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EDITOR'S NOTE: RETURN OF THE AG LAW UPDATE

Welcome to the re-introduction of the Agricultural Law Update. Serving the agricultural legal profession for more than 35 years, the American Agricultural Law Association (AALA) is a member-driven professional organization. During the AALA's development of its new strategic plan, members consistently requested the return of the Ag Law Update. The AALA has been happy to oblige and presents to its members the return of the AALA's official newsletter.

The Ag Law Update is intended to provide a practical resource to keep its members current on developments in agricultural law while also providing in-depth analysis of relevant legal issues affecting the agricultural industry. The Ag Law Update will be provided on a quarterly basis and published online as a service to its members. The Ag Law Update provides a benefit to members and is also dependent on AALA's members for feedback and, of course, articles. The membership of AALA truly possesses the most replete knowledge of agricultural law and policy. This is reflected in the AALA's Annual Conference, the organization's member listserv, and now, once again, in the Ag Law Update.

Anyone interested in writing an article, please do not be shy. We look forward to receiving and publishing diverse articles that reflect the broad and growing issues facing agriculture and the law. If interested, please send me a note at EdCox@OMMGLaw.com.

We would like to thank Thomas Redick, David Berry, and Megan Galey for taking the time to author articles for this edition, and for the authors that have already agreed to provide articles for the next editions. A special thanks is extended to Drew Kershen and the National Agricultural Law Center for composing the Agricultural Law Bibliography, a service Drew has provided since the beginning of the Ag Law Update and which will continue through the National Ag Law Center in Fayetteville, Arkansas.

The Ag Law Update Committee¹ will strive to provide engaging and, above all, useful articles. Feedback and ideas for articles from AALA members is welcome and encouraged. We look forward to hearing from you.



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GENETIC EDITING IN AGRICULTURE: PATENTING AND POTENTIAL LIABILITY ISSUES

by David C. Berry and Thomas P. Redick

I. Introduction

Genetic editing has come to agriculture promising new traits created with more speed, lower cost and greater precision than any plant breeding tool to date. Each past transition in breeding, from hybrids to mutagenesis to recombination and now gene-editing, has had challenges in acceptance. There are still corners of the world where hybrid corn is shunned for open-pollinating varieties. Some proponents, particularly in Europe, continue to promote this seemingly outdated, lower productivity approach to plant breeding. Many more nations are banning biotech crops while endorsing hybrids and mutagenesis breeding, which tools account for expanding food production exponentially over the past 100 years.

This article will discuss the role that new information about how genomes function, including the emerging field of epigenetics and editing of genomes, could be limited in its marketing by oppressive regulation overseas and associated domestic liability for unapproved-overseas biotech crops and animals. After a brief overview of the science and its place in the patenting universe, we will discuss the barriers to entry that regulation and litigation could pose for these new plant breeding methods.

II. Patenting Controversy and Path Ahead for Agricultural Gene Editing

Recent decisions in the U.S. Patent and Trademark Office and the European Patent Office have increased the uncertainty about who will control patent rights to gene-editing technology based on clustered regularly interspaced short palindromic repeats (“CRISPR”). Although the University of California recently lost the first skirmish in the on-

going dispute concerning CRISPR patents, it did little to clarify the long-term patent landscape.

In the U.S., the University of California, Berkeley (“UCB”) filed an original patent application naming Jennifer Doudna, Emmanuelle Charpentier, and two other scientists as inventors on May 25, 2012. The UCB application has not yet resulted in an issued patent. The Broad Institute and Massachusetts Institute of Technology filed a later application on December 12, 2012, but by electing accelerated examination procedures obtained an issued patent, U.S. 8,697,359, on April 14, 2014. The Broad patent names Feng Zhang as the sole inventor.

Although both patent applications disclose and claim CRISPR Cas9, the claims presented in the applications are significantly different. The UCB application claims the CRISPR Cas9 method when used to cleave a DNA molecule in any environment. It is not limited to prokaryotic or eukaryotic cells. The Broad patent, on the other hand, is limited to applying CRISPR to cleave a DNA molecule in eukaryotic cells.

After the ‘359 patent issued, UCB initiated an interference proceeding in the USPTO in an attempt to establish that it was entitled to priority based on an earlier date of invention. On February 15, 2017, the Patent Trial and Appeal Board (“Board”) dismissed the interference proceeding, ruling that the claims of the UCB application and the Broad patent are directed to different inventions. Essentially, the Board credited expert testimony that the Broad patent claims were not obvious in light of the claims in the UCB application because a person skilled in the art would not have

considered it obvious that the method claimed in the UCB application would be effective in eukaryotic cells. In part, this result was based on Dr. Doudna’s public statements regarding the difficulty in applying her invention to eukaryotic cells. Thus, the Board terminated the interference without reaching the question of priority.

As a result of the dismissal, the CRISPR patent landscape remains very uncertain in the U.S. On April 12, 2017, UCB appealed the Board’s ruling to the U.S. Court of Appeals for the Federal Circuit. A full appeal at the Federal Circuit could take 18 months or longer to reach a decision. In the meantime, Broad and MIT have obtained several issued patents, all directed to the use of CRISPR Cas9 in eukaryotes. It is likely that UCB will challenge the validity of some or all of the claims in those patents, most likely by filing a petition for post-grant review with the Board.

The dismissal of the interference proceeding does not directly affect the patentability of the claims in the pending UCB applications, although further examination of those claims will likely be postponed until after the Federal Circuit appeal.

If the USPTO ultimately issues patents to UCB, both Broad and UCB may hold patents covering aspects of the CRISPR Cas9 process. In that event, the rights of the parties will depend on the scope of the claims allowed in the UCB patents. If the UCB patent issues with claims broad enough to cover use of CRISPR Cas9 in any environment, then Broad may not be able to practice its patented method without a license from UCB. Essentially, the UCB patent claims could cover CRISPR Cas9 in all cell

types. In that event, Broad likely would challenge the validity of the UCB patent claims most probably by petitioning the Board for *inter partes* review or by filing a declaratory judgment action. Among other things, Broad could argue that any claims in the UCB patent covering eukaryotic cells are invalid because the application did not adequately disclose how to practice the method outside prokaryotic cells.

In any event, the continuing appeals and prospects for administrative challenges to both patent families are likely to cast a cloud of uncertainty over the technology for the foreseeable future. In many situations involving conflicting patent rights, adverse parties conclude that a settlement agreement resolving all disputes is prudent. In the case of CRISPR, however, the huge commercial potential for the technology may make an early settlement impossible.

If the proceedings in the U.S. did not make the patent situation complex enough, the European Patent Office announced on March 23, 2017 that it will issue a patent to UCB on the CRISPR technology. An EU patent would give UCB exclusive rights in the 38 European member states. When the UCB patent issues, it will likely be challenged by Broad in opposition proceedings before the EPO, further complicating the patent picture.

The CRISPR patent controversy will play out against the backdrop of continuing uncertainty as to the patent eligibility of DNA-related technology in the U.S. In a unanimous 2013 opinion, the Supreme Court resolved an important dispute over patenting “natural” biological material, holding that human DNA isolated from a chromosome (not a new trait created from DNA) cannot be patented because that DNA sequence is a product of “nature” excluded from the scope of patent laws.¹ After this ruling, patent lawyers who felt sure of the boundaries on patenting DNA had to update advice to clients, after their

1. Association for Molecular Pathology v. Myriad Genetics, 133 S.Ct. 2017 (2013).

understandings about patent rules were invalidated. In addition, the Supreme Court’s decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) continues to restrict patentability of processes based on natural phenomena or laws of nature. Both these decisions could affect at least some patent claims relating to the CRISPR technology.

Notably, the *Myriad* decision is narrow in excluding natural phenomena like DNA as opposed to inventions of “any new and useful ... composition of matter” such as synthetic DNA generated in laboratories. DNA sequences resulting from gene editing would be new forms of DNA and therefore presumably patentable. Similarly, the test for patent eligibility announced in *Mayo* preserves eligibility for processes marked by an “inventive concept,” which likely would include a nonconventional technique like CRISPR Cas9.

Internationally, patents might be easier to obtain for some DNA-based applications, given the US Supreme Court’s recent reluctance to allow patents of “natural” origin. Thus, for some applications, an EU patent and market might be sought. While some nations are still wary of this, the European Patent Office (“EPO”) will grant a patent on genes if the application meets other patentability requirements, with the corresponding cDNA and the protein produced by it given full compound protection.²

III. Regulatory Barriers to Entry

A. U.S. Regulation

In the U.S., the 1986 Coordinated Framework for the Regulation of Biotechnology (“Coordinated Framework”) focuses on regulating the process of recombinant DNA (“rDNA”) plant and animal breeding.³

2. Thomas Haag, *Myriad Ruling vs. Biotech Patent Eligibility In Europe*, (June 21, 2013), available at <https://www.law360.com/articles/451636/myriad-ruling-vs-biotech-patent-eligibility-in-europe> (last visited April 26, 2017).

3. See Coordinated Framework for

The biotech crop approval process falls under the jurisdiction of USDA’s Biotechnology Regulatory Services (“BRS”), which assesses the environmental impacts of biotech crops.⁴ If BRS finds no significant impact after a review of the public comments under NEPA and BRS grants the deregulation petition, the way will be cleared for the developer to commercialize the biotech crop.⁵ The EPA has roles in crops that resist herbicides (to approve herbicide uses and warnings) or pests covered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁶

B. International Regulation

Some nation states, like Canada, regulate all “novel foods⁷” and include genetic editing in that category. This encompasses those crops created using non-rDNA methods, such as an herbicide-resistant crop created using older⁸ (chemical-radiation) or newer⁹ (genetic

Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

4. *Biotechnology Regulatory Servs.*, Animal & Plant Health Inspection Serv., USDA, <http://www.aphis.usda.gov/wps/portal/aphis/oufocus/biotechnology> (last visited Oct. 17, 2015) (Follow “Program overview” hyperlink, Follow “Functions” hyperlink).

5. See Thomas Redick & A. Bryan Endres, *Litigating the Economic Impacts of Biotech Crops*, NATURAL RES. & ENV’T, Spring 2008, at 25, available at http://www.jstor.org/stable/40924948?seq=1#page_scan_tab_contents.

6. 7 U.S.C. §136 et seq. (1996).

7. Seeds Regulations, C.R.C., c. 1400 (Can.); Thomas Moran et al., *A Cause of Action for Regulatory Negligence? The Regulatory Framework for Genetically Modified Crops in Canada and the Potential for Regulator Liability*, 6 1-2 U. OTTAWA L. & TECH. J. 1, 6 (2009).

8. See *Clearfield® Delivers Effective, Season-long Weed Control*, BASF, <http://www.agro.basf.com/agr/AP-Internet/en/content/solutions/herbicides/clearfield/index?mid=1> (last visited Oct. 6, 2015) (chemical mutagenesis can create herbicide-resistant crops).

9. See Didier Breyer et al., Commentary, *Genetic Modification Through Oligonucleotide-Mediated Mutagenesis. A GMO Regulatory Challenge?*, 8 ENVTL. BIOSAFETY RES. 57 (2009), available at

editing) forms of mutagenesis. Europe is considering casting its regulatory net on the newer forms of mutagenesis plant breeding,¹⁰ and other nations are likely to follow its lead. Canada is the only nation to require regulatory review of older forms of mutagenesis breeding, which arguably carry greater risks of off-target effects in genes (the adverse nature of which remain unlinked to health concerns). Notwithstanding the lack of any scientific theory to trace harm from this technology, activists have asserted that “The behavior of synthetic biological systems is inherently uncertain and unpredictable, yet the precautionary principle is not guiding research and development of synthetic organisms. Risk assessment protocols have not yet been developed to assess the potential ecological risks associated with synthetic biology.”¹¹ Gene-edited crops would be considered products of “synthetic biology”.

The international regulatory treaty that allows nations to follow the EU Internationally is the Cartagena Protocol on Biosafety (“Biosafety Protocol”), which regulates the release and use of “living modified organisms,” also known as genetically modified organisms (“GMOs”).¹² The parties to the Biosafety Protocol are calling genetic editing a form

of “synthetic biology” and will certainly take up the question of how to regulate genetic editing when they hold their next meeting in late 2018.

As part of the implementation of this law, nations that are parties to the Biosafety Protocol enact legislation, such as the European Traceability Directive, that impose zero-tolerance for the import of any GMO that lacks regulatory approval.¹³ More nations are imposing regulatory approval requirements as the Biosafety Protocol is implemented. Any biotech crop that could be exported may also require approval in many of these overseas markets.

For innovators in agricultural biotechnology, these approval requirements for overseas markets can create a barrier to their entry. For example, the new biotech potato that the USDA approved for J.R. Simplot Company, known as the Innate™ potato,¹⁴ may require “major market approval” to avoid causing another costly recall of potato chips in Japan, where regulatory approval and genetically-modified (“GM”) food labeling could complicate the marketing of any foods containing a biotech potato.¹⁵ Simplot’s Innate™ potatoes are “cisgenic,” meaning that the genes used to transform are from the same species—wild and commercial potatoes.¹⁶ Simplot plans to get

regulatory approval for Innate™ potatoes in “Japan, Mexico, and Canada as a ‘safety blanket,’ but has no intention of exporting [the potatoes] for at least two years.”¹⁷

Other genetic editing companies, like Cibus with its genetically edited canola, are getting Canadian and US approval and waiting to see what the Biosafety Protocol will do next, in terms of precautionary regulation.

IV. Litigation Risks

With pending lawsuits in the U.S. seeking to establish whether a crop approved in the U.S. can be a nuisance or the basis of a negligence action (such as failing to meet a duty of care to protect major markets overseas), there is a significant turning point ahead. For the first time in the history of litigation over biotech crops, a claim for nuisance or negligence will be made against a crop that has full approval for marketing in the United States. Given the history of similar litigation involving StarLink™ (“StarLink”) corn and LibertyLink® (“LL”) rice, the pending Syngenta litigation could expand the boundaries of common law claims for nuisance and negligence, which courts have traditionally adapted to address novel challenges and economic harms occurring in society.

Syngenta has made itself the target for litigation and initiated its own case to defend its assumed right to sell biotech corn before having major market approval, in this instance, from China. Syngenta initiated the litigation by suing a grain trader in 2011; and then three grain traders sued Syngenta in 2014.

The litigation expanded in 2015 to include growers in 22 states who filed cases, now recognized as class actions,

http://www.cibus.com/pdfs/EU_Belgium_repo_rt_ebr0910_100709.pdf (cisgenesis and oligonucleotide-mediated mutagenesis are examples of these new gene editing techniques).

10. See Maria Lusser & Emilio Rodriguez Cerezo, *Comparative Regulatory Approaches for New Plant Breeding Techniques*, JRC SCI. & TECHNICAL REP. 2012, at 13.

11. The International Civil Society Working Group on Synthetic Biology, A Submission to the Convention on Biological Diversity’s Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) on the Potential Impacts of Synthetic Biology on the Conservation and Sustainable Use of Biodiversity (2011) <https://www.cbd.int/doc/emerging-issues/Int-Civil-Soc-WG-Synthetic-Biology-2011-013-en.pdf>.

12. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 2226 U.N.T.S. 208.

13. Council Regulation 1830/2003, 2003 O.J. (L268/24) 18.10; Council Regulation 178/2002, art. 18, 2002 O.J. (L 31) 1.2.

14. *APHIS Announces Deregulation of J.R. Simplot Company’s Potato Genetically Engineered for Low Acrylamide Potential and Reduced Black Spot Bruise*, ANIMAL & PLANT HEALTH INSPECTION SERV., USDA (Nov. 24, 2014), http://www.aphis.usda.gov/wps/portal/aphis/newsroom/news/sa_federal_register_posts/sa_by_date/sa_2014/sa_11/ct_ge_potatoes!/ut/p/a/0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9_D2MDJ0MjDzdXUyMDTZdPA2cAtz8jT1dTPULsh0VAbiDHEw!/.

15. See *P&G to Recall Pringles in Japan*, BBC NEWS (July 17, 2001, 12:52), <http://news.bbc.co.uk/2/hi/business/1443154.stm>.

16. See Rebecca Randall, *Avoiding “Foreign Genes” Trap: Tale of Two Potatoes Highlights New Era of GE Crops*, GENETIC

LITERACY PROJECT (Jan. 6, 2015), <http://www.geneticliteracyproject.org/2015/01/06/avoiding-foreign-genes-trap-tale-of-two-potatoes-highlights-new-era-of-ge-crops/>.

17. John O’Connell, *USDA Deregulates Biotech Potato*, CAPITAL PRESS (Nov. 7, 2014, 1:29 PM), http://www.capitalpress.com/Nation_World/Nation/2014/11/07/usda-deregulates-biotech-potato.

alleging damages in excess of \$5.77 billion. While MIR162 was approved by China in December 2013, another trait, Duracade 5307, still awaited approval by China, raising a risk for further disruption of U.S. corn exports in the upcoming harvest season.¹⁸ As of April 1, 2017, Duracade had yet to receive food-feed import approval from China.¹⁹

On June 23, 2017, the jury rendered a verdict against Syngenta for \$217.77 million finding negligence in failing to prevent disruption of the export market for US corn to China. More awards in this litigation could define the boundaries of tort law in agricultural biotechnology for years to come.

V. Conclusion

While genetic editing offers tools to transform both crops and animals to make them safer to eat, more efficient to produce (with lower ecological impact) and myriad potential benefits, there is a move afoot internationally to regulate these crops just as strictly (under the “precautionary approach” in the Biosafety Protocol) as their recombinant DNA counterpart crops.

Internationally, patents might be easier to obtain for some applications, given the US Supreme Court’s recent reluctance to allow patents of “natural” origin.

Such regulation overseas can impede commercial launch in the US, particularly if the launch could trigger class actions seeking billions of dollars in economic impact and perhaps punitive damages.

18. Max Fisher, Potential Forecasted Economic Impact of Commercializing Agrisure Duracade™ 5307 in U.S. Corn Prior to Chinese Import Approval (April 16, 2014), <http://www.ngfa.org/wp-content/uploads/Agrisure-Duracade-5307-Economic-Impact-Analysis.pdf>.

19. International Service for the Acquisition of Agri-Biotech Applications (“ISAAA”) GM Approval Database, Event Name: 5307 (April 1, 2017) <http://www.isaaa.org/gmaprovaldatabase/event/default.asp?EventID=157>.

Updates Elsewhere

Agricultural & Food Law Consortium: Ag & Food Law Update

A quarterly update from a four university partnership designed to enhance and expand the development and delivery of authoritative, timely, and objective agricultural and food law research and information. Available at nationalaglawcenter.org/category/quarterlyupdate/.

Ag & Food Law Blog

A blog from the National Agricultural Law Center in Fayetteville, Arkansas, which includes a daily comprehensive summary of judicial, legislative, and regulatory developments in agriculture and food. Available at nationalaglawcenter.org/ag-and-food-law-blog/.

Agricultural Law Journals

Arkansas Journal of Food Law & Policy:

law.uark.edu/academics/journals/journal-food-law-policy.php

Drake Journal of Agricultural Law: aglawjournal.wordpress.drake.edu/

Kentucky Journal of Equine, Agriculture, & Natural Resources Law: www.kjeanrl.com/

San Joaquin Agricultural Law Review: www.sjcl.edu/index.php/sjalr

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SYNGENTA GROWER AND GRAIN TRADER CLAIMS

by Megan Galey and Thomas P. Redick*

This article will sum up the current status of the lawsuits filed against Syngenta for disrupting the U.S. corn export market to China. We will suggest that the outcome of this case could pose a challenge to the future use of agricultural biotechnology in the United States.

I. Factual Background

Syngenta commercialized its biotech corn trait, Agrisure Viptera® MIR162 (“Viptera”), in the United States starting in 2011. Although Syngenta had obtained regulatory approval for the sale of Viptera in the United States, Argentina, Japan, Canada, and the European Union, Syngenta’s application for importation and cultivation approval from the Chinese Ministry of Agriculture remained pending since its submission in March 2010. Nevertheless, Syngenta told growers that it expected approval from China in March 2012.¹ In late 2011, however, several major grain trading companies (Bunge and Consolidated Grain & Barge (CGB)) told growers it would not buy Viptera corn, since it saw “market signals” coming from China about its corn needs and anticipated selling corn to China, which had a zero-tolerance policy on the import of genetically-modified corn traits that had not been approved by the Chinese government.

Despite the concerns of the grain trade and China’s increasing need for imported corn, Syngenta continued to market Viptera in the United States in 2012. Syngenta’s decision not to wait for Chinese approval had the support of the National Corn Growers Association (“NCGA”) and was consistent with industry precedent. For instance, Monsanto launched several new corn

traits (MON89034 in the Genuity VT Triple PRO stack and SmartStax with Dow) without waiting for Chinese approvals in 2010, and these traits were grown on more acres than Syngenta’s Viptera traits were grown in 2011.

Syngenta also responded to the grain traders’ decision to reject Viptera by suing Bunge for allegedly attempting to illegally block the sale of the Agrisure Viptera trait. Since Viptera was sold in compliance with all U.S. regulatory requirements and longstanding industry guidance in the U.S., Syngenta felt it had a legitimate claim. After a federal court in Iowa denied Syngenta’s request for an injunction and dismissed most of Syngenta’s claims, Syngenta dismissed the case in December 2014.²

Over two years later, China stopped accepting all U.S. corn imports in November 2013 and did not begin importing U.S. corn again until late 2014 after China approved Viptera. Although the adverse economic impact of the 13-month trade disruption will be debated for years, in April 2014, a grain trade association issued a report suggesting multi-billion dollar adverse economic impacts.³

² Syngenta’s decision to ultimately dismiss the case was likely due to the fact that its event was approved in China, and that it would have been hard to prove that a buyer does not have the right to choose not to spend money on crops or other products based on their international regulatory status. Despite the outcome of the case, one should wonder whether Syngenta’s decision to sue Bunge made it easier for the other grain traders to decide to sue Syngenta.

³ See Max Fisher, *Lack of Chinese Approval for Import of U.S. Agricultural Products Containing Agrisure Viptera™ MIR 162: A Case Study on Economic Impacts in Marketing Year 2013/14*, NAT’L GRAIN & FEED ASS’N (April 16, 2014), <http://ngfa.org/wp-content/uploads/Agrisure->

In late 2014 and early 2015, grain traders sued Syngenta seeking compensation for lost export markets (measured in millions of dollars) and growers filed class actions seeking billions of dollars for alleged impacts to corn prices quickly thereafter. The plaintiffs claimed that Syngenta failed to follow industry standards for stewardship to keep Viptera out of the export distribution channel and falsely told growers that China would approve the trait in 2012.⁴ The growers asserted claims based on public nuisance, negligence, and fraud, while the grain traders brought negligence claims and claims under consumer protection statutes. The federal cases ultimately were consolidated in the U.S. District Court for the District of Kansas in Kansas City. After dismissing some claims on summary judgment motions, the multi-district litigation (“MDL”) court certified the class action and Syngenta’s interlocutory appeal of the class certification order was denied. A grower⁵ wanting to opt out had to send a letter postmarked by April 1, 2017 to be excluded from the class.⁶ The first MDL

[Viptera-MIR-162-Case-Study-An-Economic-Impact-Analysis.pdf](#).

⁴ See, e.g., Plaintiff’s Class Action Complaint for Damages and Injunctive Relief, *Hadden Farms Inc. v. Syngenta Corp.*, No. 3:14-cv-03302-SEM-TSH (C.D. Ill. filed Oct. 3, 2014) (class action complaint for damages and injunctive relief), available at <http://www.fien.com/pdfs/IllinoisvSyngenta.pdf>.

⁵ USDA estimates around 440,000 farmers grow corn in the United States.

⁶ Notice of Class Action Lawsuit, *In re Syngenta MIR162 Corn Litig.*, No. 14-md-2591-JWL-JPO (D. Kan.), available at http://www.syngentacornlitigation.com/wp-content/uploads/2016/12/Syngenta2016_Notice_v5.pdf.

¹ Paul Christensen, *Chinese Approval of Syngenta Agrisure Viptera*, SEED IN CONTEXT BLOG (February 21, 2012), <http://www.intlcom.com/seedsiteblog/?p=268>.

case against Syngenta is set for trial in June 2017.⁷

Parallel actions in state court are also going to trial in 2017. A Minnesota class action case will also allow punitive damages under a recent ruling, with a jury trial for one Nebraska farmer starting on April 24, 2017 (a verdict is expected in May) and another test trial for class plaintiffs set for August 14, 2017. Non-class cases are also pending because some growers opted out of the class, perhaps remembering resentment of the “gift card” settlements in the StarLink™ (“StarLink”) corn litigation.

After trial of test cases in state and federal court, attorneys will have a better idea of the potential liability in the class actions. Efforts to settle may wait for final approval of the sale of Syngenta to ChemChina. This sale has cleared the EU’s competition scrutiny, and ChinaChem’s tender offer for Syngenta shares closed May 4, 2017. Even if Syngenta succeeds in winning defense verdicts in the first test trials, Syngenta may choose to wait for various statutes of limitations in key corn belt states to expire to reach a global settlement. This process could take several years. Rulings made in this case will define the future boundaries for industry stewardship in all commodity crops, with potential negligence for failing to foresee future disruption of a potentially major export market for corn, soy or other exported agricultural products.

II. Litigation Positions

For the first time in the history of litigation over biotech crops, a claim for nuisance or negligence is going to trial alleging that a crop that had full approval for marketing in the United States disrupted an overseas market causing economic impact. Given the history of

⁷ *U.S. District Judge Certifies Syngenta Corn Case as Class Action* (Sept. 27, 2016), <http://www.syngentacornlitigation.com/2016/09/26/u-s-district-judge-certifies-syngenta-corn-case-class-action/>.

similar litigation involving StarLink corn and LibertyLink® (“LL”) rice, the pending Syngenta litigation could expand the boundaries of common law claims for nuisance and negligence by finding that Syngenta had a duty to seek major market approval (e.g., China, a major market as defined by the grain trade or a court). While courts have traditionally adapted common law claims to address novel challenges and economic harms occurring in society, this case could cause a seismic shift in biotech crop innovation, shutting down some product lines and limiting others to carefully contained production that does not disrupt trade.

A. Negligence

Plaintiffs’ core claim of negligence⁸ has survived all motions and could provide the best route to recovery. To prevail on their negligence claim against Syngenta, the plaintiffs will have to prove that Syngenta had a legal duty to avoid disrupting exports to China and that its failure to exercise due care caused plaintiffs to incur actual damages.

In response, Syngenta will argue that it owed no duty to growers or grain traders to wait for approval from China and that segregation for export interests is the growers’ challenge, depending on the buyers’ needs. In support of its position, Syngenta will likely cite to the NCGA’s policy which did not require such approvals before launching Viptera.⁹ Syngenta may also seek to rely upon the Biotechnology Industry Association’s (“BIO”) published standards for stewardship, which discuss the need to seek approval in “major” markets with

⁸ See Non-Producer Plaintiffs’ Third Amended Master Complaint at 93-108, *In re Syngenta AG MIR162 Corn Litig.*, No. 2:14-md-02591-JWL-JPO (D. Kan. Sept. 19, 2016), available at <http://www.ksd.uscourts.gov/non-producer-plaintiffs-third-amended-master-complaint-doc-2530/>.

⁹ See, NCGA, *Know Before You Grow*, (2015), <http://www.ncga.com/farmers/know-before-you-grow> (last visited May 16, 2015).

“functioning” regulatory systems.¹⁰ However, it may be an open question whether the 2011 China export corn market was so minimal that it was not “major” and hence the applicable standard of care would only require approval from Japan.

While Syngenta was not a member of BIO, it has been a member of BIO’s Excellence Through Stewardship (“ETS”) program since 2008. ETS is a program that BIO members sign up for, which requires companies to engage in stewardship for exports, including analyses of market acceptance. Syngenta allegedly failed to implement stewardship to protect exports to China by segregating Viptera to domestic uses.

To defeat public nuisance claims, Syngenta will also argue that the benefits of getting corn traits into production outweighed the alleged adverse economic impacts. Its experts may claim that lower corn prices in the U.S. were due to high U.S. corn production and were not caused by Chinese rejection of U.S. corn. Indeed, there is no disputing that China had not made any signals of an intent to buy significant shipments of U.S. corn as of spring 2011 when nationwide planting of Viptera began in the United States.¹¹

B. Voluntary Undertaking

As an alternative basis for a duty, plaintiffs alleged that Syngenta owed a duty to them under the voluntary undertaking doctrine. Many states recognize that a duty can arise when a defendant offers to take action to prevent some harm, but negligently fails to fulfill its “voluntary undertaking” (like a “Good Samaritan”).¹² If Syngenta offered to

¹⁰ Biotechnology Innovation Organization, EXCELLENCE THROUGH STEWARDSHIP, <http://www.excellencethroughstewardship.org/> (last visited May 26, 2017).

¹¹ Fisher, *supra* note 4, at 5 (stating that China imports of US corn dipped below one million metric tons (“1 MMT”) from 1.2 MMT in 2009-10 (6th largest) to 980 in 2010-11 (5th largest)).

¹² See *McGee v. Chalfant*, 806 P.2d 980 (Kan. 1991).

render stewardship services but failed to exercise due care in the performance of its stewardship program, it could be liable for the harm caused to the growers and grain traders.

Syngenta has cited its relationship with its seed buyers to reject this duty, stating: “[F]armers don’t have any exposure whatsoever to Chinese corn rejection they sell their corn to the elevator” who sells into a grain trader.¹³ Willing growers must decide which buyer gets their corn. Growers who bought Viptera are excluded from the class, and while they may be the ones whose corn commingled, they have not been sued for causing trade disruption.

Syngenta alleges that growers who know of buyers’ export-related expectations arguably have a duty to protect their own economic interests. A grower can call Syngenta or check NCGA’s “Know Before You Grow” webpage or the International Service for the Acquisition of Agri-biotech Applications (“ISAAA”) database for export approval information.

Syngenta’s failed efforts to contain its corn could give rise to liability under this “voluntary undertaking” basis for imposing a duty of care. In *McGee v. Chalfant*, the Kansas Supreme Court held that, even in the absence of a special relationship, “the actor may still be liable to third persons when he negligently performs an undertaking to render services to another which he should recognize as necessary for the protection of third persons,” as set forth in Section 324A of the Restatement of Torts.¹⁴ Plaintiffs argue that Syngenta voluntarily undertook compliance with the BIO policy concerning the commercialization

of new GM products but failed to protect the China export market.

In rejecting this argument, the Court in the Syngenta Corn Class Action agreed with Syngenta, finding that Section 324A cannot apply here. Plaintiffs have not sought to recover for “physical” harm and the Restatement section provides for liability “for physical harm resulting from [the actor’s] failure to exercise reasonable care to protect his undertaking.”¹⁵ Since the Kansas Supreme Court has specifically held that Section 324A “has application only in cases involving physical harm,”¹⁶ and the court found no “physical harm” from the decline in prices (as opposed to actual commingling with particular corn), the Court granted Syngenta’s motion for summary judgment with respect to any claim of negligence in which liability is based on any alleged misrepresentation, a voluntary undertaking, a failure to warn, or a duty to recall.¹⁷

D. Damages

Lastly, Syngenta’s experts may claim that the lower corn prices were not impacted by loss of the Chinese market for around a year during a time of high U.S. corn production. It will cite NCGA’s policy of only requiring approval from Japan and other markets with functioning regulatory systems and BIO’s policy of only requiring approval from Japan and Canada. Plaintiffs alleged that Syngenta’s negligence caused damages up to \$5.77 billion for the nationwide class and up to \$235.4 million for the Kansas class, based upon opinions of plaintiffs’ damages experts.¹⁸ On June 23,

2017, the jury rendered a verdict against Syngenta for \$217.77 million finding negligence in failing to prevent disruption of the export market for US corn to China. This is the first jury verdict and it awards plaintiff farmers all the economic damages they were seeking, but no punitive damages. The decisions coming from this court could define the boundaries of tort law in agricultural biotechnology for years to come.

It remains to be seen whether the pending approval of Syngenta’s merger with ChinaChem (just approved in April 2017 by the EU antitrust authorities)¹⁹ could help this case reach settlement after the first few trials test the issues in U.S. courts.

III. Conclusion

The courts ruling on these pending cases appeared poised to find that any grower or grain trader seeking a specialized market (e.g., the benefits of export markets) should maintain their own identity preserved production. Any failure to implement such self-imposed measures may lead to economic loss, but the court may find this loss cannot be recovered in tort against the seller of a U.S.-approved biotech crop that lacked approval in certain export markets. The decisions emerging from these courts could define the boundaries of tort law in agricultural biotechnology for years to come.

¹³ SYNGENTA, FIRST QUARTER 2014 SALES TRANSCRIPT 28 (2014), available at <http://www4.syngenta.com/~media/Files/S/Syngenta/events-and-presentations/q1-2014-transcript-syngenta.pdf> (quoting Michael Mack, Syngenta CEO).

¹⁴ McGee, 806 P.2d at 983.

¹⁵ See RESTATEMENT (SECOND) OF TORTS § 324A.

¹⁶ *Barber v. Williams*, 767 P.2d 1284, 1289 (Kan. 1989)

¹⁷ Memorandum and Order at 9–10, *In re Syngenta AG MIR 162 Corn Litig.*, No. 14-md-2591-JWL (Apr. 5, 2017), available at https://ecf.ksd.uscourts.gov/cgi-bin/show_public_doc?2014md2591-3051.

¹⁸ Todd Neeley, *Syngenta Trial Set: Viptera Class-Action Case in June*, DTN/THE PROGRESSIVE FARMER (Feb. 2, 2017), available at

<https://www.dtnpf.com/agriculture/web/agnews/article/2017/02/02/viptera-class-action-case-summer>.

¹⁹ Reuters, *EU set to approve ChemChina’s bid for Syngenta*, (February 3, 2017) available at <http://www.scmp.com/business/companies/article/2067603/eu-set-approve-chemchinas-bid-syngenta>.

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