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Transgenic Seed: The High Technology Test of Antitrust?

Diana L. Moss
American Antitrust Institute

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I. INTRODUCTION

The recent flurry of publicity in transgenic (also known as genetically modified or “GM”) seed reveals a broader controversy over competition policy in high technology industries. What constitutes conduct by a patent-holder that is legitimately within its rights, versus what exceeds the scope of a patent? More specifically, how should antitrust deal with a patent-holder that is also a dominant firm, and alleged to have maintained or leveraged its monopoly by selectively enforcing its licenses? Does such conduct unduly control or influence competition and innovation, to the detriment of consumers?

Agricultural biotechnology giant Monsanto is at the center of the debate over the intersection between patent law and antitrust law in transgenic seed. In the spotlight are the markets for genetic traits and the complementary markets for transgenic seed.² There are two categories of genetic traits: input and output. Input traits affect the agronomic performance of the plant in order to enhance yield, including tolerance to herbicides (Ht traits) such as glyphosate and resistance to insects (Bt traits). These traits in corn, soybeans, and cotton have been established for some time. But other input traits (e.g., drought resistance) and output traits are more novel. Output traits affect the characteristics of the plant’s output (e.g., high oleic soybeans) and therefore the value of the crop.

With substantial market shares in genetic traits for corn (about 75 percent), soybeans (about 95 percent), and cotton (about 97 percent), Monsanto potentially holds sway over the market.³ But there are growing complaints about substantial price increases for seed—about 25 to 30 percent for corn and soybeans in recent years.⁴ Moreover, seed companies have complained that they cannot access Monsanto technologies for the purposes of developing commercially valuable transgenic products, despite the firm’s policy of licensing broadly.

¹ Vice President and Senior Fellow, American Antitrust Institute (AAI) (www.antitrustinstitute.org). The AAI has published two White Papers on competition and transgenic seed. See, Diana L. Moss, *Transgenic Seed Platforms: Competition Between a Rock and a Hard Place?* (AAI White Paper) American Antitrust Institute (October 23, 2009). Online at http://www.antitrustinstitute.org/archives/files/AAI_Platforms%20and%20Transgenic%20Seed_102320091053.pdf. See also, *Transgenic Seed Platforms: Competition Between a Rock and a Hard Place? Addendum*, (AAI White Paper Addendum), American Antitrust Institute (April 5, 2010). Online at http://www.antitrustinstitute.org/archives/files/Addendum%20to%20AAI%20White%20Paper_Transgenic%20Seed.4.5_040520101107.pdf.

² “Germplasm,” or genetic seed material might also be considered a distinct complementary market.

³ See *supra* note 1, AAI White Paper, at 13.

⁴ See e.g., U.S. Department of Agriculture biotech seed price data referenced in *supra* note 1, AAI White Paper Addendum, at 10. See also, Christopher Leonard, *Monsanto Squeezes out Seed Businesses Competition, AP Investigation Finds*, (December 13, 2010). Available online at <http://www.sott.net/articles/show/198898-Monsanto-Squeezes-Out-Seed-Business-Competitors>.

Together, the foregoing factors have had a catalyst-like effect. For example, there is an ongoing investigation into Monsanto's conduct by the U.S. Department of Justice ("DOJ"). Momentum could be gaining in several states to bring an antitrust suit against the firm. And a series of high profile DOJ/U.S. Department of Agriculture workshops on competitive issues in agriculture are scheduled throughout 2010. This article explores what is driving these antitrust concerns. Given that Monsanto's blockbuster Ht trait Roundup Ready 1® (RR1®) for soybeans goes off patent in 2014, it is also important to explore what policy tools are needed to best promote generic competition.

II. NEW INVENTIONS, OLD ANTITRUST THEORIES

It is important to recognize that transgenic seed is the embodiment of successful innovation. The industry is relatively young (about 15 years), but the rapid pace of innovation is evident not only in the displacement of conventional with transgenic seed, but the growing sophistication of genetic traits and traited seeds. Single-traited seed is still available, but seed with multiple or "stacked" traits has gained significant ground. Economic evidence indicates that the productivity gains associated with transgenic seed are substantial.⁵ Some empirical work, however, shows that a significant proportion of the gains have gone to innovators, as opposed to farmers or consumers.⁶ Rapid increases in seed prices over the last few years may also be closing the gap between gains from increased productivity and input costs.⁷ Moreover, while many measures of innovation show robust activity, economists have raised questions about whether the quality of innovation involving transgenic seed has declined over time.⁸

While the economic evidence on innovation is not conclusive, it does raise questions about the effects of changes in market structure and vertical integration. For example, Monsanto—as the dominant player in the market for genetic traits—acquired numerous independent seed companies between the mid-1990s to late 2000s, beefing up its presence in downstream markets for traited seed. The effect of this consolidation has been to create vertically integrated platforms of genetic traits and traited seed. Other biotechnology firms have also made acquisitions, but on a smaller scale, including DuPont's acquisition of Pioneer in 1999 and Dow's acquisition of Mycogen in 1998.

Competitive concerns in transgenic seed do not pose novel antitrust issues. They bear a strong resemblance to those found in the government's Section 2 cases against AT&T in 1982 and Microsoft in 2001. The fact that monopolization often afflicts industries where consumers stand to benefit substantially from innovation deserves special attention. The potential severity of monopolization concerns is compounded by the fact that transgenic seed, like telecommunications services and personal computing software, is ubiquitous. Higher prices, limited choice, and slower rates of innovation that result from anticompetitive conduct affect the daily lives, productivity, and well-being of a substantial base of consumers. In agriculture, there is an additional argument to be made for competition, in that it creates diversity and stability in a critically important supply chain.

⁵ John L. King, *Concentration and Technology in Agricultural Input Industries*, U.S. Department of Agriculture, Economic Research Service, Agriculture Information Bulletin No. 763 (March 201), at 1.

⁶ GianCarlo Moschini, *Economic Benefits and Costs of Biotechnology Innovations in Agriculture*, Iowa State University, Center for Agricultural and Rural Development, Working Paper 01-WP-264 (January 2001), at 13.

⁷ For further discussion, see *supra* note 1, AAI White Paper, at 10-11.

⁸ *Id.*, at 19.

III. STACKING AND TWO COMPETITIVE PARADIGMS

Ironically, it is the market penetration of stacked traits that creates the competitive conundrum in transgenic seed. We can argue about whether these innovations are driven by demand for new technologies or whether innovators have pushed the lucrative products into the hands of ambivalent farmers.⁹ But the reality is stacked traits are here to stay. In order to stack a developer must combine its own traits, combine its trait(s) with a Monsanto trait(s), or combine its trait(s) with the trait(s) of another rival. It is here that market structure is likely to dictate what is, and is not, possible.

In the first case, for example, there are few players in the market with their own suites of Ht and Bt traits to combine in a non-Monsanto platform. Second, the small shares problem also limits the number of possible traits combinations that could be created between non-Monsanto developers. It is therefore clear in the third case that the greatest number of possible stacking opportunities lies in stacking non-Monsanto with Monsanto traits. The first two limitations on stacking mean that there are few independent platforms of stacked traits that do not contain Monsanto traits. The implication of the third point is obvious. Namely, with the dominance Monsanto enjoys in genetic traits, the majority of stacked trait combinations contain a Monsanto trait.¹⁰

The stacking dilemma requires that we adopt a more novel way of thinking about competitive paradigms. Competition advocates tend to care about the availability of inter-platform competition when access to rival technologies or services is limited. A good analogy is airline alliances, where switching passengers to a non-alliance carrier part-way through an itinerary may prove difficult and costly. But inter-platform rivalry delivers maximum benefits only when there are equally-viable platform competitors. Due to Monsanto's market dominance in traits, the possibility for inter-platform competition is limited. In a perfect world, the intra-platform model of competition would work well if Monsanto licensed its technology equally to all comers. This would enable stacking and allow the market to be the ultimate judge of the products that succeed and fail. But that, too, may be a remote possibility.

The wrinkle is that there appears to be a degree of selectivity employed by Monsanto in its licensing decisions. The company has, for example, teamed up with certain rivals such as Dow in creating the 8-gene SmartStax corn seed product. But it is clear from data on currently available stacks that Monsanto deals less (if at all) with other rivals (e.g., DuPont and Syngenta).¹¹ That outcome, some allege, results from the potentially restrictive conditions Monsanto places on its licensees, such as prohibitions on stacking, thus limiting the products that could ultimately make it through the R&D pipeline.

When technology is made available to some, but not all, rivals, the have-nots are bound to cry foul. This is especially so if the effect of such discrimination is to promote products that might be valuable to the patent-holder but discourages others that are a competitive threat. It is this aspect of Monsanto's conduct that is potentially the most troublesome for competition advocates. It also pinpoints the nexus between what conduct is legitimately within the scope of a

⁹ Growing resistance associated with plants from transgenic seed is reflected in refuge requirements, which allow transgenic seed only on a percentage of total acreage. Stacked-traited seeds with multiple modes of action (e.g., more than one insect-resistance trait) address the resistance problem.

¹⁰ For further discussion, *see supra* note 1, AAI White Paper Addendum, at 8-9.

¹¹ *Id.*

patent and what is potentially not. But antitrust imposes no generalized duty to deal.¹² Moreover, firms can offer business justifications such as quality control for refusing to license, or selectively licensing, their technologies. While the courts grapple with these issues in notoriously difficult antitrust cases, the DOJ has clearly addressed the issue in several merger remedies. Not only does the DOJ address the question of boundaries on patent protection, it also recognizes the implications of inter-platform and intra-platform competition.

For example, the agency's recent consent decree in the Ticketmaster/Live Nation merger imposed a remedy that was arguably designed to create a viable, rival platform to the newly merged firm. The remedy centered on the ability of rivals to license the merged firm's proprietary ticketing software and ticketing assets.¹³ Closer to home, the DOJ required Monsanto to remove anti-stacking provisions in its licensees as part of its 2007 merger deal with cotton giant Delta and Pine Land.¹⁴ Together with the divestiture of germplasm and seed assets, these requirements together created a rival cotton platform, which ultimately ended up in the hands of Bayer. But not every antitrust issue is a merger. Monopolization cases are often uphill battles in courts that have tended to shy away from, and even muddled, the cross-over between legitimate patent rights and strategic anticompetitive conduct.

IV. GENERIC COMPETITION

How the current antitrust issues in transgenic seed will be resolved as part of a confidential DOJ investigation is as yet unclear. But there are equally important but related issues that have arisen in a very public arena. Namely, what policies are necessary to promote generic competition in transgenic seed? Monsanto's RR1® soybeans will go off patent in 2014, opening the door to the development of a generic Ht soybean trait. If managed properly, this transition could stimulate competition in both a generic trait and alternative stacked products containing a generic trait. That competition, in turn, would deliver benefits to farmers in the form of innovation, lower prices, and choice.

Industry stakeholders have recognized the urgency associated with planning for a smooth transition to competition in a generic Ht trait.¹⁵ This process should ideally focus on two objectives: (1) developing an institutional structure for promoting and managing generic competition and (2) working with the patent-holder (Monsanto) to facilitate development of generic products. The overriding concern behind this two-pronged strategy is to promote certainty for generic entrants in securing an ultimate path to market successful products. Certainty is necessary for developers to undertake investments in R&D and will be enhanced if the transition minimizes the possibility of a "gap" between the time RR1® goes off patent and when products containing a generic Ht trait enter the market. Such a gap could potentially jeopardize the development of competition in generic products. This is because a next generation product has already been introduced (e.g., Monsanto's RR2® soybeans). If decisions at both the R&D and farmer levels cannot be easily reversed, a lock-in effect could stymie switching to generic Ht.

¹² See, e.g., *Aspen Skiing Co. V. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).

¹³ See *U.S. v. Ticketmaster Entertainment, Inc. and Live Nation, Inc.* Proposed Final Judgment, Case: 1-10-cv-00139 (January 25, 2010). Online at <http://www.justice.gov/atr/cases/f254500/254558.htm>.

¹⁴ See *U.S. v. Monsanto Company and Delta and Pine Land Company*, Proposed Final Judgment, Case: 1:07-cv-00992 (May 31, 2007). Online at <http://www.justice.gov/atr/cases/f223600/223679.htm>.

¹⁵ Including the American Farm Bureau Federation and major companies such as Monsanto and DuPont's Pioneer.

The potential development of generic transgenic traits shares a major feature with generic pharmaceuticals, namely they both require longer lead times to develop and bring new products to market. This includes development, testing, and securing necessary regulatory approvals. The implication of a longer pipeline to market is that developers require advance access to the existing patented RR1® trait to test and breed out new stacked-traited products. While Monsanto has recently committed to not enforce patents against farmers (e.g., in regard to seed-saving), the company has been silent on the matter of whether it will enforce patents against developers who wish to stack the RR1® trait with their own traits for the purposes of developing products containing a generic Ht trait.¹⁶ Non-enforcement of seed saving provisions in farmer licenses does nothing to promote the development of a generic product or products containing an Ht trait.

The practical implication of an asymmetric policy on patent enforcement is that developers could not start R&D until patent expiry in 2014. It could thus be another several years before a generic product(s) could be brought to market. On the pharmaceutical side, the Hatch-Waxman Act makes provisions to facilitate generic entry by creating a window in which there is a hiatus on patent-infringement claims. While a Hatch-Waxman-type approach on the transgenic seed side may be a potentially useful longer-term strategy, a legislative solution for current transition issues would be time consuming and unwieldy. A more expeditious method is needed for transgenic seed.

The importance of the transition process in generic seed is punctuated by the fact that there is a significant export market for U.S. seeds. Many foreign authorities require that individual traits and stacks of traits gain necessary approvals (registrations) before they can be imported. The foreign registration process requires testing and reliance on data packages to support the application. Monsanto has committed to maintaining foreign registrations for RR1® soybeans for a period of three years post-patent expiry.¹⁷ While this is a move in the right direction, three years is unlikely to be sufficient time to allow generic developers to develop their own data packages to support foreign registrations before the Monsanto registrations expire.

A gap between expiration of Monsanto's foreign registrations for RR1® and when generics come on to the market would create perilous uncertainty and put competition in jeopardy. Developers are unlikely to undertake R&D for generic products without the certainty that the foreign registration process will be uninterrupted. A gap could also create chaos in the export and domestic markets. Because grain shipments destined for the export market and the domestic markets are not segregated, any uncertainty regarding the destiny of shipments to foreign markets will also affect domestic production decisions. Both of these possibilities would be costly outcomes, in terms of disrupting the development of generic competition and ultimately in higher prices and less choice for farmers.

A policy agenda for the transition to a generic Ht soybean platform is needed. At a minimum, that agenda should ideally address the following issues: (1) development of an independent, third-party association to represent the interests of generic developers and users; (2) access to Monsanto RR1® data packages and/or access to RR1® itself in order to allow development of generic data packages to expeditiously obtain foreign registrations, with appropriate compensation to the patent-holder; (3) extension of Monsanto's foreign registrations

¹⁶ See "Roundup Ready® Soybean Patent Expiration," (undated). Online at http://www.monsanto.com/choice_in_agriculture/seed_competition/patent_expiration.asp/.

¹⁷ *Id.*

for RR1® that would allow sufficient time to obtain registrations for generic products; and (4) removal of anti-stacking provisions in Monsanto's RR1® licenses for a period of time necessary to allow R&D to proceed at a pace that would bring generic products to market at the time the patent expires.