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Justin Brickey

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*Justin Brickey**

ABSTRACT

Agricultural seed markets have experienced significant consolidation over the past fifty years, apparently driven by private investment in research and development ("R&D") made profitable through extensive intellectual property protections. The current intellectual property law regime on plants allows an innovator to obtain a wide variety of protections on new plant varieties, whether created through natural breeding processes or genetic engineering. Investment has paid off and the United States has experienced significant benefits through increased productivity, meaning we produce significantly more food today without using more land than our grandparents. However, agricultural markets deserve, and are often given, unique consideration because of the importance of the product. Competition in these markets may be on the verge of breaking down. This Article explores the background and development of Intellectual Property ("IP") law as it relates to self-replicating technologies (plants) and speculates on two ways legislators can promote and protect competition without destroying private incentive to innovate: extending research exceptions for universities and banning the development and use of Genetic Use Restriction Technologies ("GURTs").

I. INTRODUCTION

Intellectual property rights protecting self-replicating technologies (plants) have exploded over the last several decades, making it one of the fastest growing intellectual property ("IP") law areas.[1] Debate continues to rage over the appropriate balance between protecting inventors' rights and promoting diffusion of innovations.[2] Supporters of strong IP protection for inventors argue that research and development ("R&D") is prohibitively expensive without some way of guaranteeing a return on investment.[3] They further argue badly needed innovations, which benefit all of society, would never come to fruition without strong protection.[4] Counter-arguments contend non-profit research, performed mostly by NGOs and universities, are more than adequate to further society's needs. Some even go as far as arguing there is no empirical support for patent law in general.[5] Clear answers in this debate require a strong understanding of economics and sufficient data to predict what would have been absent IP protection over plants, and reasonable experts disagree. But what about when the inventors seek to protect their inventions (and monopoly profits) by circumventing the legal system entirely? Is it appropriate for an inventor, many of whom have benefited greatly from current IP laws, to use their R&D to ensure their product only survives a single generation after sale?

This Article argues the interests IP law seeks to promote are thwarted if innovators can use Genetic Use Restriction Technologies ("GURTs") to ensure monopoly profits. Additionally, in the unique industry of agriculture, which is vital to our survival and growth, research should be encouraged in all possible avenues. Research exceptions to patent law infringement for research universities would help ensure maximum possible development without jeopardizing private innovation.

Patent law exists to promote "the Progress of Science and useful Arts."[6] Generally speaking, patent protections represent a trade-off. Society allows otherwise undesirable monopolization in exchange for incentivizing investment in innovation.[7] Diffusion is an important part of the patent law scheme, meaning after the inventor recoups their investment and receives a reasonable profit, society benefits from the free exchange of inventions. Obviously, any monopoly power gained through innovation and IP law protections is meant to be temporary.

But what if a firm took the benefits of their temporary monopoly and used those profits to develop ways of permanently protecting their inventions through extra-legal means, such that society may never gain unrestricted use of the invention? This type of behavior could result from several different motivators. It may be that traditional IP protections are inadequate to incentivize investment in the biotech

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* Justin Brickey is law student at the University of Missouri-Columbia School of law.

1. *See* Sun Ling Wang et al., *U.S. Agricultural Productivity Growth: The Past Challenges and the Future*, AMBER WAVES (Sept. 8, 2015), https://www.ers.usda.gov/amber-waves/2015/september/us-agricultural-productivity-growth-the-past-challenges-and-the-future/.

2. Jason Savich, *Monsanto v. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology*, 22 BERKELEY TECH. L. J. 115, 117 (2007). In this context, the term "consumer" includes agricultural producers (farmers) who purchase the patent protected product from the inventor.

3. *Id.* at 129.

4. *Id.* at 120.

5. Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSPECTIVES 1 (2013).

6. U.S. CONST. art. I, § 8, cl. 8.

7. Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980).

industry since the invention is self-replicating and difficult to control once the first sale is complete. Alternatively, biotech firms may be adequately protected by the current law and are simply making rational business choices to limit cost in the long run and secure profits for the future.

This Article argues current law adequately protects and incentivizes innovation and that Congress should remove the temptation for biotech firms to waste resources developing genetic use restriction technology. Part II contains a brief introduction to GURTs and a survey of IP law as it concerns self-replicating bio-organisms. Part III examines the current state of the biotech market. Part IV examines ways to improve the system to promote innovation while also protecting society's interests in competition and diffusion.

II: UNDERSTANDING GURTS AND THE CURRENT IP PROTECTION FRAMEWORK OVER PLANTS

A. How GURTs work and why they were developed

Biotechnology firms began developing GURTs as a possible way to protect their investment without resorting to patent enforcement.[8] Initial development was sponsored at least in part by the United States Department of Agriculture.[9] GURTs come in two basic forms. The first type is Variety GURT, commonly referred to as a "terminator gene," which control plant fertility by allowing the plant to developed seeds but then poisoning each embryo after development.[10] The second type, known as "traitor genes," are designed to turn a particular trait on or off.[11]

News of the terminator gene's development caused widespread condemnation among various scientific and international governmental organization.[12] Concerns ranged from possible cross-breeding with wild plant populations to negative socio-economic effects.[13] For example, many poor farmers across the globe depend on saving seeds from a crop to plant the next season.[14] If GURTs were commercialized, these farmers would be forced to purchase new seed each year, reducing their already thin profit-margins.[15]

Even some of the harshest critics of terminator genes admit that in some circumstances GURTs may be useful in preventing otherwise genetically modified

8. *See* Luca Lombardo, *Genetic Use Restriction Technologies: A Review*, 12 PLANT BIOTECHNOLOGY J. 995, 995 (2014).

9. *See* Scott Kilman, *Monsanto Won't Commercialize Terminator Gene*, WALL STREET JOURNAL, pg. B4 Oct. 5, 1999; *see also* Lombardo *supra* note 8 at 995.

10. Lombardo *supra* note 8 at 995.

11. *Id*. ("T-GURT (ironically known as traitor technology) is designed to switch on or off a trait (such as herbicide/cold/drought/stress tolerance, pest resistance, germination, flowering, ripening, color, taste and nutritional qualities of the plant, defense mechanisms, or production of industrial or pharmaceutical compounds) using inducible promoters regulating the expression of the transgene through induced gene silencing(e.g., by antisense suppression) or by excision of the transgene using a recombinase (FAO, 2001a).").

12. *Id.* at 996.

13. *Id.*

14. *Id.*

15. *Id.*

organisms from spreading into the wild and disrupting natural ecosystems.[16] Monsanto responded to growing popular concerns by announcing a pledge to not commercialize any plants containing the terminator gene.[17] Arguments related to protecting natural wildlife from GMO encroachment aside, a reasonable question arises: if this is the kind of less-than-beneficial-to-society R&D large biotechnology firms are investing resources to develop, how should we react? On the one hand, there is something perverse about a firm that has benefited under the current IP law regime by obtaining a large market share to use their resources in a way which benefits no one but their shareholders.[18] On the other hand, IP law enforcement is expensive and perhaps impossible in some developing countries that do not have an effective enforcement mechanism.[19] In typical markets, societal benefits may not be a significant concern. Agricultural markets are different, since they produce a basic human necessity. It is necessary to understand the general background of IP law as it relates to plants in order to understand why some, including the USDA, believed GURTs were a necessary and worthwhile development.

B. Intellectual Property Rights in the United States for self-replicating biological organisms

For most of United States history, living microorganisms were beyond patent protection.[20] Beginning in the 1930s, Congress recognized that innovators should receive just reward for their efforts, and therefore enacted a series of legislation providing various forms of Intellectual Property Rights ("IPR") for plants.[21] Today, there are three basic methods for obtaining IPR for innovation in plant technology, each with varying degrees of protection and application costs.

First, Congress passed the Plant Protection Act of 1930 ("PPA"), which allows inventors to new patent varieties developed through cross-breeding.[22] The patent holder is able to prevent others from asexually reproducing the protected plant and from using or selling the plant or its parts.[23] Asexual reproduction includes growing a plant from cuttings, budding, and grafting two different plants together.[24] The description requirements are less stringent under the PPA then in a typical patent

16. Food and Agriculture Organization of the United Nations, Report of the Panel of Eminent Experts on Ethics in Food and Agriculture, Risks, Uncertainties and Doubts in the use of GMOs, (2001) http://www.fao.org/3/x9600e/x9600e06.htm#P12_3335; *see also* Lombardo, *supra* note 8, at 1000–01.

17. Kilman, *supra* note 9. At the time Monsanto made the promise, it did not own the terminator gene patent but had announced merger plans with Delta & Pine Land who had developed the gene in conjunction with the USDA. *Id*.

18. *See infra*, Section III.

19. Lombardo, *supra* note 8, at 1000–01.

20. *See* Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 777 (1992); Funk Bros. Seeds Co. v. KaloInoculant Co., 333 U.S. 127 (1948) (holding that a combination of biological organisms was not patentable under 35 U.S.C. § 101).

21. 35 U.S.C. §§161–164 (1998).35 U.S.C. §§ 161–164.

22. 35 U.S.C. § 161 (2018) ("Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.").

23. 35 U.S.C. § 163 (2018).

24. Timothy P. Daniels, *Keep the License Agreements Coming: The Effects of J.E.M Ag Supply, Incorporated v. Pioneer Hi-Bred International, Incorporated on Universities' Use of Intellectual Property Laws to Protect Their Plant Genetic Research*, 2003 BYU EDUC. & L. J. 771, 775 (2003).

application under 35 U.S.C. § 101.[25] Applications under the PPA are less expensive than those under a utility patent, but PPA only protects a narrow type of innovation with limited commercial use.[26] The PPA contains no enumerated research exception, which may be understandable considering the time period in which it was enacted.[27]

Adding an additional method for protecting plant innovation, Congress enacted the Plant Variety Protection Act in 1970 ("PVPA").[28] The PVPA allows a breeder of a sexually reproduced, tuber propagated, or asexually reproduced plant variety to obtain protection for a unique plant variety.[29] Various parts of the PVPA evidence Congressional concern for society's unique interest in agriculture.[30] A major distinction from the PPA is the PVPA's research exception.[31] Plants protected under the PVPA are still usable without infringement by virtually anyone conducting research. Farmers are also permitted to save seeds from PVPA protected plants so long as they purchased the seed originally in a bona fide sale for a purpose other than reproduction.[32] Anyone can use protected varieties in cross breeding so long as they are not later marketing a derivative product.[33] Reading these provisions as a whole gives the distinct impression that Congress is deeply concerned with both innovating plant development and protecting the downstream consumer, including, in the case of food crops, the farmer and the consumer who ultimately eats the product.

Lastly, biotech inventors may also apply for a utility patent under 35 U.S.C. § 101.[34] These protections are the most stringent available, lasting 20 years, and the most expensive and difficult to obtain.[35] Protections for plants under § 101 have only recently been allowed. For almost 200 years, living matter was thought to be unpatentable.[36] However, that changed in 1980 with the Supreme Court's decision in *Diamond v. Chakrabarty*, where the Court held genetically engineered organisms were patentable under § 101.[37] The Court's holding hinged on the distinction between human-made organism and those occurring naturally.[38] Where the inventor has created something through research that does not occur in nature, it may be patentable under § 101 even though it is a living organism. The Court considered the argument that by enacting the PPA and PVPA, Congress had expressed its intent

25. 35 U.S.C. § 101 (2018); 35 U.S.C. § 162 (2018) ("No plant patent shall be declared invalid for noncompliance with section 112 if the description is as complete as is reasonably possible.").
26. *See* Savich, *supra* note 2.
27. *See* 35 U.S.C. §§ 161–164.
28. Plant Variety Protection Act of 1970, 7 U.S.C. §§ 2321–2582 (2018).
29. 7 U.S.C. § 2402(a) (2018).
30. 7 U.S.C. § 2404 (2018) (reserving the right for the Secretary of the Plant Variety Protection Office to allow open use of a protected variety "in order to insure an adequate supply of fiber, food, or feed in this country [where] [] the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair.").
31. 7 U.S.C. § 2544 (2018).
32. *Id.*
33. 7 U.S.C. § 2541(a)(1-4) (2018).
34. 35 U.S.C. § 101 (2018).
35. *See generally* Ko, *supra* note 20
36. *See generally Id.*; *see also* Diamond v. Chakrabarty, 447 U.S. 303 (1989).
37. *See Diamond,* 447 U.S. at 318; Ko, *supra* note 20 at 777.
38. *See Diamond,* 447 U.S. at 313 ("Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's micro-organism is the result of human ingenuity and research.")

to exclude living organisms from § 101 protection.[39] Ultimately, the Court was justifiably unpersuaded by this argument.[40]

The PPA was most likely enacted for just the opposite reason as exclusion: it was passed to include plant innovators in the IPR scheme. As the Court points out, Congress most likely enacted the PPA as a way to circumvent the restrictions plant innovators faced when applying for a patent under § 101.[41] First, products of nature were generally considered beyond the scope of patent protections, meaning all plant innovations were technically unpatentable.[42] Second, plant innovators could not meet the strict written description requirements of § 101.[43] The PPA and, to a lesser extent, the PVPA were designed to reward and incentivize innovators, not make a policy statement that Congress intended to keep plants outside traditional IPR protection.[44]

In all fairness, some PVPA provisions seem to indicate Congress was willing to limit IP rights in plants for several reasons.[45] As discussed below, the Court would have another opportunity to consider a slight variation of the same argument.[46] The key takeaway from the Court's decision *Chakrabarty* is that a wide array of human-made biological organisms, including plants, are patentable under § 101.[47] To qualify for a utility patent, a plant innovator "must show that he has developed a new, useful, and non-obvious" plant, meet the written description requirements of § 112, and deposit a sample of seed that is available to the public.[48]

A "trade secret" is a form of intellectual property law that can protect a developer's methodology.[49] Trade secret law combined with hybrid plant development can help protect a plant breeder's innovations. However, they are important for hybrid varieties which cannot self-pollinate,[50] where commercialized seeds ensure hybrid vigor only for the first generation of plants.[51] The valuable information is in the parent lines, which typically are not commercialized.[52] Subsequent generations are significantly less productive, creating an incentive to buy new seed each

39. *Id.* at 310–315.
40. *Id.*
41. *Id.* at 310–312.
42. Diamond v. Chakrabarty, 447 U.S. 303, 311–312 (1980).
43. *Id.*
44. *See* Savich, *supra* note 2 (discussing economic theories behind IPR in the plant research context).
45. *See* 35 U.S.C. §§ 161–164; *see also* Plant Variety Protection Act of 1970, 7 U.S.C. §§2321-2582.
46. *See infra* pp. 9–13
47. *See also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013) (unanimous decision confirming that naturally occurring DNA, despite the difficulty of identifying it, is unpatentable but DNA that has been modified through human intervention is patentable).
48. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 131 (2001) (citing 35 U.S.C. §§ 101–103, 112, and 37 C.F.R. §§ 1.801–1.809).
49. *See* 18 U.S.C. § 1839(3).
"[T]he term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if--
(A) the owner thereof has taken reasonable measures to keep such information secret; and
(B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information."
50. Lombardo, *supra* note 8, at 1000.
51. *See* Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc., 35 F.3d 1226, 1233–35 (8th Cir. 1994).
52. *See Id.* at 1226–1246.

season.[53] *Pioneer v. Holden* demonstrated that the law of trade secrets is another method for protecting investment in plant innovation by holding the defendant liable for violating Pioneer's trade secrets in its popular corn line.[54] Hybrids essentially operate as a 'natural' IP protection.[55]

C. Additional case law development post-Chakrabarty

A variation of the argument raised in *Chakrabarty* was litigated again in *J.E.M. Ag Supply, Inc. v. Pioneer*.[56] Pioneer brought a patent infringement claim against J.E.M. for violating the licensing agreement contained on its bags of hybrid corn.[57] J.E.M. countered with a general denial and an affirmative defense of patent invalidity, arguing that sexually reproducing plants are not patentable under § 101 and that the PPA and PVPA, as the more specific statutes, are meant to be the exclusive means of protecting plants.[58] Specific to the PPA, J.E.M. argued Congress considered plants beyond the scope of § 101 when it specifically limited the PPA to asexually reproduced plants, because if they thought plants were patentable under § 101 there would be no reason for additional protections.[59] The Court began by reiterating its holding in *Chakrabarty*, first noting the critical distinction between what is patentable versus unpatentable is not its status as living or inanimate, but rather whether it has been altered by humans into something that does not occur in nature.[60] Second, the Court held that the PPA is restricted to asexually reproduced plants because Congress could not have anticipated that plant science would eventually allow plant breeders to produce stable characteristics through sexual reproduction.[61] In other words, the Court contends that Congress did not think it was necessary to protect sexually reproduced plants since they thought no useful varieties could be produced that way.[62] Finally, the Court pointed out that until 1924, most farmers received free seed from the government.[63] This means commercial interests were drastically different than they are now, since producers in the fledgling seed market were primarily concerned with commoditizing seed in general. The Court was simply unwilling to make any negative inferences from Congress's intent behind the PPA.

J.E.M.'s argument stemming from the PVPA was more compelling (although equally unsuccessful). The PVPA granted specific, limited patent-like protection for sexually reproduced plants. As discussed above, several provisions of the PVPA seem to indicate Congress's intent to limit IPR protections, especially where food crops are concerned.[64] The Court was unpersuaded, finding it easy to reconcile the

53. Lombardo, *supra* note 8, at 1000.
54. *See Pioneer Hi-Bred Int'l*, 35 F.3d at 1243.
55. The word 'natural' here is meant to denote normal plant reproductive processes. It is not meant to imply that hybrids developed through selective breeding would necessarily occur in nature.
56. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145-146 (2001).
57. *Id.* at 128-29.
58. *Id.* at 129.
59. *Id.* at 132.
60. *Id.* at 134.
61. *Id.* at 135.
62. *See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 136 (2001) (citing E. Sinnott, Botany Principles and Problems 266-267 (1935) & J. Priestley & L. Scott, Introduction to Botany 530 (1938)).
63. *Id.* at 136.
64. Plant Variety Protection Act of 1970, 7 U.S.C. §§ 2321–2582 (2018); 7 U.S.C. § 2402(a) (2018).

PVPA and § 101 since: (1) the PVPA contains no express exclusionary language and (2) it is harder to qualify for a patent under § 101 than with a PVP certificate, therefore "it only makes sense that utility patents would confer a greater scope of protection."[65] In essence, the Court found that the PVPA's limited scope and specific provisions for protecting societal interests weigh against finding Congressional intent to otherwise exclude sexually reproduced plants from § 101. The Court found other reasons to hold the two provisions can co-exist, namely that utility patents require greater disclosure and repository of physical material accessible to the public, while PVP certificates do not.[66] Additionally, the Court is bound by precedent which prevents it from invalidating two statutes that are capable of co-existing without resulting in inconsistent outcomes.[67]

In dissent, Justice Breyer wrote that he would have decided along the lines argued by J.E.M., that Congress intended IPR in living plants to be regulated by the two more specific statutes.[68] Ultimately, IP rights in living plants are now well established within United States jurisprudence. Statistics show productivity in the agricultural industry has steadily increased over the last fifty years without a corresponding increase in farmed land.[69] For example, soybean yields per acre have doubled since 1948 and corn yields have quadrupled.[70] A significant reason for the increased productivity is R&D, much of which, as discussed above, is capable of being protected under IP law.[71] Private sector R&D has grown by over one-third since the 1980s,[72] possibly as a reaction to Supreme Court's decision in *Diamond v. Chakrabarty* which, as discussed above, held living organisms could be protected under a utility patent so long as they were human-made and not naturally occurring.[73] Shortly after the Court's decision in *Chakrabarty*, the United States Patent and Trademark Office, Board of Patent Appeals and Interferences, held in *Ex Parte Hibberd* that plant life was patentable under § 101.[74] With all three federal branches in agreement, investors after 1985 could be confident that any new and useful innovation would bring monopoly profits, thereby justifying risky R&D investment.

D. Enforcement Costs

Gaining a patent and marketing a successful product is only one part of profiting from patent protected innovation. Patent protection can only be effective if consumers believe patent holders will take action to enforce their rights, especially for a self-replicating technology like a plant. Seed producers like Monsanto have

65. *J.E.M. Ag Supply, Inc.,* at 138.
66. *Id.* at 142-44.
67. *Id.* at 143-44 (citing Morton v. Mancari, 417 U.S. 535, 551(1976) ("when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective")).
68. *Id.* at 147 (Breyer, J., dissenting).
69. ECON. RSCH. SERV., U.S. DEP'T OF AGRIC., ADMIN. PUB. NO. 083, AG AND FOOD STATISTICS: CHARTING THE ESSENTIALS, FEBRUARY 2020 11-12 (2020).
70. Wang et al. *supra* note 1.
71. *See Id.*
72. *Id.*
73. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).
74. Hibberd, et al., 227 U.S.P.Q. 443, 444 (B.P.A.I. 1985) (The examiner, who had denied various applications related to maize, unsuccessfully defended its decision in part by arguing the PPA of 1930 and the PVPA of 1970 evidenced Congressional intent to exclude plant life from patentability under § 101.)

engaged in vigorous enforcement actions, spending significant sums investigating and prosecuting IP infringements.[75] By 2012, Monsanto had filed over 140 lawsuits and collected more than $23 million in judgements.[76] Importantly, the Supreme Court has held the first sale doctrine, first articulated in *Adams v. Burke*,[77] does not apply to patent protected seeds.[78] The Court's unanimous decision in *Bowman v. Monsanto Co.* held that farmers who save patent protected seed for replanting in a subsequent season cannot use the first sale doctrine as a defense against a patent infringement suit.[79] Typically, a patentee losses all ability to restrict use of an item after the first authorized sale.[80] Bowman argued that by saving the seed he was simply using the items as farmers had always done.[81] The Court rejected his argument, finding that by using seed saved from one season to plant in a later season, Bowman was actually replicating patented technology without a license to do so.[82] The Court's decision sent a clear message: farmers who violate license agreements on patented plants do so at their own peril.

With the law definitively settled, agricultural innovators can be confident that enforcement endeavors will be effective at preventing infringement. Of course, investigating violations is difficult and expensive. Farmers are certainly not going to advertise violations. However, Monsanto clearly demonstrated biotech firms can investigate and successfully prosecute violators.[83] Given their significant market power, major seed producers are in a good position to pass on any enforcement costs to the consumers.[84]

III. CURRENT STATE OF THE AGRICULTURAL BIOTECH INDUSTRY: MOVING TOWARD CONSOLIDATION

Over the last 50 years, the private agricultural industry has experienced significant consolidation and the effects are easily demonstrated by the controversy surrounding the merger of Bayer and Monsanto.[85] On May 29, 2018, the Antitrust Division of the U.S. Department of Justice ("DOJ") filed a complaint in the United States District Court for the District of Columbia, challenging the merger of the two biotech giants under § 7 of the Clayton Act.[86] The DOJ was concerned that the merger would substantially eliminate competition in several important agricultural markets.[87] Monsanto and Bayer represented two sides of the same coin that is modern agricultural business: they both developed and sold 'systems' designed to

75. Center for Food Safety & Save Our Seeds, *Seed Giants vs. U.S. Farmers*, CTR. FOR FOOD SAFETY 6 (2013), http://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf.
76. *Id*.
77. Adams v. Burke, 84 U.S. 453, 456 (1873).
78. Bowman v. Monsanto Co., 569 U.S. 278, 287 (2013).
79. *Id.* at 289.
80. *Id.* at 283.
81. *Id.* at 287.
82. *Id.* at 283.
83. Center for Food Safety and Save Our Seeds, *supra* note 7; Bowman v. Monsanto Co., 569 U.S. 278, 278 (2013).
84. *See* Complaint, United States v. Bayer AG and Monsanto Co., No. 1:18-cv-01241, 2018 WL 2417887 (D.D.C. May 29, 2018); Center for Food Safety and Save Our Seeds, *supra* note 75; *Bowman*, 569 U.S. at 278.
85. *Bayer*, 2018 WL 2417887.
86. *See* Complaint, *Bayer*, 2018 WL 2417887.
87. *See* Complaint, *Bayer*, 2018 WL 2417887.

increase productivity through combining chemicals and genetically modified plant varieties and were virtually the only competitors in certain markets.[88] Specifically, the DOJ alleged the merger would all but eliminate competition in the markets for three U.S. crops: cotton, canola, and soybeans.[89] Herbicide and pesticide development has become intertwined with genetically modified plant varieties, which are engineered to withstand high exposure levels, and the two companies were the only major competitors in many markets.[90] For example, Monsanto's "Roundup Ready" soybeans were engineered for use alongside their herbicide (Roundup), greatly increasing the soybeans' resistance to the herbicide. The DOJ argued Bayer produced the only competitive alternative to Monsanto's weed-control systems.[91]

The merger was allowed to proceed only after Bayer agreed to divest $9 billion in assets to BASF (Badische Anilin und Soda Fabrik), making it one of the largest divestment agreements in United States history.[92] The divestment included all of Bayer's businesses in the canola, cotton, soybean, and vegetable seed markets.[93] The important thing to take away from this merger is the insight it provides into the current market concentration in several key agricultural industries. Pre-merger, Bayer and Monsanto had a combined market share of approximately 59% of genetically modified cotton seeds sold in the United States, [94] 74% market share of genetically modified canola seeds,[95] and a significant portion of soybean seeds.[96] Monsanto's only competitors in the soybean market either relied on licenses for Roundup Ready traits or used post-patent versions of the original Roundup Ready trait.[97] This case demonstrated that many agricultural seed markets in the United States are highly concentrated and dominated by private mega-firms like Bayer and BASF, who have profited from extensive investment in R&D. These innovations are typically patent protected and have revolutionized American food production.[98]

Patents are designed to reward innovation by allowing an inventor of a useful new product to collect monopoly profits for a limited time.[99] Patent law reflects a theoretical bargain between the inventor and society. The inventor is allowed a time-limited monopoly and society is rewarded with unrestricted use of the invention after the period ends.[100] There is a delicate balance, however, between stimulating innovation and preventing societal harms resulting from failed market competition.[101] Evaluating the effects of patent protections on competition in the

88. *Id.* at pg. 2.
89. *Id.*
90. *Id.*
91. *Id.*
92. United States v. Bayer AG, No. 18-1241, 2019 WL 1431903, at *1 (D.D.C. Feb. 8, 2019); Dan Mangan, *US Forces Germany's Bayer to shed $9 billion in ag business in biggest ever antitrust sell-off*, CNBC (May 29, 2018), https://www.cnbc.com/2018/05/29/bayer-will-sell-basf-9-billion-in-assets-to-allow-monsanto-purchase.html.
93. *Bayer AG*, 2019 WL 1431903, at *2, *4.
94. Complaint at pg. 9, *Bayer AG*, No. 1:18-cv-01241, 2018 WL 2417887.
95. Complaint at pg. 10, *Bayer AG*, No. 1:18-cv-01241, 2018 WL 2417887.
96. Complaint at pg. 11, *Bayer AG*, No. 1:18-cv-01241, 2018 WL 2417887.
97. *Id.*
98. *See* Wang et al. *supra* note 1.
99. 35 U.S.C. § 101 (2018).
100. Kris J. Kostolansky and Daniel Salgado, *Does the Experimental Use Exception in Patent Law Have a Future?,* 47 COLO. LAW. 32 (2018).
101. *See generally*, HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAWS OF COMPETITION AND ITS PRACTICE 22–33 (West Academic Publishing, 5th ed. 2015)(discussing societal harms of monopoly).

agricultural industry, which includes many distinct markets, is beyond the scope of this Article. There is ongoing debate as to whether the current plant-related IP scheme is beneficial to society, i.e., whether the current protections strike the appropriate balance between stimulating innovation while maintaining efficient market competition.[102] If we assume the theoretical premise behind patent law is true and patent protections stimulate innovation by offering monopoly profit rewards, then the increased productivity in United States agriculture following private investment in agricultural R&D is probably the result of modern IP law developments. It is also clear that several key agricultural markets have experienced significant consolidation.[103]

With key agricultural markets dominated by a few large international firms, incentives to innovate provided by patent protections are probably less important. The firms must continue to innovate or risk losing their market position. R&D costs necessary to develop competitive plant traits represent a significant barrier to entry into markets dominated by genetically modified seeds.[104] It may be time to re-examine the actual balance in the agricultural industry between innovators' need for monopoly profits and society's benefit in subsequent use of the invention. Regardless of whether the current regime is a net positive for society, there is no need to allow continued development of systems designed to ensure perpetual monopolies. Additionally, industry giants are unlikely to face a credible threat from research universities, but society stands to gain significant benefits from a robust research exception to patent infringement. These ideas are more fully explored in the next section.

IV. SOLUTIONS: PROTECTING RESEARCH EXCEPTIONS AND RESTRICTING GENETIC USE RESTRICTION TECHNOLOGIES

A. Expanding research exceptions for universities

Experimental use is a defense against a patent infringement claim.[105] This defense arises from the same interests underpinning the experimental use doctrine, which allows an inventor to test their invention publicly before filing for a patent.[106] Under the experimental use defense, a potential infringer must show they used the patented invention "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[107] Research universities operated for some time under the belief that they could not be held liable for patent infringement so long as they limited

102. *Compare* Michele Boldrin and David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSPECTIVES 1 (2013), *with* Jacob Moscona, *Flowers of Invention: Patent Protection and Productivity Growth in US Agriculture*, (July 27, 2020) (on file with the Department of Economics, M.I.T.).

103. *See generally* Complaint, *United States v. Bayer AG and Monsanto Co.*, No. 1:18-cv-01241, 2018 WL 2417887 (D.D.C. May 29, 2018).

104. *See generally* Moscona, *supra* note 102.

105. Kostolansky, *supra* note 100 at 36.

106. City of Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126, 135 (1877) (establishing the experimental use exception to the public use bar to patent protection); *see also* Kostolansky, *supra* note 100 at 33-36.

107. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000) (citing Roche Products, Inc. v. Bolar Pharm. Co., 733 F.2d 858, 862 (Fed. Cir. 1984) (suspended by statute related to development of pharmaceuticals)).

their use of patented inventions to furthering their research endeavors.[108] But the Federal Circuit in *Madey v. Duke* drastically limited the scope of the exception as applied to private research universities.[109] The court held the research exception does not shield universities from liability when "the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry…"[110] The holding affects private institutions disproportionately to public ones since sovereign immunity insulates public research universities from suit.[111]

The court's holding attempts to correct an apparent imbalance in the way the research exception had been applied. Universities, both public and private, were able to use patent protections to profit from innovation but were essentially immune to liability.[112] Far from using patented inventions for purely philosophical inquiry, institutions were able to earn substantial profits enforcing their patent rights.[113]

Blanket research exceptions may run contrary to IP law's theoretical underpinnings, but society's interests in agricultural development are better served by the pre-*Madey* research exception. Agricultural innovators are not competing to develop 'a better mouse-trap,' or build the next iPhone. Instead, the results of their innovations may increase access to a basic human necessity. A statutory repeal of *Madey*, with some additional tailoring, would leave intact traditional patent incentives for private innovators while simultaneously increasing overall development and possibly introducing some healthy competition into concentrated markets. Additionally, university researchers (and offices of general counsel) would conserve significant resources now used to investigate potential patent violations in agricultural research projects.

B. Prohibition of Genetic Use Restriction Technologies

Governments around the world reacted with great suspicion when GURTs first gained notoriety.[114] Following recommendations from the United Nations Convention on Biological Diversity, countries like Canada and India prohibited field testing and commercialization of GURTs.[115] Public concern centered on the unknown and potentially negative environmental impacts of GURTs.[116] In support of GURTs, some scholars have speculated they could be used to stop genetically modified plants from contaminating wild ecosystems.[117] However, if a genetically modified plant is potentially so dangerous that rendering it infertile is necessary to stop it from spreading, then perhaps we should consider whether such a plant should be used at all. Leaving aside unknown environmental impacts, there is an economic

108. Kostolansky, *supra* note 100 at 36.
109. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002).
110. *Id.*
111. Kostolansky, *supra* note 100 at 38.
112. *Id.*at 36.
113. *Id.*
114. Lombardo *supra* note 8 at 1000.
115. *Id.* at 996; *Genetic Use Restriction Technologies (GURTs)*, GOV'T OF CAN. (May 19, 2012), https://www.inspection.gc.ca/plant-health/plants-with-novel-traits/general-public/gurts/eng/1337406710213/1337406801948.
116. Lombardo *supra* note 8 at 1000.
117. *See Id.*

reason to prohibit GURTs. They can be used to guarantee monopoly profits on new genetic traits indefinitely.

Agricultural seed and chemical developers could use GURTs to circumvent costly patent applications and enforcement litigation. For example, if a company developed a new herbicide-ready soybean variety and equipped it with a GURT which prevents farmers (or anyone else) from saving seed from the first planting, they could forgo patenting the product since it would be impossible for anyone to replicate it through normal reproduction. A GURT-equipped seed would not need to be patented since it would be impossible to save seeds from one crop to plant the next season.[118] Nothing could compel the company to enter their new variety into the public domain and there would be no time limit on their new monopoly. GURTs provide no obvious benefit to society, yet the risks to the environment and market competition is clear.[119] Since the developer of a GURT-equipped seed would not have to worry about patenting their product to ensure monopoly profits, they would never need to disclose their innovation to the public, meaning generic versions would be difficult or impossible to develop. Public outcry originally kept GURTs from being commercialized.[120] Public sentiment, however, is a fickle thing. If fear of GURTs ever dissipates, there is nothing to prevent agri-business giants from taking advantage of them, circumventing the IP scheme altogether and potentially decreasing competition in an already highly concentrated area.

One reasonable economic argument in support of GURTs is that companies will save money on IP enforcement actions, which may lead to lower prices. However, this would only happen if the GURT users were operating in a competitive market. As we have seen, many seed markets are not highly competitive and there is thus no reason to expect a market participant to lower prices after obtaining an indefinite monopoly on a new innovation.

Detractors may further argue that a company able to develop a product incapable of being replicated by its competitors is entitled to whatever benefits result, even a de facto monopoly. For-profit corporations, after all, have an obligation to their shareholders to pursue profit-seeking behavior.[121] There may come a time when public sentiment against GURTs wanes to the point where it would be profitable for a developer to implement them in a commercial line. We should not rely on seed producers to voluntarily exclude GURTs from their products forever.[122]

A few uncertain benefits do not outweigh the potentially enormous cost to competition. Since the potential harm is great and any benefits are small and speculative, Congress should utilize its broad power under the commerce clause to ban GURT-equipped organisms from being sold in in the United States.[123] Congress could determine a ban on GURTs is rationally related to protecting market competition, the environment, and society's interest in maintaining affordable food products.

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118. *Id*. at 996.
119. *See Id*. at 1002.
120. *Id*.
121. *See generally* Leo E. Strine, Jr., *Our Continuing Struggle with the Idea That For-Profit Corporations Seek Profit*, WAKE FOREST L. REV. 135 (2012).
122. Kilman, *supra* note 9.
123. *See* U.S. v. Lopez, 514 U.S. 549, 565–68 (1995) ("We do not doubt that Congress has authority under the Commerce Clause to regulate numerous commercial activities that substantially affect interstate commerce…").

V. CONCLUSION

Agricultural innovations continue to increase productivity in the United States. Patent protections for crop plants are firmly established in our jurisprudence and provide ample protection to innovators, incentivizing private investment in R&D through the promise of limited monopoly profits. However, the numerous agricultural seed markets have become highly concentrated, diminishing competition and threatening to reduce incentives to innovate. Therefore, our government should carefully scrutinize current market conditions to ensure society's interests are not being unduly subjugated to corporate profits. Two ways of safeguarding society's interests are increasing research exceptions available to all research institutions and eliminating GURTs as a method of circumventing IP law.[124]

124. *See e.g*. Kilman, *supra* note 9; Lombardo, *supra* note 8; Ko, *supra* note 20.