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Expiration of Biotech Crop Patents - Issues For Growers

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Overview

In the near future, the last of the Roundup Ready soybean patents will expire. That expiration will be followed by the expiration of other patents on biotech crops and expiring approvals in overseas markets like the European Union and China. Those expirations could lead to the planting of so-called “generic” versions of Roundup Ready seeds that lack approval in overseas markets, complicating the export process and potentially disrupting billions in trade. Whether the expirations will lead to lower seed prices and more choices for farmers is an open question and greater use of the historic practice of saving some seed and replanting it in the next crop season remains to be seen. But, as patents expire and regulatory approvals for overseas markets become uncertain, a significant question exists as to whether farmers will continue to have access to these markets.¹ Certainly, as patents begin to expire on various biotech crops, those crops will remain for a period of time in the commercial grain supply chain. That means that steps will likely be necessary to ensure that the crops will still meet requirements imposed by certain buyers such as the European Union and China. Without those steps, U.S. farmers could face problems in maintaining access to those markets. Another potential problem could arise if the holder of the expired patent develops and markets a new product that could potentially compete with the product for which the patent has expired (the so-called generic product).

Laws Governing Seed Sales

Federal Seed Act. The Federal Seed Act² was enacted in 1939 and is basically a truth-in-labeling law that is designed to protect buyers against purchasing mislabeled or contaminated seed by imposing stringent labeling requirements under which the class and variety of seed must be specified on the label of the seed product.

Plant Patent Act (PPA). Before 1930, it was generally believed that plants and other living organisms were not eligible for patent protection because they were products of nature and were not thought amenable to the written description requirement of patent law. The PPA³ addressed both of these concerns by statutorily recognizing that plant breeders created products that were more than mere products of nature, and specifically exempted plant patent applications from the written description requirement of general utility patent law. So, the PPA extended patent protection not only to inventors, but also to “discovers” of eligible subject matter. Under the PPA, protection is limited to plants and plant varieties that have already reproduced asexually. So, the PPA does not grant patent protection to plant species comprising most of commercial agriculture and is generally unavailable to plant breeders. The PPA should not be confused with utility patents for plants, a more recent development discussed below.

Plant Variety Protection Act (PVPA). The PVPA was enacted in 1970 and substantially modified in 1994. The PVPA grants “copyright-

like” protection to developers of novel varieties of sexually reproducible plants. Under the PVPA, it is unlawful to sell or grow a protected variety without permission of the holder of a plant variety protection certificate. Protection under the PVPA lasts for 20 years, but the major disadvantage of the PVPA to plant breeders is the so-called “saved seed” or “farmer exemption” that permits farmers to save an amount of seed necessary to plant the farmer’s next crop thereby eliminating their need to buy the protected variety directly from the seed company or authorized seed producer/seller.⁴

Patent Law. Article I, Section 8, Clause 8 of the U.S. Constitution gives the Congress the power to grant patents. A patent is a grant by the federal government to an inventor of the right to exclude others from making, using or selling the invention for a limited time. Patent law creates ownership rights in the results of innovation, and provides an economic incentive for the development of new products. A patent is a claim describing the boundary of the inventor’s property right that contains a written description of the invention, how the invention is made and used, and a series of drawings. To be patentable, an invention must consist of patentable subject matter, and be useful, novel and non-obvious.

In a key decision, the U.S. Supreme Court ruled in 1980 that living things such as genetically engineered microorganisms can be patented under general patent law so long as they satisfied the statutory criteria.⁵ The Court’s language was sufficiently broad to suggest that even plants that could be protected under the PPA or the PVPA could be the object of a general utility patent. Indeed, in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*,⁶ the Court specifically held that newly developed plant breeds fall within the terms and scope of general utility patent law, and that neither the PPA nor the PVPA limits the scope of coverage of the general utility patent law. The Court noted that the Congress has not given any indication of narrowing the scope of the general utility patent law’s application to plants since the *Chakrabarty* decision and that the

United States Patent and Trademark Office has issued nearly 2,000 utility patents for plants, plant parts and seeds since 1985. The Court held that something that can be protected under the PVPA may also qualify for patent protection as a utility patent under the general patent laws. Thus, biotech seeds can be patented and obtain 20-year protection without the problem of the “farmer exemption.” In addition, it is important to note that patent protection is not necessarily limited to genetically modified varieties. Conventional varieties may also be patented. The result is that no seeds can be saved from crops resulting from patented seeds – whether biotech or conventional.

The Current Landscape

Monsanto Corporation has developed the most popular soybean trait in use – Roundup Ready (RR). RR crops are not harmed by glyphosate which destroys practically all vegetation to which it is applied. It is estimated that about 95 percent of all soybean acres and 80 percent of corn acres are currently planted with RR seeds.⁷ However, Monsanto’s RR soybean patent will expire in the U.S. at the close of the 2014 planting season.⁸ That means that, starting with the 2015 planting season, producers will be able to use or stack the original RR trait without paying royalties to Monsanto, and may be able to save seed. In light of the patent expiration of its first generation of RR soybeans, Monsanto has developed a new gene – Roundup Ready 2 Yield (RR2Y) that it has incorporated in soybean varieties that are now coming onto the market. Monsanto has also obtained a patent for the RR2Y gene. As of June 2010, the RR2Y gene had been sold in 70 soybean varieties on six million acres in the United States.⁹ Farmers who are not convinced of a sufficient yield advantage with RR2Y varieties could be anticipated to generally prefer to use the original RR varieties after the patent expires to avoid paying the technology fee that is associated with use of varieties containing the RR2Y gene, and possibly to be able to save seed from the original RR varieties for replanting purposes.

Another issue is whether seed companies and soybean breeders will be able to incorporate the original RR gene into varieties after the patent expires. Monsanto presently has licensing agreements with breeders and seed companies concerning the use of either the original RR gene or the RRY2 gene. In addition, farmers are required to sign agreements when they plant these varieties stating that they cannot and will not save back the seed for replanting.¹⁰ The big question is whether Monsanto will issue additional licensing agreements for the original RR gene, and whether the failure to do so will prevent the gene from being used once the patent expires. If the original gene could still be used by a seed company (via license from Monsanto), then any new RR varieties with the original RR gene could possibly be grown and used by farmers in a whole new manner (depending on what kind of arrangement the seed companies (other than Monsanto) strike with farmers). Seed companies breeding RR varieties after the patent expiration may still have farmers sign agreements that the seed cannot be saved and replanted.

Some commentators have speculated that Monsanto will not share its RR2Y gene with other seed companies to the same degree that they did the original RR gene.¹¹ If that is true, and if the original RR gene could not be used due to expired licensing agreements that are not renewed, these commentators argue that Monsanto will be able to corner the soybean market in a short period of time. However, Monsanto has sought and continues to seek other seed companies to be licensees of the RR2Y trait, including “stacking” it with other traits.¹² Indeed, in late 2009, Monsanto announced that it had extended all of its RR seed licenses through the expiration of the patent term, and that seed company licensees who choose to work with RR2Y will be able to continue to sell varieties with the original RR gene after the patent expires. That will allow each licensee to decide on its own how to handle its own breeding and product offerings for customers. In addition, universities will be able to offer soybean varieties that contain the original RR gene. While some universities have been breeding

with the original RR gene for some time, they will be able to continue to do so even after the patent expires. But, Dupont Pioneer has decided to not be a licensee and instead has claimed that it has a legal right to use the original RR gene in stacks with other soybean traits.¹³

Based on Monsanto’s actions to date, it appears that potential trade disruption due to patent expiration and/or expiration of regulatory approvals will be minimal. But, as noted above, biotech crops may also be protected by the PVPA in addition to a general utility patent. That can bar U.S. producers from saving seed, but Monsanto has expressed its commitment to allowing growers to save RR varieties from the 2014 crop.¹⁴ But, some system may be desirable to allow companies to obtain and/or renew regulatory approvals in overseas markets for products that will contain non-patented traits.¹⁵ As time passes, if regulatory approvals are not renewed, trade disruption could result.¹⁶ Monsanto has also announced that it will keep filing for regulatory approval through at least 2021, that it won’t enforce the seed-retrieval aspects of soybean seed license contracts and that it is willing to make available health and safety data needed for regulatory approvals.¹⁷

Some foreign markets establish GMO tolerance levels for crops used for animal feed but not other uses. So, for U.S. farmers that grow crops for use as animal feed in foreign markets, the commingling of generic (off-patent) RR soybeans with conventional soybeans will probably not encounter any marketing problems if the amount of commingling is within an acceptable tolerance level. So, it will be important to keep informed as to various tolerance levels in global markets to make sure that such levels are not exceeded and global markets remain open. In light of this potential problem, as noted above, Monsanto announced in late 2009 that it would maintain the necessary registrations for RR soybeans in foreign markets through at least 2021. That will provide protection against the loss of the European Union and China markets to U.S. soybean producers.¹⁸ Monsanto has also stated its willingness to partially purchase international

agreements related to the RR trait for three years following the expiration of the patent at a cost of between \$1 million and \$2 million per year. Monsanto has also stated that it is willing to enter into contracts with other companies that want to begin their own research and development with respect to the RR trait.

Conclusion

The patent expiration of the first generation of RR soybean trait in 2014 will be the first time that a major biotech trait will become potentially subject to competition with generic traits. That could result in lower prices and more choices for farmers. That will most likely be the case if Monsanto sticks to its pledges to maintain and extend current licensing agreements and regulatory approval for overseas markets. Certainly, Monsanto has legal options that it can utilize to extend its existing monopoly and prevent competition among generic seed products. It appears at the present time that Monsanto does not plan to utilize those options to the extent of diminishing competition in the seed market. But, this entire matter is one that is developing.

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¹ The issue is significant inasmuch as approximately 50 percent of the U.S. soybean crop is exported annually.

² 7 U.S.C. §1551 *et seq.*

³ 35 U.S.C. §§161-164.

⁴ See, e.g., Asgrow Seed Co. v. Winterboer, 513 U.S. 179 (1995).

⁵ Diamond v. Chakrabarty, 447 U.S. 303 (1980).

⁶ 534 U.S. 124 (2001).

⁷ See, Stumo, "Anticompetitive Tactics in Ag Biotech Could Stifle Entrance of Generic Traits," 15 Drake Journal of Agricultural Law No. 1, pp. 139-140 (2010).

⁸ Monsanto's RR soybean patent expires in Canada in 2011.

⁹ Joint Press Release, "Monsanto Dow AgroSciences Reach New Licensing Agreement," Jun. 2, 2010, as cited in Redick and Hawker, "Legal Issues Arising

From Generic Biotech Crops," Agricultural Law Update (Dec. 2010). The RR2Y trait was first available to growers for planting in 2009.

¹⁰ This is a big issue with respect to soybeans. From an agronomic perspective, there is no problem in replanting soybean seed (unlike there is with corn hybrids).

¹¹ See, Stumo, "Anticompetitive Tactics in Ag Biotech Could Stifle Entrance of Generic Traits," 15 Drake Journal of Agricultural Law No. 1 (2010). However, serious errors are contained in this article. For example, Monsanto had already publicly announced its commitment to renew approvals before the article was published.

¹² See, Redick and Hawker, "Legal Issues Arising From Generic Biotech Crops," Agricultural Law Update (Dec. 2010). The authors note that Monsanto's licensing agreement with Dow Agrosciences with respect to RRY2 allows the licensee to "stack" the gene with other traits.

¹³ *Id.* The authors note that Monsanto has publicly stated that it has offered Dupont Pioneer a license that would provide these rights for an additional royalty. In turn, Monsanto claims that Dupont Pioneer does not have the legal right to stack the original RR soybean gene with traits that also resist Roundup. Dupont Pioneer has developed soybean varieties that include a trait that it has developed in combination with the original RR gene, and Monsanto has sued Dupont Pioneer to bar the commercialization of these products.

¹⁴ Other major seed companies, however, have not addressed the issue at the present time.

¹⁵ The American Soybean Association has become a leader in pushing for the creation of a system of data access and compensation for the acquisition and renewal of regulatory approval for generic traits in overseas markets.

¹⁶ If regulatory approvals are not obtained, not only could trade disruption result, but liability risks could also be involved along the lines of what happened with the Starlink matter and the genetically modified rice litigation in the U.S. in recent years.

¹⁷ Letter to stakeholders dated December 15, 2009 and letter to Stephen Censky dated July 8, 2010, reference in Redick and Hawker, "Legal Issues Arising From Generic Biotech Crops," Agricultural Law Update (Dec. 2010). If registration were to expire the technology would have to go through the testing process again to ensure that the soybeans are environmentally safe and safe for consumption.

¹⁸ This is an important point. As stated in Redick and Hawker (see FNs 9 and 12 above), according to the USDA, China's soybean imports for the 2009-2010

fiscal year could reach 46 million tons (over \$17.4 billion), rising to 49 million tons (over \$18.5 billion) in 2010-2011.