULD STIFLE ENTRANCE OF GENERIC TRAITS

Michael Stumo[*]

I. INTRODUCTION

The development of agricultural biotechnology ("ag biotech") has caused major changes, substantial controversy, and many legal issues to be resolved. Most ag biotech traits used by producers enable crops to tolerate certain herbicides and resist harmful insects. Genetically modified crop seeds have deeply penetrated the American and world markets. Since their introduction in 1996, the total worldwide acreage of crops produced from genetically modified seeds has grown from 4.2 million in 1996 to over 300 million in 2008, an almost 100-fold increase.[1] The present size of the global genetically modified seed market is in excess of seven billion dollars, a level that is likely to continue increasing.[2]

Traits are patented, commercially valuable seed characteristics engineered by ag biotech companies. The current generation of commercial traits

---

* Michael Stumo is currently in private practice and CEO of the Coalition for a Prosperous America, Sheffield, Massachusetts.

1. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, THE PEW CHARITABLE TRUSTS, FACTSHEET: GENETICALLY MODIFIED CROPS IN THE UNITED STATES 2 (2004), http://www.pewtrusts.org/uploadedfiles/wwwpewtrustsorg/Fact_Sheets/Food_and_Biotechnology/PIFB_Genetically_Modified_Crops_Factsheet0804.pdf; Press Release, Int'l Serv. for the Acquisition of Agri-Biotech Applications, Biotech Crops Poised for Second Wave of Growth (Feb. 11, 2009), *available at* http://www.isaaa.org/resources/publications/briefs/39/pressrelease/default.html.

2. Press Release, SeedQuest, GM Crops: Thirteen Successful Years of Commercialisation (Feb. 12, 2009), *available at* http://www.seedquest.com/News/releases/2009/february/25131.htm.

consists of Input Traits, those that affect the agronomic performance of the plant.[3] Input Traits are what make genetically modified crops resistant to insects and allow farmers to spray fields with particular herbicides without damaging crops.[4] Approximately 91% of all soybeans and 85% of all corn—the two largest cash crops in the United States—are grown from seed containing biotech traits.[5] The next generation of traits consists of Output Traits, those affecting certain plant characteristics that are targeted to the end-use consumer. For example, soybeans have been engineered to produce a higher amount of oleic oils, promoted as being nutritionally beneficial.[6]

The players within the ag biotech markets are limited to a few relatively large companies because barriers to new entrants are high. Small companies can develop new, conventional hybrids through standard plant breeding. However, successful entry into the market for the discovery, development, production and distribution of these traits is difficult, time-consuming, research-intensive, and costly. New trait development and commercialization costs may be $100-150 million, taking up to ten years from discovery to launch.[7] A major controversy in plant biotechnology has been whether plant traits are patentable. However, that question was resolved in the affirmative by the U.S. Supreme Court.[8]

The next issue has become the interplay of patent rights and antitrust law. Patent protection is designed to reward innovation by granting the patent holder exclusive rights to—or a government enabled monopoly on—the technology contained in the patent. Patents allow patent holders to capitalize on their "nonobvious" inventions and provide incentives to develop new products.[9] Patents are, however, limited to a fixed duration of twenty years.[10] The expiration of a patent enables new companies to enter the market, often with generic prod-

---

3. Linda A. Castle, Gusui Wu & David McElroy, *Agricultural Input Traits: Past, Present and Future*, 17 CURRENT OPINION IN BIOTECHNOLOGY 105, 105 (2006), *available at* http://www.plantsci.cam.ac.uk/Haseloff/teaching/PlantBiotech2006/page4/assets/Castle2006.pdf.

4. *Id.*

5. AGRIC. STATISTICS BD., USDA, ACREAGE 24—25 (2009), *available at* http://jan.mannlib.cornell.edu/usda/Acre/Acre-06-30-2009.pdf.

6. *See, e.g.*, Press Release, Pioneer Hi-Bred Int'l, Inc., Research Confirms Better Oil from New DuPont High Oleic Soybean Trait (Mar. 18, 2008), *available at* http://www.pioneer.com/web/site/portal/menuitem.050fd1b82f72972cbc77e964d10093a0/.

7. Doug Cameron, *U.S. Regulators Speed Seed Oversight After Delays – DuPont Executive*, DOW JONES NEWSWIRES, Sept. 2, 2009, *available at* http://english.capital.gr/news.asp?ID=805738.

8. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001).

9. *See* 35 U.S.C. § 101 (2006).

10. 35 U.S.C. § 154(a)(2) (2006).

ucts, which results in greater choices and lower prices.[11] Patent expiration also typically results in significantly lower revenues and margins for the prior patent holder.[12] By limiting the amount of time a product is patent protected, the intellectual property ("IP") regime thus endeavors to strike a balance between granting exclusivity and encouraging competition and choice.

As the ag biotech industry has matured, a number of important traits are coming off-patent.[13] The loss of revenue resulting from patent expiration tempts trait developers to thwart new generic entry in imaginative ways. To the detriment of patients, the pharmaceutical industry, for example, has tried to develop mechanisms to maintain monopolies after patents expire.[14] There are signs that the ag biotech industry may similarly try to restrain generic competition to maintain higher prices and revenues.

II. A LEADING AG BIOTECH TRAIT IS ABOUT TO LOSE PATENT PROTECTION

The Monsanto Company ("Monsanto") is a major ag biotech trait developer. The company's Roundup Ready ("RR") trait is the leading herbicide tolerant soybean trait used by farmers worldwide.[15] RR was the first trait that enabled crops to tolerate the herbicide glyphosate which kills virtually all vegetation on which it is applied.[16] Farmers planting RR corn and soybean seed can spray glyphosate over the top of the resulting plants to kill a broad spectrum of weeds without damaging the crop. Glyphosate is the herbicide most widely used by farmers, covering approximately 95% of soybean acres and 70% of corn acres.[17] Monsanto's RR glyphosate-tolerant trait is used on 95% of soybean

---

11. *See, e.g.*, DAVID BALTO, CTR. FOR AM. PROGRESS, REMOVING OBSTACLES TO GENERIC DRUG COMPETITION: A CRITICAL PRIORITY FOR HEALTH CARE REFORM 6, 14 (2009), http://www.americanprogress.org/issues/2009/06/pdf/generic_drug.pdf.

12. *Id.*

13. *See, e.g.*, Monsanto Co., Annual Report (Form 10-K), at 5 (Oct. 23, 2008), *available at* http://www.monsanto.com/pdf/pubs/2008/annual_report.pdf [hereinafter Annual Report].

14. *E.g.*, BALTO, *supra* note 11, at 14.

15. JUAN LOPEZ VILLAR ET AL., FRIENDS OF THE EARTH INT'L, WHO BENEFITS FROM GM CROPS?: FEEDING THE BIOTECH GIANTS, NOT THE WORLD'S POOR 6 (2009), http://www.foei.org/en/resources/publications/food-sovereignty/2009/gmcrops2009full.pdf/view (follow "10 foei gmo full vlr.pdf" hyperlink).

16. *See* Monsanto Co., Who We Are—Company History, http://www.monsanto.com/who_we_are/history.asp (last visited Apr. 9, 2010).

17. Gil Gullickson, *The Best Way to No Weeds is to Know Weeds*, AGRICULTURE ONLINE, Jan. 26, 2010, http://www.agriculture.com/ag/story.jhtml?storyid=/templatedata/ag/story/data/1264524811431.xml.

acres and over 80% of the corn acres planted with glyphosate-tolerant seeds.[18] Because of its widespread adoption and the exclusivity afforded by the patent laws, Monsanto has enjoyed substantial profits from its RR franchise.

The RR patents in soybeans are set to expire in 2014,[19] marking the first time a leading biotech trait will be subject to the prospect of generic competition. Generic entry will likely result in lower prices, increased competition and more choices for farmers. Generic versions of RR would allow farmers to purchase equally effective alternatives at lower costs or even to save and replant their soybean seeds from one season to the next (a practice called "brown bagging").[20] Generic entry also would allow competing trait developers to "stack," or combine, their proprietary traits with generic versions of the RR traits. The result would allow farmers a greater choice of products and increased competition.[21] There are concerns, however, that "product hopping" strategies similar to those employed in the pharmaceutical industry may allow Monsanto to extend its RR monopoly beyond the 2014 expiration of its original RR patents.

III. "PRODUCT HOPPING" TO PREVENT GENERIC COMPETITION

Some branded pharmaceutical manufacturers have delayed generic entry through a strategy known as "product hopping."[22] Product hopping involves making trivial changes to a previously patented product. Pharmaceutical manufacturers sometimes try to achieve a longer period of exclusivity by securing an additional patent on the "new" product and, through their pre-existing market power, switching the market to the "new" protected version before widespread adoption of the generic version. The same practice may be occurring in the ag biotech industry.

Monsanto could be tipping the balance away from competition by preventing the entry of generic RR soybean traits. Monsanto appears to be doing so by trying to switch the market to its Roundup Ready 2 Yield ("RR2") trait.[23]

---

18. *E.g.*, Answer at 26, Monsanto Co. v. E.I. DuPont de Demours, No. 4:09-cv-00686 (E.D. Mo. June 16, 2009), *available at* http://www2.dupont.com/Media_Center/en_US/assets/downloads/pdf/20090616DuPontCounterclaim.pdf.

19. Annual Report, *supra* note 13 ("[Monsanto's] herbicide-tolerant products (*Roundup Ready* traits in soybean, corn, canola and cotton seeds) are protected by U.S. patents that extend at least until 2014").

20. John Russnogle, *Back to Brown Bag Beans*, CORN AND SOYBEANS DIGEST, Nov. 1, 2008, *available at* http://cornandsoybeandigest.com/soybeans/back_brown_bag_1108/.

21. *E.g.*, VILLAR, *supra* note 15.

22. BALTO, *supra* note 11, at 14.

23. VILLAR, *supra* note 15.

Even Monsanto has asserted that RR and RR2 are covered by the same core patent.[24] RR2 uses the same gene to confer glyphosate tolerance as RR, but merely uses a different promoter (*i.e.* genetic switch) to activate that gene.[25] The promoter modifies how much of the desired enzyme the gene produces and ultimately how glyphosate tolerance is expressed in the cell. By using a different promoter, Monsanto can pursue additional patents only for that promoter, enabling it to claim longer patent protection for the identical RR gene. Furthermore, there appears to be no independent evidence, outside of Monsanto assertions, that RR2 offers farmers increased yields or improved tolerance to glyphosate over RR.[26]

Despite the substantial similarities, Monsanto may be trying to force the market to adopt RR2 over RR. Indeed, Monsanto CEO Hugh Grant already has acknowledged the need to convert growers to RR2 so that its sales will not be cannibalized by RR.[27] In a June 24, 2009 investors call, Grant stated:

> As we enter the next decades we stand alone in the technology arena that we alone have created. Our products will be fundamentally differentiated and thus we'll compete against our own older technologies. Our job then will be to *replace every old biotech acre with a new one* and [again] lift the value proposition for [growers].[28]

As part of this strategy, Monsanto also has announced a dramatic price increase. RR2 costs approximately 40% more than RR,[29] meaning farmers will be left paying substantially more for essentially the same product.

Notwithstanding that RR and RR2 are virtually identical, it is widely known in the seed industry that Monsanto recently informed independent seed companies ("ISCs") that they must begin to convert all of their soybean seed lines from RR to RR2 within three years if they wish to continue licensing RR. Otherwise, Monsanto will terminate the ISC's license for RR soybeans and re-

---

24. *See generally* U.S. Patent No. 6,660,911 (filed Dec. 15, 2000); U.S. Patent No. 6,949,696 (filed May 1, 2003); U.S. Patent No. 7,141,722 (filed Aug. 18, 2004); U.S. Patent No. RE 39247 (filed July 18, 2003) (referencing RR and RR2 soybeans).

25. *See generally* Andy Coghlan, *Playing Safe*, NEW SCIENTIST, Sept. 4, 1999, at 20, *available at* http://www.newscientist.com/article/mg16322023.200-playing-safe.html (describing the use of marker genes for introducing new traits).

26. *See* VILLAR, *supra* note 15, at 14—15, 23; JIAYING J. MEYER, MONSANTO CO., PETITION FOR THE DETERMINATION OF NONREGULATED STATUS FOR ROUNDUP RREADY2YIELD™ SOYBEAN MON 89788, at 79 (2006), http://www.aphis.usda.gov/brs/aphisdocs/06_17801p.pdf.

27. *See, e.g.*, Hugh Grant, CEO, Monsanto Co., Monsanto Company F3Q09 (Qtr End 5/31/09) Earnings Call Transcript (June 24, 2009) (emphasis added), *available at* http://seekingalpha.com/article/152631-monsanto-company-f3q09-qtr-end-5-31-09-earnings-call-transcript?page=-1&find=crop%2Band%2Bseeds.

28. *Id.*

29. Monsanto Co., Monsanto Roundup Ready 2 Yield Investor Presentation (2009), http://www.monsanto.com/pdf/investors/2009/roundup_ready2_yield.pdf.

quire the ISC to destroy all of its RR soybean germplasm. Because many farmers today will not purchase soybean seeds without a glyphosate-tolerant trait, ISCs face the prospect of losing their Monsanto license and being driven from the soybean seed market unless they agree to switch to RR2 completely. Also, there are indications that Monsanto intends to withhold certain key fees from any ISC that does not agree to make this switch. Because an ISC's ability to turn a profit often hinges on its ability to earn these fees, withholding them is an additional way to ensure that ISCs sell only RR2 soybeans before a generic version of RR can enter the market.

Forcing ISCs to switch to RR2 is not the only way that Monsanto could prevent the entry of a generic version of RR. Also, Monsanto could potentially use the regulatory process to accomplish the same goal. Although no further U.S. regulatory approval will be required for generic RR, major export markets will not accept imported grain unless the varieties are approved by the local regulatory authorities.[30] Because 40% of soybeans produced in the U.S. are exported and grain elevators do not segregate soybeans by destination,[31] it may not be feasible for U.S. farmers to produce and sell soybeans unless they are approved in foreign export markets. Consequently, Monsanto could adopt a strategy of obstructing the foreign approvals of generic RR soybeans and thus prevent them from being marketed in the U.S. For example, Monsanto could let its own foreign RR registrations expire, or it could deny generic competitors access to RR data containing technical information that may be required for foreign regulatory approvals.

Moreover, Monsanto's effort to switch ISCs from RR to RR2 is not the first time it has required ISCs to switch technologies in the face of competition. In its 2004 antitrust lawsuit, Syngenta AG ("Syngenta") alleged that Monsanto employed an almost identical strategy after it lost rights to GA21, the original RR trait in corn.[32] Monsanto lost the rights to that trait after courts ruled that DeKalb Genetics Corporation, which Monsanto acquired in 1998 and who developed GA21 in collaboration with Rhone-Poulenc (now Bayer Cropscience ("Bayer")), had misappropriated Rhone-Poulenc technology.[33] Syngenta alleged that, after losing its rights to GA21, Monsanto required ISCs to switch to NK603, another glyphosate tolerant trait it owned, and destroy all existing germplasm containing

30. *See* Biotechnology Indus. Org., Product Launch Stewardship Policy, http://www.bio.org/foodag/stewardship/20070521.asp (last visited Apr. 9, 2010).

31. Missy Ryan, *Economists Call U.S. Farm Subsidy Bitter Medicine*, REUTERS NEWS, Mar. 1, 2007.

32. *See* Monsanto Co. v. Syngenta Seeds, Inc., No. 04-305-SLR, slip op. at 1 (D. Del. Aug 4, 2006), http://www.ded.uscourts.gov/SLR/Opinions/Aug2006/04-305a.pdf.

33. *See* Rhone-Poulenc Agro S.A. v. Monsanto Co., No. 1:97CV1138, 2000 U.S. Dist. LEXIS 21330, at *5, *20 (M.D.N.C. Feb. 8, 2000), *aff'd*, 272 F.3d 1335 (Fed. Cir. 2001).

GA21.[34] Despite GA21's proven track record, Syngenta, which acquired GA21 from Bayer in 2004, claims it was unable to license this technology widely because of Monsanto's success in switching ISCs to NK603.[35] Syngenta's suit settled on undisclosed terms in 2008.[36]

If Monsanto is as successful in converting ISCs to RR2 as it was in converting them from GA21 to NK603 in corn, RR2 will replace RR as the dominant herbicide tolerant trait in soybeans, even though the two traits are essentially the same. This will enable Monsanto to place its finger on the scale to tip the balance toward exclusivity and away from competition. In the absence of generic competition, farmers will be left paying more for what is essentially the same product.

IV. AG BIOTECH INDUSTRY SIMILARITIES TO THE PHARMACEUTICAL INDUSTRY

Although techniques to avoid generic competition currently may be new to the ag biotech industry, they are not new in the pharmaceutical industry.[37] Monsanto's conduct is reminiscent of similar product hopping strategies employed by branded pharmaceutical companies to deny consumers access to lower priced generic drugs. In this regard, the pharmaceutical industry experience provides a useful road map as to the direction which ag biotech industry may be heading. There are a number of parallels between the two industries that make competition difficult, and thus render them susceptible to similar practices by branded manufacturers to deter competition from generics.

Regulatory regimes can be a barrier to new entrants. Like the pharmaceutical industry, the ag biotech industry is subject to regulatory approval(s) before product introduction. New pharmaceutical products must be approved by the Food and Drug Administration ("FDA") as being both safe and effective. Ag biotech must receive approval from the U.S. Department of Agriculture. New genetically modified products can require approval from the FDA (for those products that may enter the food supply), and, in some cases, the Environmental

---

34. Phillip B.C. Jones, *Patent Challenges to Agribiotech Technologies in 2004*, INFO. SYS. FOR BIOTECH., Feb. 2005, http://www.isb.vt.edu/articles/feb0504.htm.

35. *See id.*

36. *Syngenta Settles with Monsanto*, BUS. J., May 23, 2008, *available at* http://triad.bizjournals.com/triad/stories/2008/05/19/daily59.html.

37. *See* BALTO, *supra* note 11, at 14 (explaining how "brand-name pharmaceutical companies make trivial changes to a drug to secure an additional patent and a longer period of exclusivity").

Protection Agency.[38] Further, before an ag biotech trait is commercialized in the United States, trait developers also generally must secure approval in key foreign export markets to ensure farmers that their crops can be imported overseas.[39] The host of regulations that ag biotech companies must navigate significantly impacts the ability of new companies to enter the market and provide meaningful competition.

Both the pharmaceutical industry and the ag biotech industry have long pre-commercialization lead times and high Research and Development ("R&D") costs, but low marginal costs for post-commercialization production.[40] Pharmaceutical companies spend hundreds of millions of dollars in R&D and years developing and testing new products. Comparatively, the costs of manufacturing and marketing a drug are comparatively low. Similarly, the ag biotech industry also has very long lead times and high R&D costs.[41] The research and development process to bring a new biotech seed to market can take more than ten years and typically costs upwards of $100 million,[42] including the costs involved in obtaining regulatory approval, while it is much cheaper to produce and market a trait. These costs make it prohibitive for new companies to enter the market easily.

Finally, both pharmaceutical companies and ag biotech companies require access to IP rights to develop new traits and to reap the profits from their development. Publicly available technology from land grant universities was accessible in the early to mid-twentieth century, but they do not serve that role well now. Access to adequate IP rights is becoming an increasingly insurmountable barrier to entry for many market participants, given the substantial patenting activity that has occurred in ag biotech over the past fifteen years. Patent litigation—or the threat thereof—has become almost routinely expected by actual and potential new entrants.

Patents in both the pharmaceutical and the ag biotech industries are of limited duration, allowing for the prospect of generic entry.[43] No generic entry in

---

38. MEYER, *supra* note 26, at 21; Foreign Agric. Serv., USDA, Agriculture Biotechnology: Questions and Answers, http://www.fas.usda.gov/ITP/BIOTECH/Qs_As.asp (last visited Apr. 9, 2010).

39. *See* MEYER, *supra* note 26, at 21.

40. CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 4 (2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.

41. *E.g.*, Annual Report, *supra* note 13, at 9.

42. Dale Hildebrant, *Consolidation in the Seed Industry is a Concern to Some*, FARM & RANCH GUIDE, Jan. 31, 2009, *available at* http://www.farmandranchguide.com/articles/2009/01/31/ag_news/regional_news/reg5.prt.

43. CATHERINE L. IVES ET AL., U.S. AGENCY FOR INT'L DEV., AGRICULTURAL BIOTECHNOLOGY: A REVIEW OF CONTEMPORARY ISSUES 11 (2001), *available at* http://pdf.usaid.gov/pdf_docs/PNACN153.pdf.

ag biotech has occurred to date. However, generic glyphosate herbicide competition is now widespread after Monsanto's glyphosate patent expired. This new competition has driven product prices down. Any generic entry into the trait markets would predictably have a similar effect, substantially reducing sales and taking market share from a corresponding branded product. This would result in immediate and substantial savings for farmers, while at the same time it would likely cause the branded company to lose millions in revenue overnight.

To prevent these huge losses, pharmaceutical companies have engaged in a number of strategies designed to thwart generic competition, including product hopping.[44] This is identical to the strategy that we are seeing with Monsanto's switch from RR to RR2, a strategy that is available to Monsanto because of the similarities between the pharmaceutical and ag biotech industries. Just like with generic drugs, preventing the introduction of generic ag biotech traits denies choices and results in potential monopoly profits.

V. COURT AND REGULATORY CONCERN REGARDING STIFLING GENERIC ENTRY

Because no widely used ag biotech traits have gone off-patent to date, there are no court decisions involving tactics used to prevent generic competition. However, there are a number of decisions involving pharmaceutical companies who have engaged in strategies to switch customers to a new product that contains only superficial changes to the old product.

The leading product hopping case is *Abbott Labs v. Teva*.[45] Teva, the leading manufacturer of generic drugs, and several other pharmaceutical companies challenged Abbott's product hopping strategies concerning its blockbuster cholesterol-lowering drug Tricor.[46] Teva had litigated patent disputes for a number of years against Abbott over one formulation of Tricor.[47] When Teva won that patent litigation, Abbott twice made trivial changes to the product formulation, first changing it from a capsule to a tablet, then modifying the tablet version slightly so it did not have to be taken with food.[48] After each minor modification, Abbott pulled the "obsolete" version of the drug and purchased existing supplies back from pharmacies, eliminating the market for the generic before it could be launched.[49]

---

44. *Id.* at 14 ("product hopping" occurs when a brand-name company makes "trivial changes" to obtain a new patent and switches public demand to the new product, thereby further preventing entry of generic products).
45. Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006).
46. *Id.* at 415.
47. *See, e.g., id.* at 415—16.
48. *Id.* at 416, 418.
49. *Id.*

In addition to removing the original product formulations from the market, Abbott changed the code for those formulations to "obsolete" in the National Drug Data File ("NDDF"), effectively removing them from the NDDF.[50] Because generic drugs can enter the market only if the branded product is listed in the NDDF, Abbott's change prevented pharmacies from filling prescriptions using the generic formulation.[51]

Teva filed suit against Abbott alleging that these practices violated antitrust laws.[52] The court agreed that Teva's allegations were sufficient to state an antitrust claim.[53] The court's analysis hinged on the impact of Abbott's conduct on competition and its limiting of consumers' choices. According to the court, Abbott allegedly prevented consumer's choices "by removing old formulations from the market while introducing new formulations."[54] By doing so, Abbott allegedly "suppressed competition by blocking the introduction of [a] generic [product] . . . ."[55]

Similarly, the Federal Trade Commission ("FTC") has also expressed concern about product hopping in the pharmaceutical industry.[56] In 2003, Cephalon attempted to acquire all of the stock of CIMA Labs.[57] Cephalon manufactured a drug (which was about to go off-patent)[58] that alleviated pain after cancer treatments, and CIMA was preparing to enter the market with a competing product.[59] In analyzing the merger, the FTC expressed concern that the merger would occur before generics of Cephalon's product could enter the market, and Cephalon would be able to shift patients to the CIMA product.[60] Such switching, according to the FTC, would "depriv[e] consumers of the full benefits of generic competition."[61] To provide consumers with a choice among all available products, the FTC required Cephalon to license its product to allow generic entry.[62]

---

50. *Id.*
51. *See id.* at 416.
52. *Id.* at 415.
53. *Id.* at 422.
54. *Id.*
55. *Id.* at 424.
56. *See* Cephalon, Inc. et al.: Analysis to Aid Public Comment, 69 Fed. Reg. 52,270 (F.T.C. Aug. 25, 2004).
57. *Id.* at 52,271.
58. *Id.* at 52,272.
59. *Id.* at 52,271.
60. *Id.*
61. *Id.*
62. *Id.* at 52,271—52,272 ("With the licenses and technology transfer provided by Cephalon, [the generic] will be able to compete aggressively in the BTCP market against [Cephalon].").

Preventing competition by making trivial product changes is by no means limited to the pharmaceutical industry. In the antitrust case brought against Microsoft by the U.S. Department of Justice and several states, one of the many strategies that Microsoft engaged in to deter competition was making a change to its Windows operating system that discouraged original equipment manufacturers—an important distribution channel for competing software developers—from including rival Internet browsers in the computers they manufactured.[63] In its unanimous *en banc* decision, the DC Circuit found that this product change was anticompetitive because, "through something other than competition on the merits," Microsoft's conduct had "the effect of significantly reducing usage of rivals' products and hence protecting its own operating system monopoly . . . ."[64]

VI. CONCLUSION

The ag biotech industry has been controversial, and continues to generate controversy. The dominant player, Monsanto, has been aggressive in prosecuting farmers for alleged patent infringement, spurring changes in the traditional "brown bagging" or seed saving practice, buying and merging its way to market dominance, and allegedly using exclusive dealing contracts to combine independent seed dealers licensing with potentially problematic restrictions on competing product offerings.

Among the top emerging issues is the appropriate balance between IP rights and antitrust rules. Because the first ag biotech traits are slated to go off-patent soon, ag biotech companies will face the prospect of generic competition. A focus on detecting potential strategies to prevent post-patent competition is appropriate.

The pharmaceutical industry experience is instructive. Practices including product hopping were used to effectively extend the lives of their patents and prevent generic competition. Supra-competitive prices were maintained, and consumers' choice was reduced or prevented. With the impending expiration of patents for RR traits, state and federal antitrust regulators, as well as the industry, should be alert to similar strategies by the patent holder. The FTC, partnered in some instances with State antitrust enforcers, has past experience enforcing antimonopoly laws in the context of generic competition in the pharmaceutical industry.[65] Similar vigorous antitrust enforcement now is needed in ag biotech to

---

63. United States v. Microsoft Corp., 253 F.3d 34, 65—66 (D.C. Cir. 2001).

64. *Id.* at 65.

65. *See, e.g.*, FTC v. Cephalon, Inc., 551 F. Supp. 2d 21 (D.D.C. 2008); FTC v. Warner Chilcott Holdings Co. III, No. 05-2179, 2007 WL 158746 (D.D.C. Jan. 22, 2007).

prevent companies from engaging in product hopping and similar patent-extending strategies. Vigorous enforcement will help prevent the foreclosure of generic entry and ensure robust competition from generic traits.

If generic competition is allowed to develop, and mere minor or insubstantial improvements do not quash that competition, lower prices and more choice for farmers will develop, enabling the opportunity for more producer profitability. Farmers will be allowed to save and replant seeds from year to year as well. Additionally, competing biotech companies will have to produce real, not *de minimus*, product improvements to achieve another twenty-year period of patent protection.