

Policy Pennings by Dr. Daryll E. Ray

Roundup Ready generics: New opportunities but also new obstacles?

The impending loss of Monsanto's patent on its Roundup Ready soybean in 2014 raises a number of important policy issues in addition to those raised in DuPont's anti-trust case against Monsanto and the opening of an antitrust investigation of Monsanto by the US Department of Justice.

Monsanto's Roundup Ready genetics is used in 90 percent of all soybeans grown in the United States. Other major crops containing the Roundup Ready genetics are corn and cotton.

The advent of this technology in soybeans in 1996 spelled the end to bean walking and bean bars as a means of controlling weeds in soybeans. Spraying glyphosate on soybeans with the Roundup Ready gene killed the weeds while allowing the soybean plants to continue growing and providing farmers with a superior weed-control technology.

While the technology did not affect yields appreciably, it saved farmers time and effort. The Roundup Ready technology also provided weed control for no-till agriculture.

One of the contractual obligations farmers accepted in buying Roundup Ready soybeans was a prohibition on the saving of seed as had been common among soybean farmers before the advent of the technology. In addition to paying a higher price for the seed, farmers pay a technology fee.

Monsanto was able to achieve the 90 percent utilization rate in part by licensing the technology to competing seed firms, subject to contractual obligations. The lawsuit between Monsanto and DuPont involved a restriction in the contract between the two parties that did not allow DuPont to use the Roundup Ready gene in its Optimum GAT line of seeds.

In that case, the court narrowly ruled that DuPont violated its contract with Monsanto. At the same time it allowed DuPont's antitrust case to move forward. That part of the lawsuit alleges that by restricting other seed producers from combining the Roundup Ready technology with their own genetic technology Monsanto is engaged in anti-competitive behavior.

These issues get more complicated with Monsanto losing its patent protection in a couple of years. To protect itself, Monsanto has created Roundup Ready 2 Yield using the same glyphosate-tolerant property but inserting it in a different location in the soybean gene. Monsanto is beginning to work to persuade its licensees to begin switching to the new technology-covered by a new patent-before its old patent runs out.

While the regulatory environment for the production of generic medicines is clear when a drug patent runs out, no such set of rules is in place for the production of a generic glyphosate-tolerant-undoubtedly "Roundup Ready" will remain a trademark of Monsanto, so those who produce a generic will not be able to use that term-soybean, let alone any other genetically modified organism (GMO).

In the absence of public policy in this area, the company is free to initially determine the rules. This will undoubtedly spark lawsuits in addition to DuPont's.

Below is a sampling of the issues that need to be clarified with regard to saving glyphosate-tolerant soybeans by farmers or its production by other seed firms:

- While farmers would be allowed to save Roundup Ready seed, will they be able to find seed that is not "stacked with other patented traits?" This possibility, which was identified in a National Public Radio (NPR) January 12, 2010 story, would be a problem for farmers but less so for seed companies who want to produce a generic glyphosate-tolerant seed. On the other hand, will seed companies go to the trouble of producing a generic glyphosate-tolerant seed knowing that once farmers buy it, farmers could/will tap their soybean granaries for seed from then on?
- In obtaining permission to sell seeds with the Roundup Ready trait in them, Monsanto had to provide a large amount of technical data to federal agencies. As NPR says, "generic providers would probably still need access to Monsanto's proprietary data to get federal approval to sell the Roundup Ready trait."
- They'd also need closely held technical data to update licenses that keep the trait legal in big, important markets like China and the EU," NPR reports.
- Monsanto has indicated that they will not enforce some of the other patents they have on technology that is necessary to insert the Roundup Ready gene in the seed gene, but how far does that go? Could Monsanto change its mind? Could Monsanto put limits on those other "process" technologies in the Roundup Ready 1

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trait when used in combination with additional traits developed by others?

- If a farmer does manage to find glyphosate tolerant soybean seeds that are not stacked with other patented genes, how will they prove to Monsanto that they are using seeds with the Roundup Ready 1 trait and not the Roundup Ready 2 Yield trait, especially if they try the new trait and decide to go back to the earlier technology?

After the patent runs out, can farmers sell some of their Roundup Ready soybean seeds to their neighbors who have never used the technology?

The permutations of potential issues seem end-

less in the absence of a clear set of public policies.

In coming years a large number of seed technologies will lose their patent protection. It would seem that a well thought out set of publicly developed rules and regulations is preferable to those announced by a private firm. This could provide protection for seed firms and farmers alike.

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