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Expiring Seed Patents and the Farming Communities of North Dakota: Where Gaps in Patent Protection Offer Opportunities for Innovation

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EXPIRING SEED PATENTS AND THE FARMING COMMUNITIES OF NORTH DAKOTA: WHERE GAPS IN PATENT PROTECTION OFFER OPPORTUNITIES FOR INNOVATION

ABSTRACT

As genetically modified (“GM”) seed patents held by massive corporations like Monsanto begin to expire, generic seed makers have an opportunity to enter the market. What does this mean for farmers in North Dakota and elsewhere across the nation? First, it could end a cycle of reliance on a single manufacturer, which has been reinforced and perpetuated by agreements preventing farmers from saving seeds from one season to the next. Second, it could create new research opportunities for state-funded seed variety development programs to develop similar genetically modified seeds for local farmers. North Dakota’s legislature should work to create a statutory framework to support innovation in biotechnology, as opportunity for competition arises with the expiration of certain GM seed patents.

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PREFACE

While guarding the most comprehensive and rare seed collection in the world, a group of Russian scientists starved to death, choosing to forego consumption of the subject of their research in favor of its preservation.¹

In the early 1920s through the 1940s, Russian geneticist and plant geographer, Nikolay Vavilov, tirelessly defended his “mission for all humanity,” the study, collection, and preservation of the largest seed collection in the world.² Vavilov, a proponent of the Mendelian theory of genetics, which embodies the notion that genes are passed on unchanged between generations, faced harsh opposition from Stalin who complained that the slow process of seed breeding and selection caused famine in the Soviet Union.³ Frustrated with low yields and decreased farm productivity, Stalin imprisoned

1. David Greene, *Researchers Fight to Save Fruits of Their Labor*, NPR (Aug. 30, 2010), <http://www.npr.org/templates/story/story.php?storyId=129499099>.

2. Rakesh Krishnan Simha, *The men who starved to death to save the world's seeds*, RUSSIA & INDIA REPORT (May 12, 2014), https://in.rbth.com/blogs/2014/05/12/the_men_who_starved_to_death_to_save_the_worlds_seeds_35135.

3. *Id.*

Vavilov and subjected him to hours of questioning during which he unwaveringly stood behind his science.⁴ A year and a half into his subsequent period of imprisonment, Vavilov starved to death.⁵ At the same time, beyond the confines of imprisonment, a group of Vavilov's scientists, guarding their secret collection of 370,000 seeds, starved to death while nobly protecting the seeds for future generations.⁶ The Vavilov crew's extreme devotion to the protection of seeds shows how important early advances in seed modification were perceived. The slow and delicate process of growing, breeding, and documenting modification of traits in seeds could have been completely destroyed in an instant and to replace the collection would have taken decades at a minimum.

Preservation of seeds and the study of their genetic inheritance traits is now as important as it was then. Modification of traits can result in higher yielding crops. What started out with Mendel as the calculated breeding of populations to better understand the inheritance of traits, has developed now to the current study of commercial production of hybrid seeds and genetic modifications of agricultural seeds to ensure seeds can withstand pesticides and regional disease threats.⁷ Legal protections in patenting have developed alongside the developments in seed production to ensure the technology is protected and compensation provided.⁸ Patentability of nature in and of itself poses unique challenges in the indefiniteness of patent protection, the ethical roadblocks associated with patenting living matter, and the public policy concerns for encouraging innovation.⁹ In addition to the formal patent framework protecting advances in seed production, agricultural state statutes have

4. *Id.*

5. *Id.*

6. *Id.*

7. Harold Wright, *Commercial Hybrid Seed Production*, DEKALB AGRERESEARCH, INC (1980), <https://dl.sciencesocieties.org/publications/books/abstracts/acesspublicati/hybridizationof/161?access=0&view=pdf>; *see also* SEEDS, <http://www.monsanto.com/products/pages/monanto-agricultural-seeds.aspx> (last visited June 19, 2017).

8. ROUNDUP READY SOYBEAN PATENT EXPIRATION, <http://www.monsanto.com/newsviews/pages/roundup-ready-patent-expiration.aspx> (last visited June 19, 2017).

9. Jeremy A. Cubert, *Are Biotechnology Patents Dead?*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (June 19, 2017, 8:50 PM), <http://www.genengnews.com/insight-and-intelligence/are-biotechnology-patents-dead/77900698> (discussing patentability of nature); George Goodno, *BIO Opposes H.R. 9, The Innovation Act*, BIO (June 11, 2015), <https://www.bio.org/media/press-release/bio-opposes-hr-9-innovation-act> (expressing opposition to the proposed Innovation Act); H.R.9 - INNOVATION ACT, 114TH CONGRESS (2015-2016), <https://www.congress.gov/bill/114th-congress/house-bill/9>; Antonio Regalado, *As Patents Expire, Farmers Plant Generic GMOs*, MIT TECHNOLOGY REVIEW (July 30, 2015), <https://www.technologyreview.com/s/539746/as-patents-expire-farmers-plant-generic-gmos/> (discussing indefiniteness of patents).

developed across the nation to address the regulatory aspect of farmers using products derived from advances in the biotechnology industry as a whole.¹⁰

I. INTRODUCTION

To understand the relationship between private seed companies like Monsanto and the farming industry in the United States, it is important first to contextualize the introduction of genetically modified seeds into the larger development of changing farming practices in the last two hundred years.

In the 1700s, farm “technology” included oxen and horses, wooden plows (the first cast-iron plow was patented in 1797), hoes, sickles, and flails; the labor was exclusively powered by humans and animals.¹¹ In 1849, the first mixed chemical fertilizers began being sold commercially with average annual consumption growing from 1,845,900 tons in 1890-99 to 21,800,000 tons in 2011.¹² Although the technology for tractors had begun development as early as 1892, the total change from horses to tractors, signifying the “second American agricultural revolution” did not occur until the period between 1945-70.¹³ Advancements in farm technologies and practices meant that what once took 250-300 labor-hours to produce 100 bushels of wheat in 1830, took only three labor hours to yield that same amount in 1987.¹⁴ And finally, arguably the most recent American agricultural revolution came in 1997 with the first commercially available genetically modified weed and insect-resistant soybean and cotton crops.¹⁵

During the late 1990’s and early 2000’s, Tennessee farmer, Kem Ralph, engaged in an intense legal battle with agricultural biotechnology corporation, Monsanto.¹⁶ What prompted nearly a decade’s worth of litigation resulting in time behind bars for Ralph, in addition to a \$3 million judgment for Monsanto? Saving seeds.

As the top seed company in the world, with sales at \$11.8 billion and a 27% control over the global proprietary seed market, Monsanto takes steps

10. *State Biotech Statutes*, NATIONAL CONFERENCE OF STATE LEGISLATURES (2011) <http://www.ncsl.org/research/agriculture-and-rural-development/state-biotech-statutes.aspx>.

11. *Historical Timeline: Farm Machinery & Technology*, GROWING A NATION; THE STORY OF AMERICAN AGRICULTURE, http://www.agclassroom.org/gan/timeline/farm_tech.htm (last visited June 19, 2017).

12. *Id.*; see also EPA, REPORT ON THE ENVIRONMENT: AGRICULTURAL FERTILIZER, https://cfpub.epa.gov/roe/indicator_pdf.cfm?i=55.

13. GROWING A NATION, *supra* note 11.

14. *Id.*

15. *Id.*

16. Andy Meek, *Down and Out in Covington*, DAILY NEWS (June 22, 2006), <https://www.memphisdailynews.com/editorial/Article.aspx?id=30496>.

to insure its innovations in genetically modified seed production are protected.¹⁷ Those steps include patenting the genetically modified seed, developed to guarantee compensation for the products which are the result of investments of over \$2.6 million a day in research and development.¹⁸

When purchasing the patented seeds, farmers are required to sign a contract prohibiting them from saving and replanting seeds produced from the purchased patented seed.¹⁹ When farmers violate these contracts and Monsanto learns of that violation either on its own or through third-party notifications (like neighboring farmers noticing the offender), an attempt is made to settle the issue or if no settlement is reached, to proceed with litigation.²⁰ Monsanto's website offers three justifications for engaging in litigation with those farmers who save seeds in breach of their contracts: first, Monsanto says that no business can survive without compensation for its product; second, the loss of revenue would curtail future funding for research; and, third, failing to enforce the contracts would be unfair to those who honor the agreements at greater costs.²¹

Monsanto is just one example, albeit the most prominent, of large seed companies patenting genetically engineered seeds. Other large seed companies in the market include Bayer, BASF, Dow, and DuPont--the aggregate accounting for more than half of the world's sales of seeds.²² Such widespread control of the seed industry leads to a centralization and isolation of the technologies developed by those companies to manufacture genetically modified seeds.

The seed patents, however, are not indefinite, and expiration dates present opportunities for farmers to do what would formerly have been forbidden: save seeds.²³ In 2015, the patent on one of Monsanto's earliest genetically modified seeds, Roundup Ready soybeans, expired.²⁴ On its website, Monsanto issued a news release acknowledging the expiration of the Roundup Ready soybean patent and the ensuing possibility for farmers to

17. Arjylee Shing Castro, *Top 7 Seed-Provider and Giant Companies in Agriculture Industry*, FOUNDEREED-PROV (July 10, 2015), <http://foundersguide.com/top-agricultural-companies-in-the-world/>.

18. *Why Does Monsanto Sue Farmers Who Save Seeds?*, MONSANTO, <http://www.monsanto.com/newsviews/pages/why-does-monsanto-sue-farmers-who-save-seeds.aspx> (last visited June 19, 2017).

19. *Id.*

20. *Id.*

21. *Id.*

22. Nathanael Johnson, *The world's biggest seed companies are wooing*, GRIST (July 19, 2016), <http://grist.org/business-technology/the-worlds-biggest-seed-companies-are-wooing/>.

23. Regalado, *supra* note 9.

24. *Id.*

save seed from that variety of soybean.²⁵ There are some steps farmers must take to make sure they are operating with applicable licenses and observing the rules of seed saving, including the limitation that seeds being saved from their farms can only be used back on their own farms.²⁶ In the same release announcing the expiration of Roundup Ready soybeans, Monsanto also mentioned the advances in research and development that have led to the mapping of the soybean genome, the development of better trait insertion techniques, and the identification of specific traits that ensure higher yields for farmers.²⁷ The product encompassing these developments is called Genuity Roundup Ready 2 Yield and was launched in 2009, making it as of 2017, still under patent protection.²⁸

The tradeoff is pretty clear in Monsanto's release: farmers can have access to seeds no longer protected by patents but newer developments in seed modifications make patent-protected varieties more appealing and higher-yielding.²⁹ Some say that the tradeoff is so imbalanced that choosing off-brand generics of the expired Roundup Ready soybeans instead of the newer Genuity Roundup Ready 2 Yield would actually result in losses for farmers.³⁰ Harry Stine, head of Iowa's Stine Seeds, said that even if the off-patent seeds were free, "farmers would still lose money by growing fewer beans."³¹

If farmers are choosing to save seeds instead of getting generic versions of patent-expired seeds, there are also costs associated just with the process of saving seed that may also outweigh the higher cost associated with buying a newer patent-protected seed.³² Costs such as extra time spent during harvest to protect handling of the seed, extra cost of storing the seed, increased cost of cleaning the seed, and getting it treated, might dissuade farmers from getting licenses to save seed.³³

Even in light of the tradeoff, the expiring patent has enticed competitors to produce generic genetically modified seeds.³⁴ At the University of Arkansas' Crop Variety Improvement Program, plant breeder, Pengyin Chen, developed a generic Roundup Ready soybean, which since the expiration of the

25. *Roundup Ready Soybean Patent Expiration*, MONSANTO (Apr. 9, 2017), <http://www.monsanto.com/newsviews/pages/roundup-ready-patent-expiration.aspx>.

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. Regalado, *supra* note 9.

31. *Id.*

32. J.H. Orf, *Implications for Growers When Roundup Ready® (RR1) Goes Off Patent*, INSTITUTE OF AG PROFESSIONALS (Dec. 2013), <https://www.extension.umn.edu/agriculture/ag-professionals/cpm/2013/docs/UMN-Ext-CPM13-Orf.pdf>.

33. *Id.*

34. *Id.*

Roundup Ready soybean patent, has sold in 2400 bags as of July 2015.³⁵ The Roundup Ready patented soybeans are genetically engineered to withstand glyphosate, the active weed-killing ingredient in Roundup (also developed by Monsanto).³⁶ When universities undertake development of genetically engineered seeds, they can add traits targeted to threats specific to the geographic region in addition to the glyphosate-resistant trait, making a product specifically tailored to the region, with the benefits of Roundup Ready technology.³⁷ Along with the University of Arkansas, the University of Missouri has developed generic Roundup Ready seeds with additional protections for dangers unique to the Missouri geography including nematodes, sudden death syndrome, and frogeye leaf spots.³⁸

The cost of the generic seeds (as with pharmaceutical generics) typically run cheaper than the original patent protected seed. The University of Arkansas sold its generic GM soybean seeds for less than half the original \$55-\$70 price of the Monsanto patented seeds.³⁹ Randy Baker, a seed salesman in Northeast Missouri, told Harvest Public Media in 2015 that “[t]his is the perfect time for generics . . . [w]ith low returns on commodity prices the past two years, farmers are looking to cut input costs.”⁴⁰

North Dakota State University (“NDSU”), through the North Dakota Agricultural Experiment Station, published trial results for 2016 soybean variety selection with special attention to geographic-specific soybean susceptibilities.⁴¹ The trial results note that phytophthora root rot, white mold, iron-deficiency chlorosis, and soybean cyst nematode are four problems in North Dakota facing soybean farming.⁴² The NDSU soybean breeding will incorporate the Roundup Ready traits, in addition to updated disease and yield traits specific to the conditions and susceptibilities of North Dakota farms with release to public anticipated for 2018.⁴³ Like the seeds developed at the University of Arkansas and the University of Missouri, those developed at

35. *Id.*

36. Kristofor Husted, *Business Beat - University-made Roundup Ready seeds ready for market*, KBIA (Dec. 2, 2015), <http://kbia.org/post/business-beat-university-made-roundup-ready-seeds-ready-market#stream/0>.

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. *North Dakota Soybean Variety Trial Results for 2016 and Selection Guide*, N.D. ST. U. – N.D. AGRIC. EXPERIMENT STATION (Dec. 2016), https://www.ag.ndsu.edu/pubs/plantsci/rowcrops/a843_16.pdf.

42. *Id.*

43. Lon Tonneson, *NDSU to release Roundup Ready seed you can save*, DAKOTA FARMER, (Feb. 2015), <http://magissues.farmprogress.com/DFM/DK02Feb15/dfm021.pdf>.

NDSU will be able to be saved and planted without the fines and penalties associated with the formerly patent protected Roundup Ready variety.⁴⁴

II. BRIEF HISTORY OF PATENTING SEEDS

Early United States history began with seed trades between European settlers and Native Americans.⁴⁵ In 1839, the U.S. Patent Office established an Agricultural Division whose mission was to “acquire, propagate, evaluate and distribute seeds and plants, and to collect agricultural statistics and production information.”⁴⁶ Then in 1862 that branch of the Patent Office separated, creating the U.S. Department of Agriculture, which focused at least one-third of its budget on collection and distribution of seeds to U.S. farmers.⁴⁷ This government-run seed saving and genetic-breeding program (which included public funding to land grant universities and experimental and research services for rural communities), continued until the emergence of a desire to privatize and commercialize those programs induced the creation of various intellectual property rights and patent regimes providing protections for seed developments.⁴⁸

A. LEGAL BACKGROUND OF PATENTING NATURE

In 1930, Congress passed the Townsend-Purnell Plant Patent Act⁴⁹ in an effort to amend existing general patent law so that the language could be construed to provide patenting protection to asexually reproduced plants.⁵⁰ In 1970, after discovering that “true-to-type” reproduction (similar to the results from asexual reproduction) could be achieved via sexually reproduced plants,

44. *Id.*

45. *History of U.S. Seed Development and Patent Regimes*, CENTER FOR FOOD SAFETY, <http://www.centerforfoodsafety.org/issues/303/seeds/history-of-us-seed-development-and-patent-regimes#> (last visited June 20, 2017).

46. *The History of USDA Slide Show*, U.S. DEP'T OF AGRIC.; AGRIC. RES. SERV (Aug. 12, 2016), <https://www.ars.usda.gov/northeast-area/docs/barc-centennial/aboutus/>.

47. *Id.*; CENTER FOR FOOD SAFETY, *supra* note 45.

48. *Development of the Seed Patent System*, CENTER FOR FOOD SAFETY, <http://www.centerforfoodsafety.org/issues/303/seeds/development-of-the-seed-patent-system> (last visited June 19, 2017).

49. 35 U.S.C. §§ 161-164.

50. Ann K. Wooster, Annotation, *Construction and application of Plant Patent Act (35 U.S.C.A. §§ 161 et seq.)*, 135 A.L.R. Fed. 273, *2; see also *Plant Reproduction*, UNITED STATES PATENT AND TRADEMARK OFFICE, *General Information About 35 U.S.C. 161 Plant Patents*, <https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/general-information-about-35-usc-161#heading-4> (last visited July 19, 2017) (“Asexual reproduction is the propagation of a plant to multiply the plant without the use of genetic seeds to assure an exact genetic copy of the plant being reproduced.”).

Congress passed the Plant Variety Protection Act⁵¹ (“PVPA”) to provide similar protection for novel varieties of sexually reproduced plants, as those that already existed for asexually reproduced plants.⁵² The PVPA is implemented by the Plant Variety Protection Office (“PVPO”), an office within the United States Department of Agriculture, which grants certificates to protect varieties for twenty years for plants and twenty-five years for vines and trees.⁵³

In 1980, the Bayh-Dole Act was created and provided universities the right to obtain patents on inventions created with the use of government grants.⁵⁴ The Act affords protection to university innovations and a source of revenue for university research.⁵⁵ However, there is some indication that the intellectual property rights granted to universities via the Bayh-Dole Act might hinder the free flow of ideas and discourse between universities that would otherwise encourage innovation.⁵⁶

With updates to the United States Code Title 35 on Patents, subsequent litigation has clarified ambiguities in the scope of the patentability of natural products. In the 1980 Supreme Court case, *Diamond v. Chakrabarty*, the Court upheld a utility patent for a genetically engineered bacterium.⁵⁷ In deciding the case, the Court was tasked with determining whether a microorganism constituted a “manufacture” or “composition of matter” within the meaning of 35 U.S.C. § 101, which provides, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁵⁸ The Court held that the intent of Congress in drafting the Plant Patent Act was to distinguish between products of nature, whether living or not, and products of human-made inventions, not between living and inanimate things.⁵⁹

In 2001, the Court again looked at the scope of patentability under 35 U.S.C. § 101 in *J.E.M. Ag Supply v. Pioneer Hi-Bred International*.⁶⁰ In

51. 7 U.S.C. § 2321.

52. Wooster, *supra* note 50.

53. *Plant Variety Protection*, U.S. DEP’T AGRIC.: AGRIC. MARKETING SERV., <https://www.ams.usda.gov/services/plant-variety-protection> (last visited June 19, 2017) (The most recent PVP certificate issued to NDSU Research Foundation was in May 2016 for the “Dakota Ruby” variety of the potato crop. In comparison, that same issuance of certificates included 42 separate PVP certificates to Monsanto (out of 108 total certificates issued)).

54. John H. Barton & Peter Berger, *Patenting Agriculture*, Vol. 17, SUMMER 2001, ISSUES IN SCIENCE AND TECHNOLOGY (2001), <http://issues.org/17-4/barton/>; *see also* 37 C.F.R. § 401.

55. *Id.*

56. *Id.*

57. *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

58. *Id.* at 307 (citing 35 U.S.C. § 101).

59. *Id.* at 313.

60. *J.E.M. Ag Supply v. Pioneer Hi-Bred international*, 534 U.S. 124 (2001).

J.E.M., the Court upheld a utility patent⁶¹ held by Pioneer Hi-Bred, finding that plants were afforded protection under the PVPA, the PPA, and utility patents under 35 U.S.C. § 101.⁶² Pioneer Hi-Bred sold patented hybrid seeds⁶³ with a limited label license, which restricted the use of the seeds or the progeny thereof, “for propagation or seed multiplication or for production or development of a hybrid or different variety of seed.”⁶⁴

Pioneer Hi-Bred alleged that one of its purchasers, Farm Advantage, was infringing on the utility patent by selling or marketing the protected variety or sexual multipliers of the variety without notice that the variety was protected.⁶⁵ The Court held that newly developed plant breeds did fall within the terms of § 101, and a utility patent for plants issued under that section could not be limited by the PPA or the PVPA.⁶⁶

Patent exhaustion is the principle the Supreme Court relied on in ruling that farmers “saving seeds” from one harvest to the next violates patent protection.⁶⁷ In *Bowman v. Monsanto*, a farmer who had repeatedly purchased and planted Monsanto-developed patented seeds decided instead one season to save money by purchasing seed intended for consumption directly from a grain elevator.⁶⁸ Relying on the accurate assumption that most of the seed in the elevator was grown from Monsanto-patented seed (and would therefore also possess the same glyphosate-resistant traits), the farmer planted the seed, harvested it, and then continued to save and replant the harvested product.⁶⁹

61. Under 35 U.S.C. § 101 (1994 ed.), a utility patent is issued to, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” See 35 U.S.C. § 101. In addition, §§ 102 and 103 specify that the utility patentable plant must be new, useful and nonobvious. See 35 U.S.C. §§ 102-03. The utility patent is contrasted with the PVP, which requires no such showing of usefulness or nonobviousness. *Id.*

62. *J.E.M.*, 534 U.S. at 124.

63. Justice Thomas’s opinion in *J.E.M.*, explains that a hybrid seed is:

[P]roduced by crossing two inbred . . . plants and are especially valuable because they produce strong and vibrant hybrid plants with selected highly desirable characteristics . . . [They] generally do not reproduce true-to-type, *i.e.*, seeds produced by a hybrid plant do not reliably yield plants with the same hybrid characteristics. Thus, a farmer who wished to continue growing hybrid plants generally needs to buy more hybrid seed. *J.E.M.*, 534 U.S. at 128.

64. *J.E.M.*, 534 U.S. at 128 (quoting U.S. Patent No. 5,491,295).

65. *Id.* at 139.

66. *Id.* at 145.

67. *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013).

68. *Id.* at 1763.

69. *Id.*

Once Monsanto brought suit for patent infringement, the farmer raised the patent exhaustion⁷⁰ defense, claiming that the initial sale of seeds terminated Monsanto's patent rights in the elevator-purchased seed.⁷¹ Rejecting that defense, the Court reasoned that the patent exhaustion doctrine would not prevent a farmer from purchasing seed from an elevator and then reselling it, consuming it, or using it as feed, but it would prevent a farmer from using it to make⁷² additional patented seeds.⁷³ Were it any other way, the Court speculated, patent protection would afford little protection for the innovation and research expenses incurred in developing genetically modified seeds, and that would be directly contrary to Congress's intent in drafting patent legislation.⁷⁴

The farmer then attempted to claim that because of the way plants grow--naturally self-replicating--the patent-protected seed acted on its own in making additional seeds, and therefore he was not involved in "making" the additional patent-protected seeds.⁷⁵ The Court rejected this argument as well, reasoning that the peripheral actions he took in buying the seed and moving it from the elevator to the field, planting it, harvesting, saving the seeds, and then replanting the saved seeds was enough to qualify him (and not the seed) as the actor responsible for making the infringing products.⁷⁶ However, in coming to this conclusion, the Court did note that its holding was limited to the particular facts of the *Bowman* case, recognizing that the complexities of self-replicating products might challenge the contours of the patent exhaustion doctrine in future instances.⁷⁷

B. CONTEMPORARY INTERPRETATIONS OF PATENTING NATURE

In 2015, the Supreme Court denied certiorari on a case involving a patent claiming certain uses of cell-free fetal DNA ("cffDNA"), thereby affirming the ruling of the Court of Appeals for the Federal Circuit.⁷⁸ In *Ariosa Diagnostics v. Sequenom*, the court reviewed a claim of infringement by Sequenom, a company that manufactured a method for detecting "the small

70. "Under the patent exhaustion doctrine, 'the initial authorized sale of a patented article terminates all patent rights to that item,' . . . and confers on the purchaser, or any subsequent owner, 'the right to use [or] sell' the thing as he sees fit." *Id.* (citing *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 625 (2008); *United States v. Univis Lens Co.*, 316 U.S. 241, 249-50 (1942)).

71. *Bowman*, 133 S. Ct. at 1763.

72. Patent protection affords the patent-holder the right to exclude others from *making* the article. 35 U.S.C. § 154(a)(1) (2015) (emphasis added).

73. *Bowman*, 133 S. Ct. at 1766.

74. *Id.* at 1767-68.

75. *Id.* at 1768-69.

76. *Id.* at 1769.

77. *Id.*

78. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).

fraction of paternally inherited cffDNA in maternal plasma or serum to determine fetal characteristics, such as gender.”⁷⁹ Sequenom alleged that Ariosa Diagnostics had developed a product, the Harmony Test, which is a non-invasive test used to identify certain fetal characteristics based off of genetic information in fetal DNA in the blood of the pregnant woman.⁸⁰

In evaluating the *Sequenom* case, the court referred to the framework established in the predecessor *Mayo* case, which allows for distinguishing patents “that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.”⁸¹ The first step in the *Mayo* analysis, is to determine whether the claims are directed to patent-ineligible concepts.⁸² The court in *Sequenom*, found that under the first prong, method claims (like the one at issue) are generally eligible subject matter.⁸³ However, because the methods at issue were directed to detecting a naturally occurring phenomenon, and because the method used to detect that phenomenon began and ended with naturally occurring phenomenon, the claim did not fulfill the first prong of the *Mayo* test and required examination under the second prong.⁸⁴ The second prong of the *Mayo* framework requires an examination of the elements of the claim to determine whether the claim “contains an inventive concept sufficient to ‘transform’ the claimed naturally occurring phenomenon into a patent-eligible application.”⁸⁵ Under this prong, the court found that Sequenom’s patent contained no additional new and useful subject matter to elevate the claim into a patent-eligible application.⁸⁶ The steps in *Mayo* and *Sequenom* show a recent trend for limiting patent protections for biotechnology inventions.

C. TENSION BETWEEN STRENGTHENING AND WEAKENING PATENTABILITY

On one hand, advocates of broader applicability of patentability claim that limiting patentable subject matter discourages investment and therefore innovation.⁸⁷ On the other hand, opposing that view is the notion that restricting patentable subject matter actually encourages competition. Advocates of this school of thought see the trend in diagnostics as relying heavily

79. *Id.* at 1374.

80. *Id.*

81. *Id.* at 1375.

82. *Id.*

83. *Id.* at 1376.

84. *Sequenom, Inc.*, 788 F.3d at 1376.

85. *Id.*

86. *Id.* at 1377.

87. Cubert, *supra* note 9.

on “data mining platforms” and products that rely much more on speed rather than the longevity afforded by patent protections.⁸⁸

In response to this tension, inventors and developers in biotechnology fields creating products that rely on or are closely dependent on natural products, could increase the likelihood of a court finding patentability by making deliberate changes to the molecules at issue.⁸⁹ This strategy applies equally to diagnostics as it does to genetically modified agricultural advances.

III. SEED PATENT RELATED NORTH DAKOTA LAW

Agriculture is one of North Dakota’s most valued economic contributors. Not surprisingly, regulatory and statutory frameworks have emerged to support the relationship between the state and its agricultural production.⁹⁰ In addition to federal patent laws, state administrative agencies provide a mechanism for governing that impacts the seed manufacturing industry.

A. REGULATORY BACKGROUND IN NORTH DAKOTA

In 1890, the North Dakota Agricultural Experiment Station (“NDAES”) was established pursuant to the Hatch Act,⁹¹ in order to “promote efficient production, marketing distribution and utilization of products of farm as essential to health and welfare of our peoples and . . . to assure agriculture’s position in research equal to that of industry.”⁹² The 2016 Highlights for NDAES feature three new crop varieties developed using traditional breeding methods.⁹³ These include ND Bison, a conventional soybean variety; ND Dylan, a winter rye variety; and ND Palomino, a slow-darkening pinto bean released jointly by the NDAES and the U.S. Department of Agriculture - Agricultural Research Service.⁹⁴ NDSU also has a program called North Dakota Foundation Seed Stock Program, where breeders plant new varieties of plants, evaluate their performance, plant it to the point where they have 2000 to 4000 bushels of the new seed, and then distribute it to county seed increase

88. *Id.*

89. *Id.*

90. *Agriculture*, NORTH DAKOTA DEP’T OF COM., <http://www.business.nd.gov/agriculture/>.

91. Federal legislation passed in 1887 establishing state Experiment Stations. *North Dakota Agricultural Experiment Station*, NORTH DAKOTA STATE UNIVERSITY, <https://www.ag.ndsu.edu/research/history> (last visited June 19, 2017).

92. *North Dakota Agricultural Experiment Station*, *supra* note 41.

93. As opposed to genetically modified breeding methods, traditional breeding methods do not require the use of genetic transformation and may take a decade if not longer to develop.

94. *New Crop Varieties Offer Opportunities*, NDSU AGRIC. COM., at 6 (2016), https://www.ndsu.edu/fileadmin/vpag/Annual_Highlights/2016_Annual_Highlights_final.pdf.

programs across North Dakota.⁹⁵ The Foundation Seedstocks Project (“FSS”) aims to (1) “[i]ncrease, maintain and distribute genetically pure foundation class seed of new and established crop cultivars”; (2) “[c]oordinate the Seedstocks program with other agencies in North Dakota and other states or countries”; and (3) “[i]mplement improved systems for foundation seed increase and distribution.”⁹⁶ FSS “purifies the genetics” of new varieties of plants using “labor intensive field rouging, single head selections and head row increases.”⁹⁷ Within the FSS, is the Seed Increase Program, which distributes new field crop varieties (protected by the Plant Variety Protection Act) released by plant breeders at NDAES.⁹⁸

In 1931, the North Dakota Legislature established the Seed Department to oversee all seed certification and regulatory matters.⁹⁹ Apart from providing services relating to inspection, testing, and regulatory enforcement for all crops, the Department also operates laboratory services on the NDSU campus.¹⁰⁰

B. STATE STATUTORY FRAMEWORK FOR BIOTECHNOLOGY

North Dakota Century Code § 4-24-13, titled “Genetically modified seed - Patent infringement - Sampling - Mediation” enacted in 2001, provides a statutory framework relating to the sampling of genetically modified crops.¹⁰¹ The 2001 House Agriculture Committee meeting minutes reflect the discussions surrounding the introduction of what is now § 4-24-13.¹⁰² In introducing House Bill 1442, Representative Lemieux paints a picture of children cooperating with one another on a playground:

When we were younger we all played games and every game had it’s [sic] own rules. When we played games on the playground when we were little the rules tried to make it fair for the little guy to play with

95. Dale Hildebrant, *Foundation seed stocks program plays vital role in developing new varieties*, FARM & RANCH GUIDE (Feb. 13, 2015), http://www.farmandranchguide.com/feature/seed_guide/foundation-seed-stocks-program-plays-vital-role-in-developing-new/article_909f611a-b3ab-11e4-8f53-af799a62496d.html; *North Dakota Foundation Seedstocks*, NORTH DAKOTA STATE UNIVERSITY (last updated Dec. 29, 2015), <https://www.ag.ndsu.edu/fss>.

96. *Foundation Seedstocks Program (FSS)*, NDSU AGRICULTURE, https://www.ag.ndsu.edu/fss/copy_of_FoundationSeedstocksProgram.pdf.

97. *Id.*

98. *North Dakota Foundation Seedstocks*, *supra* note 95.

99. Welcome, *North Dakota State Seed Department*, NORTH DAKOTA STATE GOVERNMENT, <http://www.nd.gov/seed/> (last visited June 19, 2017).

100. *Id.*

101. H.R. 1442, 57th Leg. Assemb., Reg. Sess. (N.D. 2001).

102. *2001 House Standing Committee Minutes: Hearing on H.R. 1442 Before the House Agric. Comm.*, 57th Leg. Assemb., Reg. Sess. (N.D. 2001) (statement of Rep. Lemieux, sponsor of 1442).

the big guys. No one got hurt, everyone had fun and it was an enjoyable afternoon on the playground. HB 1442 is an attempt to establish some rules by which we all play.¹⁰³

Lemieux then goes on to state that farmers were at that time farming with GMO crops and that HB 1442 was an effort to insure farmers were not infringing on “Monsanto rights to protect their patent.”¹⁰⁴

Present at the 2001 hearing was a Monsanto representative who voiced concerns over the five-day waiting period imposed on patent holders wishing to enter the land of a supposed-infringer.¹⁰⁵ The proposed bill required, “[u]nless a shorter period of time is agreed to in writing or ordered by the district court, samples may not be collected until a period of at least *five days* has passed from the time the farmer gave written permission or from the date of the court order.”¹⁰⁶ (emphasis added). The Monsanto representative objected to the five-day moratorium on entering potential-infringer’s property by saying that the five-day period “. . . creates a[n] opportunity for mischief. Within five days you can do a lot to alter, damage or destroy evidence that we would need to gather to demonstrate that patent[s] had been violated.”¹⁰⁷

The current version of § 4-24-13 includes no mention of the five-day moratorium, and instead permits the patent-holder to enter upon the land of the alleged patent-infringer after (1) notifying the agriculture commissioner, (2) notifying the farmer, and (3) obtaining the farmer’s permission.¹⁰⁸ The House Committee minutes reflect the close relationship between the patent-holding companies (like Monsanto) and the state legislature in establishing a framework to regulate biotech patents. Monsanto has a voice and an audience in the House Committee meetings and the ability to influence favorable legislation in North Dakota.

IV. EXPIRING SEED PATENTS

With the life of patents lasting twenty years from the filing of the application,¹⁰⁹ some of the big seed corporation’s seed patents are set to expire and with that comes two new avenues for farmers. First, the utility patents

103. *Id.* at 1.

104. *Id.* at 2.

105. *Id.* at 4.

106. Proposed Amendments to House Bill No. 1442, ND House Agriculture Committee, February 14, 2001.

107. 2001 House Standing Committee Minutes: Hearing on H.R. 1442 Before the House Agric. Comm., 57th Leg. Assemb., Reg. Sess. (N.D. 2001) (statement of Rep. Lemieux, sponsor of 1442).

108. N.D. CENT. CODE § 4-24-13(2)(a)(1)-(3) (2017).

109. *Patents: Getting Started*, UNITED STATES PATENT AND TRADEMARK OFFICE (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents>.

will no longer apply, which would have formerly prevented farmers from saving seed and replanting seeds generated from GM patent-protected crops.¹¹⁰ Second, the market opens for competitors to offer seeds with the previously patent protected traits.¹¹¹

A. WHAT ARKANSAS HAS DONE

In December of 2014, UA 5414RR was released after being developed by the University of Arkansas System Division of Agriculture.¹¹² The soybean variety was developed in anticipation of the expiration of Monsanto's Roundup Ready soybean patent expiration, and although it's not the top-yielding variety of Roundup Ready seeds, as that title now belongs to Monsanto's newly patented seed, the creator, Chen, says, "that's offset by lower production costs, including lower initial purchase price, no technology fees and the ability to save seed for planting in following seasons."¹¹³

Agriculture is Arkansas' largest economic contributor, bringing in approximately sixteen billion dollars to the state per year.¹¹⁴ Like North Dakota, Arkansas has developed a number of statutory and regulatory provisions to address the agricultural industry and to help monitor it.¹¹⁵ Arkansas statute § 19-12-115 establishes the Arkansas Biosciences Institute ("ABI") to promote biotechnology research.¹¹⁶ Reports indicate that since its inception, the Arkansas Biosciences Institute has had impressive patent activity that attracted \$38.2 million in outside research funding in 2014.¹¹⁷ Robert McGehee, Ph.D., Director of ABI, and Dean of the University of Arkansas for Medical Sciences Graduate School, said of the Institute's work in patents: "[p]atent activity that moves research from the laboratory to the workplace has been especially booming in the past two years . . . As agricultural and biomedical research supported by ABI matures, increased patent activity is expected."¹¹⁸

110. Dennis Crouch, *When Monsanto's Patents Expire*, PATENTLYO (Sept. 26, 2011), <http://patentlyo.com/patent/2011/09/when-monsantos-patents-expire.html>.

111. *Id.*

112. Fred Miller, *Arkansas Releases First Roundup Ready Soybean*, DIVISION OF AGRIC. COM., RES. & EXTENSION, U. OF ARK. SYSTEM (Dec. 3, 2014), <http://arkansasa-gnews.uark.edu/8273.htm>.

113. *Id.*

114. *Arkansas Agriculture*, FARM BUREAU ARK., <http://www.arfb.com/pages/arkansas-agriculture/> (last visited June 19, 2017).

115. NATIONAL CONFERENCE OF STATE LEGISLATURES, *supra* note 10.

116. *Id.*; ARK. CODE ANN. § 19-12-115 (West 2015)

117. Spencer Watson, *Arkansas Biosciences Institute Reports Strong Patent Numbers, Research Funding*, U. OF ARK. FOR MED. SCIENCES (Feb. 25, 2015), <https://uam-health.com/news/2015/02/25/arkansas-biosciences-institute-reports-strong-patent-numbers-research-funding/>.

118. *Id.*

B. AGACCORD

In anticipation of Roundup Ready soybeans exiting their patent protections, the American Seed Trade Association¹¹⁹ and the Biotech Industry Organization¹²⁰ partnered to create AgAccord, a private sector contractual framework to “support business opportunities for those seeking to use off-patent events in the United States while ensuring important regulatory commitments are maintained for off-patent events so that U.S. exports of products containing these events are not disrupted.”¹²¹

In pursuit of its mission, AgAccord has developed two main agreements, the Generic Event Marketability an Access Agreement (“GEMAA”) and the Data Use and Compensation Agreement (“DUCA”).¹²² GEMAA is an outlet for companies with upcoming expiring patents to maintain some level of regulation on their product following the expiration of the patents. Companies that have developed the previously patented technology are referred to, under this agreement, as “Proprietary Regulatory Property (PRP) Holders” and as a member of AgAccord per the requirements of GEMAA, must notify the Administrator of patent expirations at least three years prior to the expiration.¹²³

AgAccord’s website indicates publicly only two companies who have joined per the requirements of GEMAA and who have sent notifications for patent expiration. Those two notices are for “Monsanto’s 40-3-2 Soybean” and for “Monsanto’s MON 810 Corn”.¹²⁴ The form linked to “Monsanto’s 40-3-2 Soybean” shows that Tom Carrato, Associate General Counsel for Global Regulatory Law & Stewardship with the company Monsanto, has signed it.¹²⁵ The form indicates the patent expired in March of 2015, and that

119. “Founded in 1883, the American Seed Trade Association is one of the oldest trade organizations in the United States. Its membership consists of over 700 companies involved in seed production and distribution, plant breeding, and related industries in North America. . . . ASTA’s mission is to be an effective voice of action in all matters concerning the development, marketing, and movement of seed, associated products and services throughout the world.” *Who We Are*, AM. SEED TRADE ASSOC. (2016), <http://www.betterseed.org/about-asta/who-we-are/>.

120. “BIO is the world’s largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.” *About BIO*, BIO (2017), <https://www.bio.org/about>.

121. *About the AgAccord*, THE AGACCORD, <http://www.agaccord.org/?p=about> (last visited June 19, 2017).

122. *Id.*

123. *Id.*

124. *Id.*

125. *J. Thomas Carrato, Esq.*, (Jan. 4, 2012), <http://sapba.co.za/uploads/files/conferences/2012/Tom%20Carrato.pdf>.

Monsanto elected to “[i]ndependently maintain and obtain Covered Authorizations for this Covered Event.”¹²⁶ The form for “Monsanto’s MON 810 Corn” indicates the same, except for a patent expiration date of November 2014.¹²⁷

V. CONCLUSION

The expiration of patents on certain genetically modified seeds creates an opportunity for innovation, and certainly one that can and should be pursued by North Dakota. The North Dakota State University Extension Service is the region’s center for innovation when it comes to soybean production and seed breeding as alternatives to the more expensive genetically modified seeds available through private companies like Monsanto. North Dakota should enhance agriculture’s share in its economy by focusing on state-run science initiatives, much like Arkansas, to increase production of seeds available to farmers at lower costs.

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126. *The Accord: Generic Event Marketability & Access Agreement (GEMAA) Notice of Patent Expiration*, THE AGACCORD (Jan. 15, 2013), <http://www.agaccord.org/include/NoticeofPatentExpiration40-3-2Soybean.pdf>.

127. *Id.*

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