IPI Institute For Policy Innovation

ISSUE BRIEF

The Seeds of IP Policy:
A Growing Agricultural Success Story

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Synopsis

The first of the biotech seeds, Roundup Ready, goes off patent in 2014, and many more will soon follow. While the industry needs a process to govern how other seed companies create a generic seed, it should try to create a private sector process that relies on negotiations and contracts, and not the costly and litigious adversarial approach Congress imposed on the pharmaceutical industry.

Introduction

For millennia farmers and scientists have tried to improve plants to make them heartier, more productive and less susceptible to insects, disease and drought—and those efforts have led to some significant successes. However, there is only so much that can be achieved through traditional plant-breeding techniques.

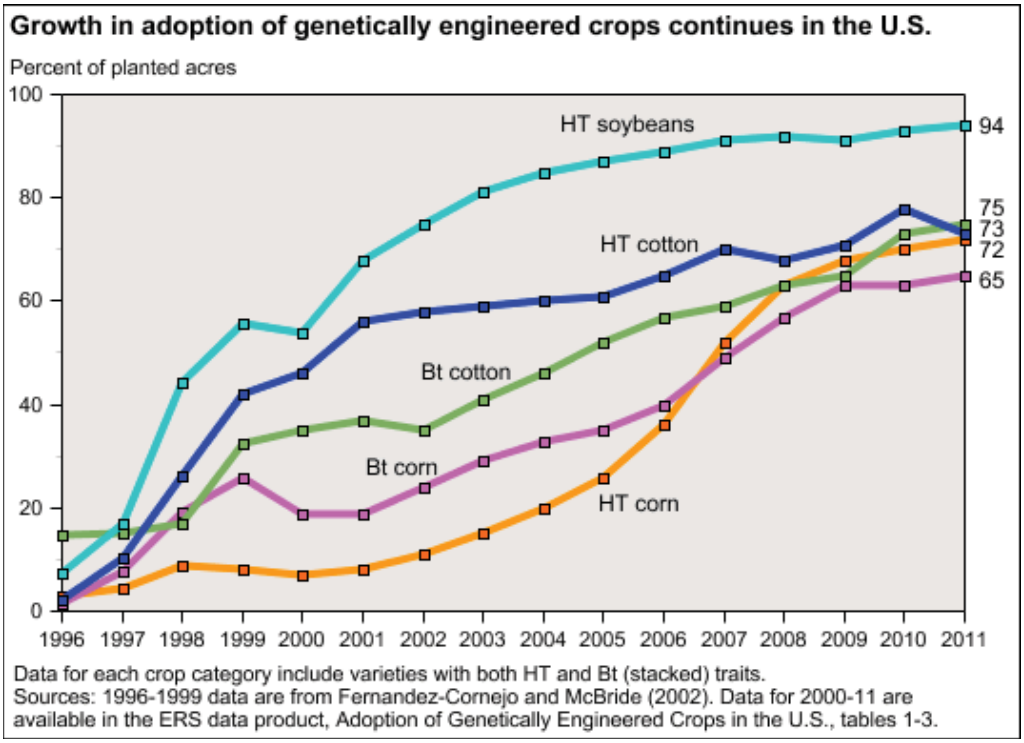
And there's still the problem of weeds. While scientists have created some very effective herbicides to kill weeds, most did not discriminate adequately between weeds and crops. But things began to change in 1996. That's when the Monsanto Company turned to biotechnology to fundamentally revolutionize farming by introducing a genetically modified (GM) soybean seed that tolerated the herbicide glyphosate. That success was soon followed by infusing other gene traits that could fight certain insects and diseases, and opened the door to a wide range of new possibilities.[1]

Over the past 15 years the use of GM crops has exploded. According to the U.S. Department of Agriculture (USDA), there were about 366 million acres of GM crops worldwide in 2010, up about 10 percent from 2009. The U.S. accounts for about 45 percent of those crops. With respect to the U.S. in 2011:

- Plants with herbicide-tolerant traits represent 94 percent of the soybean acreage, 73 percent of cotton, and 72 percent of corn;

- Plants with insect-resistant traits represent 75 percent of the cotton acreage and 65 percent of corn.

1. "Agricultural Biotechnology: Adoption of Biotechnology and Its Production Impacts," U.S. Department of Agriculture, Economic Research Service Briefing Rooms.



Source: USDA Economic Research Service

However, the initial Roundup Ready soybean patent will expire in 2014, creating opportunities for other companies to introduce an off-patent generic version of the glyphosate-tolerant gene trait into soybeans, including "stacking" the seeds with other engineered traits, such as a pest-fighting gene. Herein a public policy problem arises: How will the innovator companies work with others to transfer the genetic material, maintain the regulatory authorization to ensure no disruption in international trade, and maintain the necessary data and seed stewardship?

There is currently no framework governing the transition, which could create regulatory chaos when seed manufacturers try to move forward with generic versions of the product. What should be avoided is the type of adversarial, litigation-heavy process that governs such issues in the pharmaceutical industry.

With patents beginning to expire, it is important that guidelines be developed, preferably by the industry, that identify a clear and enforceable framework that governs the transition, encourages timely arbitration in case of disputes, and minimizes disruption in traditional agricultural principles and practices.

The Introduction of the First Biotech Seed

Farmers have long struggled with the problem of weeds. While new chemical herbicides developed in the 1960s allowed farmers to treat for weeds before (pre-emergence) and during planting, they had to mechanically remove them after crop germination.

In 1973 Monsanto introduced Roundup, a very effective broad-spectrum herbicide with the active ingredient glyphosate. But while Roundup did an excellent job of killing weeds, it would also harm the crops, which meant that farmers could not spray it after planting their crops, reducing the herbicide's effectiveness.

In addition, farmers normally have had to leave space between the rows and plants to allow access to the weeds that emerged post-planting, which reduced the number of

plants growing in a given field because farmers needed room to weed. This practice was less efficient, labor intensive and costly—but also necessary.

Rising Costs and Liability

Monsanto released Roundup Ready soybean seeds in 1996. The seeds are genetically modified to make them glyphosate-tolerant. With them, Roundup could then be sprayed post-planting, killing the weeds without hurting the crops. Thus plants could also be placed closer together improving soil conservation and crop yield, not so much from increased plant production as from being able to plant more per acre.

Monsanto's Roundup Ready seeds cost more than traditional seeds, and technology use agreements are used to protect intellectual property rights and prevent seed saving. Even so farmers apparently are willing to make that trade-off and buy new seeds yearly. Roundup Ready-licensed seeds have become by far the dominant soybean seed. Monsanto estimates that 90 percent of the 78.9 million U.S. acres of soybeans are Roundup Ready.[2] That land produced about 3.345 billion bushels of soybeans in 2010, exporting about 1.37 billion bushels of that total.[3] That last figure is very important. Because of the significance of foreign trade in agriculture, foreign regulatory approval is integral to the discussion of a pathway to generic versions of the seeds.

Other seeds have followed the soybean lead: corn, alfalfa, canola, wheat, cotton and sugar beets. Today, all come with genetically engineered traits. Some have fared better in the marketplace than others, but collectively they are demonstrating that a biotech revolution in farming is underway.

How Intellectual Property Protections Help Feed the World

The introduction of the Roundup Ready trait is fundamentally changing the agriculture business by reducing the need for weeding, improving soil conservation techniques, and increasing crop yield. But these new intellectual property protections are changing farming practices.

Seed Saving

Historically, farmers bought—or borrowed or were given—the seeds they used for their crops. Once the crops were harvested, they often saved the seeds—or a portion of them—to be used for the next crop. Saving seeds was part of the culture and has become a metaphor for the prudent handling of one's finances. The phrase "eating the seed corn" came to represent the immediate, and foolish, consumption of the means for providing for the future.

The Introduction of Intellectual Property Protection

The introduction of intellectual property protection with genetically modified seeds has fundamentally altered the seed-saving process. For example, Monsanto has IP rights to the traits in its seeds, and it owns several patents that protect those rights from infringement—at least until 2014 when the first of Monsanto's patents expires. Thus Monsanto has the right under law to determine how, when and by whom its traits are used until its patents expire.

Purchasers (i.e., farmers) of Roundup Ready seeds must sign a technology agreement. And they pay a technology fee for each bag of seeds on top of the purchase price.[4] Depending upon which seed company is selling the Roundup Ready-licensed seed, the fee is either listed separately on the bill of sale or included in the total price.

2. Jennifer M. Latzke, "Roundup Ready Soybean Trait Patent Nears Expiration in 2014," High Plains/Midwest Ag Journal, 2010, http://www.hpj.com/archives/2010/aug10/aug2/0716SeedMACOAug2sr.cfm

3. Ibid.

4. General Accounting Office, "Information on the Prices of Genetically Modified Seeds in the United States and Argentina," GAO/RCED/NSIAD-00-55, January 2000, p. 13.

Like virtually all IP protected goods, seeds with patented gene traits come with restrictions—though the restrictions can vary with the type of plant. With Roundup Ready seeds, the purchaser cannot harvest seeds for use the following year—which historically farmers had always done—nor can he profit from the seeds by other means. Monsanto owns the patent and so farmers are, in essence, just using the seeds to create a crop.

The Benefits of IP

The introduction of genetically modified seeds has produced significant benefits. While a small group of critics continues to push the notion that farmers should drop GM seeds and return to the traditional varieties, and claims that such a move can be more financially rewarding, most farmers don't buy the argument—neither in the U.S. nor in several other countries. And the reason is clear: Farmers are making more money with GM seeds, or are working less allowing them to make more money elsewhere.

Authors George B. Frisvold of the University of Arizona, Terrance M. Hurley of the University of Minnesota, and Paul D. Mitchell of the University of Wisconsin point out that worldwide an estimated 79 million hectares of plants are herbicide-resistant (HR) varieties of soybean, maize, canola, cotton, alfalfa and sugar beets. The authors go on to say:

> HR crops, thus, may provide multiple pecuniary and non-pecuniary benefits, including environmental benefits. Herbicides used with most HR crops tend to be less toxic and persistent than the herbicides they replace, while HR varieties can complement the use of no-till systems that reduce soil erosion and fossil fuel emissions. Thus, benefits of HR crops are multi-faceted and difficult to quantify.[5]

Because farmers are willing to pay extra for GM seeds, researchers are plugging away at trying to introduce new genetic modifications, including stacking several traits within the same seed, in order to bring new and more effective biotech versions to the market.

The Challenges of IP In Agriculture

As mentioned earlier, the manifest benefits of GM seeds do not come without some new challenges. One has to do with when and to what extent farmers who have GM crops in their field, even if they did not intentionally plant them, owe royalties on those plants. However, assertions that patented GM seeds have created a litigation-heavy environment are overblown.

There have been relatively few infringement actions with regard to Monsanto's Roundup Ready patent, according to the company.

> Since 1997, we have only filed suit against farmers 145 times in the United States. This may sound like a lot, but when you consider that we sell seed to more than 250,000 American farmers a year, it's really a small number. Of these, we've proceeded through trial with only eleven farmers. All eleven cases were found in Monsanto's favor.[6]

To be clear, an innovator company must protect its intellectual property or risk losing control of it. If Monsanto did not aggressively protect its IP rights, future defendants could claim that Monsanto was relinquishing those rights in Roundup Ready seeds.

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5. George B. Frisvold, Terrance M. Hurley and Paul D. Mitchell, "Overview: Herbicide Resistant Crops—Diffusion, Benefits, Pricing, and Resistance Management," AgBio Forum, 12(3&4), p. 244.

6. See Monsanto's website, "Saved Seeds and Farmer Lawsuits," http://www.monsanto.com/newsviews/Pages/saved-seed-farmer-lawsuits.aspx

All Good Things Come to an End: The Patent Expires

Intellectual property protection is established in Article I, Section 8, of the U.S. Constitution, which says: "The Congress shall have Power … To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

A patent by law usually lasts for about 20 years from the time it is filed. Innovators frequently have to continue with their research and development after the patent is filed and before they can bring the new product to market. That R&D plus regulatory approval time cut into the effective patent life because the product is not yet commercially available. Even though Monsanto introduced Roundup Ready seeds to market in 1996, the patent expires in 2014. Then other companies will be able to create a generic version of the product without paying royalties. Those generics will likely be cheaper than Monsanto's and, in their effort to gain market share, they may have found ways to improve on the original version. As a result of the patent expiration, Monsanto will likely not make nearly the money it has been making on Roundup Ready soybean seeds while the patent has been in effect. But that's the tradeoff: The patent gives the innovator exclusive rights to profit from the discovery for a limited amount of time, after which the public gets access to a less-expensive generic version. It is a public policy balance to encourage innovation and yet let the public benefit, eventually, from lower prices.

Monsanto has already produced a newer patented trait called Roundup Ready Yield 2, or RRY2, which is currently on the market. Farmers will have to decide for themselves whether the benefits of RRY2 justify signing a technology agreement and paying the technology fee, or whether they should just stay with the original Roundup Ready or switch to a generic alternative.[7]

Is There a Pathway to Generic Trait Production?

With Monsanto's patent on Roundup Ready soybeans ending in 2014, the question has been raised about how to manage an orderly transition to allow generic versions of the trait. Stakeholders will want access to the genetic material and the regulatory authorization to be maintained.

However, no government agency has stepped forward to impose guidelines to govern such issues; and the industry is already addressing the challenge. It makes sense to begin discussing a framework for data sharing. Doing so would avoid some of the pitfalls that have troubled the patent-to-generic transition process evident in the pharmaceutical industry.

How Hatch-Waxman Established a Pathway in Pharmaceuticals

There is a model for transitioning from a brand name product to a generic in the pharmaceutical industry—and the agricultural industry *should not follow it*. In the early 1980s, some of the brand name pharmaceuticals were facing patent expiration. Like many patent holders, they were not eager to see the end of their IP protection. Having patents—whether applying for them based on one's own research and development efforts or buying patents from someone or company that owns them—can be very financially rewarding. Once "copycat" companies enter the market, competition can escalate dramatically forcing prices down—sometimes way down. The result is that the financial windfall from holding the IP rights can decline, sometimes significantly. Thus innovator companies have an economic incentive to resist or delay the patent expiration when possible, which can hinder a quick and orderly process whereby generic manufacturers enter the market.

Senator Orrin Hatch (R-Utah) and Representative Henry Waxman (D-Calif.) addressed the challenge by introducing The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act. Its purpose was to create a

7. Some stories claim that RRY2 does not justify the additional costs. "Monsanto Faces West Virginia Probe Over Roundup Ready 2 Soybean Seed Claims," NewsInferno, July 1, 2010. http://www.newsinferno.com/consumer-fraud/monsanto-faces-west-virginia-probe-over-round-up-ready-2-soybean-seed-claims/21677

pathway for generics to file for an Abbreviated New Drug Application (ANDA) to gain FDA approval and move to market. The legislation attempted to recognize the innovator companies' need for sufficient intellectual property protection to ensure they would continue to innovate and create new drugs, but its authors decided that an even more important goal was to meet the public's desire to have access to much less-expensive generic versions of brand name drugs. While the Hatch-Waxman Act achieved its goal, the framework has created numerous problems over the years.

Generic manufacturers were allowed to piggyback off the research and clinical trials of the brand name drug. As long as the generic manufacturer could demonstrate that its follow-on drug was "bioequivalent" with the brand name drug, meaning the molecule was essentially identical, the generic version could be approved based on the brand name company's research and clinical trials.

While Hatch-Waxman did create a process for moving from branded to generic drugs, the legislation has a flaw: Rather than encouraging or promoting a climate such that innovator companies worked cooperatively with generic companies, Hatch-Waxman created an adversarial approach. It was all about speed to market: The first generic company to successfully challenge a brand name company's patent got a financial bonus: six months as the exclusive generic manufacturer before other companies could offer the product. That six-month exclusivity period helped create name recognition and a customer base for the first generic, often enhancing profitability.

But the financial incentive to be the first to challenge the patent also encouraged generics to push the patent envelope, such as challenging a patent too early. Of course, the innovators still had their financial incentive to postpone the patent expiration if possible. That tension has resulted in millions of dollars in wasteful court fights and legal fees.

In essence, Hatch-Waxman magnified the "transaction costs" of creating a generic version of a drug. Those are the additional costs associated with making some form of economic exchange. For pharmaceuticals, those millions of dollars in wasted time and litigation increased the cost of pharmaceuticals and doubtless delayed access to less-expensive generic versions of the drugs. Much of that waste could have been reduced had the players been better able to operate under a system of voluntary negotiations and contracts. Surely the agricultural industry can and should do better.

The Challenges for Seeds

Roundup Ready will be the first biotech seed to go off patent (in 2014) though others will soon follow. That fact has raised several questions about how the transition to off-patent seeds will proceed. While there may be some lessons to be learned from the pharmaceutical process, seeds also pose different questions.

Stacking—One of the most important issues is that of "stacking." Scientists are not limited to only one genetic modification in seeds; GM seeds can hold a number of traits that can fight disease, insects and other challenges. When seeds have two or more patented technologies included, it is known as stacking. A cottonseed was the first commercially stacked seed, released in 1997.

Through licensing, the technology developed by Monsanto is either distributed by other companies or combined with other proprietary technologies and distributed broadly. The result has been a variety of seed options for farmers.

In general, Monsanto has been supportive of such efforts, with the exception that it restricted seed companies from stacking another glyphosate-tolerant gene on top of Monsanto's, and it sued one company for doing so.

Access to Data—For generic drug companies, access to the innovator company's data as to how it created the patented product allows the generic manufacturer to recreate the product without going through the costly R&D process.

Current law grants pharmaceutical innovators a "data exclusivity" period—i.e., the ability of the innovator to control access to its proprietary research data, at least until the law requires the company to release it.

With respect to seeds, access to data will also be important if a new product is being developed, both for manufacturing and for gaining regulatory approval abroad. Companies seeking to add the Roundup Ready gene trait to other existing traits, or to newly created ones, must present regulatory agencies with the appropriate data. And yet there is no current framework for governing regulatory authorization.

Foreign Trade—Food security is becoming a very sensitive issue. For one thing, most developed countries have large farming sectors, and those farmers often have political clout. If they feel threatened by certain food products, they will lobby their representatives to restrict or prohibit those products. In addition, there is a growing trend for purer food in many of the wealthier countries, and some people see GM food products as failing the pure-food test.

To address these and other issues, foreign officials want access to the regulatory data. As mentioned earlier, gene stacking could alter a plant's characteristics, posing a threat that a single modification might not pose. In order for others to assess the risk, they want access to the data behind stacked products.

Dispute Resolution—The last thing the agricultural industry—or any industry, for that matter—needs is an adversarial pathway like that created under Hatch-Waxman. Negotiations, licenses and contracts, not challenges and extended litigation, are the right way to go. So far, that is the direction the industry is headed, but other issues will arise. Clear, equitable guidelines need to be established that encourage contracts and a seamless transition, and that do not hinder current trade arrangements.

A Way Forward for Patented Seed Traits

In order to ensure an orderly transition to the off-patent production of patented gene traits, companies with a vested interest need to ensure that:

- A mutually agreed upon framework be developed. This process should be initiated soon to cover the 2014 expiration of the Roundup Ready patent.

- When disputes arise there should be a dispute resolution process that, as much as possible, minimizes adversarial action. Voluntary arbitration is the preferred method of dispute resolution between IP holders and those companies seeking to include an expired patent.

- Puts a priority on trade. Food is one of the country's top exports. Yet foreign concerns over genetically modified food has resulted in a very delicate balance. Other countries want to know what farmers are growing and how GM seeds could affect their own agricultural industry and if there are any human health concerns.

- Recognize that farming has a long history with long-established practices and traditions. Bio-engineered food will necessarily alter some of those practices, like saving seed, but those changes should be as undisruptive as possible.

To date the industry has approached the upcoming challenges in a way that recognizes that all parties have a stake in a voluntary and workable process. There are proprietary and intellectual property rights to be respected, even as the patents expire. Fortunately for the seed industry, innovator companies may also be involved in creating their own generic seeds, which helps reduce the "us against them" mentality that has characterized the pharmaceutical industry—though even in that industry the division between innovator and generic company is blurring.

Hopefully, the seed industry's effort to address the transition from patent to generic will stand as a model for how to establish a voluntary process that embraces private negotiations and contracts and avoids, as much as possible, government-imposed solutions.

About the Author

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