THE FUTILE EXERCISE: *OSGATA V. MONSANTO*

I. INTRODUCTION

In 2013 alone, seed giant Monsanto won two major cases for its patented, genetically modified crops. In the first, *Bowman v. Monsanto*, the United States Supreme Court held that a farmer who desired to exploit Monsanto's patented technology without paying a royalty could not do so because patent protection of self-replicating technologies carries forward into subsequent generations.[1] In the second, *OSGATA v. Monsanto*, the Federal Circuit held that inevitable contamination was not enough to allow the organic food industry a voice to assert claims of patent invalidity because of a lack of standing.[2]

This article explores the legal strategy used in *OSGATA v. Monsanto* by Mr. Daniel Ravicher through his non-profit organization known as PUBPAT. PUBPAT has successfully challenged the intellectual property interests of big corporate interests such as pharmaceuticals, computer software, and genetics.[3] Simply stated, PUBPAT believes itself to be a balancing voice in a world of growing, pervasive patent rights.[4] To do this, PUBPAT seeks to invalidate or limit patent protection in order to promote unrestricted use of the technology.[5] PUBPAT sought to apply a similar strategy to *OSGATA v. Monsanto*.[6]

It is incongruous for PUBPAT to join forces with the organic food industry by seeking to invalidate all of Monsanto's patents. The stated goals of the organic industry are to work to curb and prevent use of genetically modified crops, yet the logical and immediate consequence of PUBPAT attempting to invalidate Monsanto's patents is to allow unrestricted use of the Roundup Ready technology by any of

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[1] Bowman v. Monsanto Co.,133 S.Ct. 1761, 1769 (2013).
[2] Organic Seed Growers & Trade Ass'n v. Monsanto Co.,851 F. Supp. 2d 544 (S.D.N.Y. 2012) aff'd, 718 F.3d 1350 (Fed. Cir. 2013).
3 See generally Protecting the Public Domain, Pub. Pat. Found., http://www.pubpat.org/Protecting.htm (last visited Dec. 30, 2013); About PUBPAT, Pub. Pat. Found., http://www.pubpat.org/About.htm (last visited June 24, 2013).
4 About PUBPAT, supra note 3.
5 See Id.
[6] Organic Seed v. Monsanto, PUB. PAT. FOUN (Dec. 30, 2013), http://www.pubpat.org/monsanto-seed-patents.htm.

Monsanto's competitors. Making generic the patented Roundup Ready technology only further complicates OSGATA's ultimate goals - life without genetically modified crops in a world where modern farming has grown dependent upon the benefits genetically modified crops confer.[7]

Part I of this Article gives context to the involvement of PUBPAT in connection with OSGATA and then analyzes the weight of OSGATA's claims against the relevant body of patent case law to determine if such a legal challenge (for plaintiffs having actual legal standing) is likely to succeed in the future. Part II utilizes the expiration of Monsanto's Roundup Ready Generation One Technology ("RR1") patents, which are set to expire in 2014, as a means by which to discuss the potential implications were PUBPAT to ultimately succeed using its patent invalidity theories. Part III analyzes the many issues triggered by domestic and international regulatory approval processes in the use of genetically modified crops as a means by which to further flesh out the implications of patent invalidation.

II. PUBPAT & OSGATA: AN UNLIKELY PAIR

A. Who or What is PUBPAT?

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization whose mission is to protect and strengthen the patent system by introducing non-patentee input in hopes of achieving balanced policies.[8] PUBPAT is a self-appointed voice against what the organization believes to be excessive patent rights in a free market economy by advocating on a number of levels: education, legislation, and litigation.[9] PUBPAT educates through public presentations, one-on-one discussions, and widespread literary publication.[10] Legislatively, PUBPAT advocates for substantive patent reform.[11] For

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[7] *About OSGATA, OSGATA, http://www.osgata.org/about/ (last visited June 24, 2013).*

8About PUBPAT, supra note 3.

9Id.

10Educating and Advocating, Pub. Pat. Found., http://www.pubpat.org/Educating_and_Advocating.htm (last visited June 25, 2013).

[11] *PUBPAT in Congress, PUB. PAT. FOUND. (June 25, 2013), http://www.pubpat.org/advocacytocongress.htm (last visited June 25, 2013).*

example, in 2005, Ravicher addressed Congress regarding the Patent Reform Bill of 2005.[12] In his statement, Ravicher wrote that:

> The interests of the non-patent holding public are almost always absent from any meaningful participation in decision making about the patent system, despite the fact that they bear the brunt of its burdens. Patent policy should be made with consideration of all the public's interests, not just the specific interests of the Patent and Trademark Office, patent practitioners, and large commercial actors.[13]

The most overt means by which PUBPAT strives to accomplish its mission is by engaging in litigation and initiating reexamination procedures against patents believed to have an undesirable effect on society.[14]

In its relatively short history, PUBPAT has enjoyed success when acting against patents in the fields of pharmaceuticals, software, and computers. In 2004, PUBPAT challenged the validity of Microsoft's FAT Patent.[15] The FAT file system was originally developed as a file allocation table file system for use in early computer operating systems.[16] Today, the FAT file system is widely used in flash memory systems and other means of media exchange between computers and digital devices.[17] This resurgence led Microsoft to demand royalty-bearing licenses, and PUBPAT responded.[18] PUBPAT succeeded in

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[12] *See U.S. Congress Invites PUBPAT Executive Director to Testify About Patent Reform, PUB. PAT. FOUND., http://www.pubpat.org/Congressional_Testimony_June2005.htm (last visited June 24, 2013).*

[13] *Id.*

[14] *See About PUBPAT, supra note 3.*

[15] *See generally Microsoft FAT Patent, PUB. PAT. FOUND., http://pubpat.org/microsoftfat.htm (last visited June 24, 2013); PUBPAT's Request for Reexamination of Microsoft's FAT Patent, PUB. PAT. FOUND., http://www.pubpat.org/assets/files/MicrosoftFAT/Reynolds_517_Reexam_Request.pdf (last visited June 24, 2013); Patent Office's Order Granting PUBPAT's Request for Reexamination of Microsoft FAT Patent, PUB. PAT. FOUND., http://www.pubpat.org/assets/files/MicrosoftFAT/Reynolds_517_Reexam_Granted.pdf, (last visited June 24, 2013).*

[16] *FAT File System, MICROSOFT LEGAL AND CORPORATE AFFAIRS, http://www.microsoft.com/en-us/legal/intellectualproperty/IPLicensing/Programs/FATFileSystem.aspx, (last visited June 24, 2013).*

[17] *Id.*

[18] *PUBPAT Challenges Microsoft Patent to Protect Competition in Software Markets, PUB. PAT. FOUND.,*

having Microsoft's patent to the FAT technology provisionally revoked in a proceeding before the Patent and Trademark Office ("PTO").[19] Microsoft ultimately elected to amend its patent claims, so PUBPAT accomplished its goal by injecting its voice into the patent process in a way that drew attention to the claim of excessive use of patent rights by big corporate entities.[20]

Also in 2004, PUBPAT challenged the patents held by pharmaceutical giant Pfizer.[21] At the time, Lipitor was one of the best-selling cholesterol medicines on the market.[22] Lipitor lowers cholesterol in the body by blocking an enzyme in the liver that is used to make cholesterol.[23] PUBPAT utilized PTO reexamination proceedings as a means by which to argue that the Lipitor patent was anticipated by earlier work of other inventors and never should have been granted.[24] As a result, the patent office rejected Pfizer's Lipitor patent in mid-2005.[25]

In 2009, on behalf of the Association for Molecular Pathology and other plaintiffs, PUBPAT joined to support the American Civil Liberties Union ("ACLU") in federal court to challenge the validity of patents on human genes held by Myriad Genetics.[26] Myriad had

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http://www.pubpat.org/Microsoft_517_Reexam_Filed.htm (last visited July 25, 2013).

[19] Patent Office's Office Action Rejecting Microsoft FAT Patent, PUB. PAT. FOUND., http://www.pubpat.org/assets/files/MicrosoftFAT/Reynolds_517_Rejected_040916.PDF (last visited June 24, 2013).

[20] See Microsoft FAT Patent, supra note 15.

[21] Pfizer Lipitor Patent, PUB. PAT. FOUND., http://www.pubpat.org/pfizerlipitor.htm (last visited June 24, 2013).

[22] Id.

[23] How Lipitor Tablets Work, LIPITOR, http://www.lipitor.com/aboutLipitor/howLipitorWorks.aspx, (last visited June 24, 2013).

[24] PUBPAT's Request for Reexamination of Pfizer's Lipitor Patent, PUB. PAT. FOUND., http://www.pubpat.org/assets/files/PfizerLipitor/Briggs_156_Reexam_Request.pdf (last visited June 24, 2013).

[25] Patent Office Action Rejecting Pfizer's Lipitor Patent, PUB. PAT. FOUND., http://www.pubpat.org/assets/files/PfizerLipitor/Briggs_156_Rejected_050613.pdf (last visited June 24, 2013).

[26] See generally AMP v. Myriad: Gene Patents, PUB. PAT. FOUND., http://www.pubpat.org/brca.htm (last visited June 24, 2013); Complaint, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013), available at http://www.aclu.org/files/images/asset_upload_file939_39568.pdf.

discovered the genetic sequence and location for the BRCA1 and BRCA2 genes, mutations of which increase the likelihood of a woman's risk for breast and ovarian cancer, and this discovery led Myriad to patent the genes and also develop tests to detect mutations.[27] PUBPAT asserted that Myriad's patents on the genes afforded Myriad a monopoly that sequestered further research on the genes – testing that would benefit society and public health as a whole.[28] PUBPAT also argued that Myriad's patents allowed them to charge over $3,000 dollars per test, a cost that effectively prevented many women from receiving the valuable test.[29] Combined, these factors led PUBPAT and the ACLU to challenge the validity of Myriad's patents.[30] In 2013, after nearly four years of litigation and appeals, the United States Supreme Court held that isolated, naturally occurring DNA is not eligible for patenting simply because it has been isolated; however, synthetic DNA, because it is not naturally occurring, is patentable.[31] PUBPAT declared the decision a victory, stating, "diagnostic genetic testing is now free from any patent threat, forever, and the poor can now have their genes tested as freely as the rich."[32]

With the FAT, Lipitor, and BRCA gene patents, PUBPAT effectively sought to limit the rights of those specific patentees in hopes that a more widespread use of the technology would benefit the public as a whole.[33] In 2011, in joining suit on behalf of the Organic Seed Growers and Trade Association ("OSGATA") and in a direct attack against Monsanto's patented genetically modified seed technology, PUBPAT sought to apply that same strategy.[34]

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[27] *Complaint, Ass'n for Molecular Pathology, 133 S. Ct. 2107, 186 L. Ed. 2d 124 at 2.*

[28] *See generally AMP v. Myriad: Gene Patents, supra note 26; Complaint, Ass'n for Molecular Pathology, 133 S. Ct. 2107, 186 L. Ed. 2d 124 at 2.*

[29] *Complaint, Ass'n for Molecular Pathology, 133 S. Ct. 2107, 186 L. Ed. 2d 124 at 27.*

[30] *AMP v. Myriad: Gene Patents, supra note 26.*

[31] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).*

[32] *Supreme Court Invalidates Patents on Breast and Ovarian Cancer Genes, PUB. PAT. FOUND., http://www.pubpat.org/ampsctdecision.htm (last visited June 24, 2013).*

[33] *See AMP v. Myriad: Gene Patents, supra note 26; Microsoft FAT Patent, supra note 15; Pfizer Lipitor Patent, PUB. PAT. FOUND., http://www.pubpat.org/pfizerlipitor.htm (last visited June 24, 2013).*

[34] *Complaint, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*

B. OSGATA

Formed in 2007, OSGATA is a national non-profit organization committed to protecting, promoting, and developing the organic seed trade for its growers.[35] Comprised of organic farmers, seed breeders, seed companies, and other affiliate organizations, OSGATA serves as a voice in the organic community.[36] OSGATA claims that genetically modified seed may be the greatest clear and present threat to the organic industry because organic seed is in short supply due to genetic contamination of conventionally bred crops with genetically modified crops.[37] OSGATA works to promote freedom from transgenic contamination in the agricultural marketplace.[38] At the beginning of the case, OSGATA and PUBPAT publicly declared two goals for their lawsuit against Monsanto: (1) to challenge Monsanto's patents on genetically modified seed and (2) to insulate farmers who have inadvertently become contaminated by Monsanto's patented seed from being accused of patent infringement.[39]

III. OSGATA – CLAIMS IN SUIT

OSGATA and a host of other named plaintiffs brought suit against Monsanto because of the ever-increasing threat of genetically modified seed contamination.[40] In the initial complaint for declaratory relief, OSGATA sought to prospectively insulate its organic farming operators from a patent infringement suit were their crops eventually to become genetically contaminated with Monsanto's patented GMO seed.[41] The logic of the complaint was threefold: (1) contamination from transgenic seed is inevitable and will eventually overtake

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[35] *About OSGATA, supra note 7.*
[36] *Id.*
[37] *Why Organic Seed?, OSGATA, http://www.osgata.org/why-organic-seed/ (last visited June 6, 2013); About OSGATA, supra note 7.*
[38] *About OSGATA, supra note 7.*
[39] *OSGATA et al. v. Monsanto, OSGATA, http://www.osgata.org/osgata-et-al-v-monsanto/ (last visited June 26, 2013).*
[40] *Organic Farmers and Seed Sellers Sue Monsanto to Protect Themselves from Patents on Genetically Modified Seed, OSGATA, http://archive.constantcontact.com/fs074/1104248386985/archive/1110848049754.html (last visited June 24, 2013); Complaint, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[41] *Complaint, Organic Seed Growers & Trade Ass'n, 851 F. Supp. 2d 544.; See Generally OSGATA et al. v. Monsanto, supra note 39.*

conventional (non-GMO) seed; (2) because contamination is inevitable, organic farmers will live in fear of Monsanto's expensive patent infringement claims, making it necessary for them to bring suit in order to protect themselves from ever being accused of patent infringement; and (3) Monsanto's transgenic seed is the most prevalent, and it appears that Monsanto has an aggressive litigation policy.[42] In light of their concerns, PUBPAT and OSGATA chose to frame the issue this way: does a party at seemingly imminent risk of inevitable, inadvertent, and undesired genetic contamination have standing to seek a declaratory judgment to redress its injuries?[43] Since no named plaintiffs had yet been contaminated, PUBPAT could not frame the case as a contamination issue; instead, PUBPAT approached the litigation forcefully asserting patent invalidity, non-infringement, and patent misuse.[44]

The complaint alleged that all of Monsanto's patents were legally invalid based on numerous theories.[45] First, PUBPAT alleged Monsanto's patents were not useful and thus failed to meet the beneficial utility requirement as outlined in Art I, § 8, cl. 8 of the Constitution and 35 U.S.C. §101.[46] Second, pursuant to 35 U.S.C. § 103, the complaint alleged Monsanto had "unjustly extended its period of patent exclusivity by duplicating its ownership of a field of invention already covered by other patents."[47] Third, by referencing 35 U.S.C. § 102, the complaint alleged "Monsanto's patents are invalid because prior art exists that anticipates or renders obvious each of their claims."[48] Fourth, citing 35 U.S.C. § 112, the complaint stated, "each patent fails to satisfy the requirements of written description, enablement and best mode."[49]

OSGATA then argued, alternatively, that even if Monsanto's patents were valid, Monsanto was nonetheless precluded from enforcing any GMO patents under the doctrines of patent exhaustion, patent misuse, equitable estoppel, trespass, and a lack of economic harm to Monsanto.[50] The complaint further asserted that the doctrine of patent

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[42] *Complaint, Organic Seed Growers & Trade Ass'n, 851 F. Supp. 2d 544 at 2-3.*
[43] *Id.*
[44] *Id. at 3-4.*
[45] *Id.*
[46] *Id. at 3.*
[47] *Id. at 39.*
[48] *Id. at 39, 44.*
[49] *Id. at 4, 39, 44.*
[50] *Id. at 4.*

exhaustion effectively precluded Monsanto from enforcing its patent rights because those rights had exhausted upon the authorized distribution by Monsanto to its customers.[51] In a similar vein to patent exhaustion, the affirmative defense of patent misuse serves to stop a patentee from abusing the exclusive right to the patented article.[52] The complaint alleged that Monsanto misused its patents on transgenic seed to achieve dominance and maintain anticompetitive benefit and that Monsanto had used this dominance to diminish competition and slow innovation, and as a result, markets have seen a dramatic rise in seed prices.[53] Furthermore, the plaintiffs claimed Monsanto had sought to enhance its dominant market power through abusive litigation practices and anticompetitive licensing agreements.[54]

To further bolster its allegations of patent misuse, the complaint alleged Monsanto had asserted infringement "against literally hundreds of farmers, including those farmers who became contaminated by Monsanto's transgenic seed through no fault of their own."[55] OSGATSA also claimed unenforceability of Monsanto's patents due to equitable estoppel.[56] Finally the complaint alleged, "to the extent that Monsanto's transgenic seed contaminates plaintiffs, Monsanto has wrongfully interfered with plaintiff's rights to possess, enjoy, and exploit their property."[57]

IV. PROCEDURAL HISTORY

Immediately after filing the complaint, PUBPAT sent a letter to Monsanto asking for a broad covenant not to sue any organic producer that was a party to the suit.[58] The letter stated: "[W]e hereby request that Monsanto expressly waive any claim for patent infringement it may ever have against our clients and memorialize that waiver by providing a written covenant not to sue."[59] The letter went on to state

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[51] *Id.*
[52] *Robert Patrick Merges & John Fitzgerald Duffy, Patent Law and Policy: Case Materials 1349-1350, 3d ed. 2002.*
[53] *Complaint, Organic Seed Growers & Trade Ass'n, 851 F. Supp. 2d 544 at 40.*
[54] *Id. at 40, 41.*
[55] *Id. at 3.*
[56] *Id. at 4, 43, 45.*
[57] *Id. at 4, 42, 43, 45.*
[58] *Amended Complaint Exhibit 3 at 73, 74, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[59] *Id.*

that failure to respond in a timely fashion would be considered affirmation that Monsanto would assert patent infringement against one or several of the plaintiffs.[60] Monsanto responded by acknowledging that if in fact the circumstances were as the plaintiffs represented them to be, Monsanto would see no reason why they would bring suit against the plaintiffs.[61] The letter highlighted Monsanto's public policy, which "has never been, nor will be, to exercise its patent rights where trace amounts of its patented seed or traits are present in a farmer's fields as a result of inadvertent means."[62]

The suit progressed, and Monsanto filed a motion to dismiss for lack of subject matter jurisdiction, explaining there was no "substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[63] Monsanto persuaded the district court that no justiciable controversy was at hand.[64] OSGATA appealed to the Federal Circuit Court of Appeals, the court reserving appellate jurisdiction for all patent appeals.[65]

On appeal, OSGATA argued that the immediacy to the controversy at hand was a restricted use of land and loss of potential crops.[66] In its June 2013 opinion, the Federal Circuit acknowledged OSGATA's concern regarding the substantial risk of genetic contamination, noting that even *de minimus* infringement can constitute infringement.[67] Despite this inevitability of infringement, the appellate court nonetheless believed a declaratory judgment to be inappropriate at that time.[68] The court based its decision, in part, on Monsanto's assurances of having no intention to sue farmers having contamination in only trace amounts of GMO genetic content.[69] Because the entirety of the

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[60] *Id.*
[61] *Id. at 76*
[62] *Id.*
[63] *Organic Seed Growers & Trade Ass'n v. Monsanto Co.,851 F. Supp. 2d 544 (S.D.N.Y. 2012) aff'd, 718 F.3d 1350 (Fed. Cir. 2013).*
[64] *Id.*
[65] *Organic Seed Growers & Trade Ass'n v. Monsanto Co., 718 F.3d 1350 (Fed. Cir. 2013).*
[66] *Brief of Appellant at 11, Organic Seed Growers & Trade Ass'n v. Monsanto Co.,851 F. Supp. 2d 544 (S.D.N.Y. 2012) aff'd, 718 F.3d 1350 (Fed. Cir. 2013).*
[67] *Organic Seed Growers & Trade Ass'n, 718 F.3d at 1356.*
[68] *Id. at 1350.*
[69] *Id. at 1360-61.*

plaintiffs fell within the scope of people Monsanto proclaimed to have no intention to sue, the court reasoned there was not a real, substantial, or immediate controversy at hand, which is necessary to satisfy Article III's case or controversies requirement.[70] However, the Federal Circuit Court of Appeals did hold that Monsanto's statements were binding as a matter of judicial estoppel.[71] The effect of Monsanto's statement was limited to parties whose seed contained less than 1% of Monsanto's patented technology.[72]

V. DISCUSSION

Monsanto's timely motion challenging OSGATA's standing to sue prevented what many in the organic community might have hoped for: a direct challenge to Monsanto's patents and business tactics. But one wonders, what could have happened if OSGATA was found to have standing to attack the validity of Monsanto's patents. Indeed, if OSGATA's true motive was to invalidate all Monsanto GMO patents, then why would PUBPAT present such an attack using plaintiffs having neither standing nor any proof of contamination? If PUBPAT had the necessary clear and convincing evidence to invalidate Monsanto's patents, then why would PUBPAT not step forward and work alongside producers already involved in litigation with Monsanto where standing to assert invalidity of the patents-in-suit would be unassailable? This point cannot have been a mere lapse, especially since OSGATA's argument in hoping to preserve standing was that Monsanto aggressively asserts its patents against many others producers.

A. Patent Invalidity Challenges

"What the opponents of biotechnology seek – to deny patents for subject matter they consider immoral – is not unknown in the history of patent law."[73]

OSGATA's complaint begins by asserting Monsanto's patents should be declared invalid due to a failure to satisfy the beneficial

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[70] *Id. at 1360.*
[71] *Id. at 1358-59.*
[72] *Id. at 1359.*
[73] *Merges, supra note 52, at 226.*

utility requirement.[74] Specifically, the complaint sets forth that "because transgenic seed, and in particular Monsanto's transgenic seed, is injurious to the well-being, good policy, or sound morals of society, and threatens to poison people," that Monsanto's patents on transgenic seed fail to satisfy the moral elements of the beneficial utility requirement of the patent code.[75] Unfortunately, the complaint relies on Justice Story's 1817 definition of "beneficial".[76] Justice Story wrote that to be patentable, an invention must not be "injurious to the well-being, good policy, or sound morals of society," and "a new invention to poison people or to promote debauchery, or to facilitate private assassination . . . is not a patentable invention."[77] In support of its position, the complaint cites to Art I, § 8, cl. 8 of the Constitution, "to promote the progress of science and useful arts," and 35 U.S.C. §101, "whoever 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 therefore."[78]

On its face, § 101 requires that an invention be useful and capable of providing some identifiable benefit.[79] Beneficial utility asks whether the invention does what it is supposed to do and is it something society wants done?[80] Although it might appear that that beneficial utility therefore harbors a moral component, the courts have been reluctant to rely on such grounds to invalidate a patent.[81] In *Juicy Whip, Inc. v. Orange Bang Inc.*, the Federal Circuit Court of Appeals stated,

> The threshold of utility is not high: An invention is "useful" under section 101 if it is capable of providing some identifiable benefit. *See Brenner v. Manson*, 383 U.S. 519, 534 (1966); *Brooktree Corp. V. Advanced Micro Devices*, *Inc.,* 977 F.2d 1555, 1571 (Fed. Cir. 992). (To violate § 101 the claimed device must be totally incapable of achieving a useful result"); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903) (test for utility is whether

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[74] *Complaint at 3, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[75] *Id.*
[76] *Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817). Abrogated by in re fisher; Complaint at 3, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[77] *Lowell, 15 F. Cas. at 1019. Abrogated by in re fisher; Complaint at 3, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[78] *Complaint, Organic Seed Growers & Trade Ass'n, 851 F. Supp. 2d 544 at 3.*
[79] *35 U.S.C.A. § 101 (2013).*
[80] *Merges, supra note 52, at 226.*
[81] *Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366-67 (Fed. Cir. 1999).*

> invention is incapable of serving any beneficial end") . . . Courts have continued to recite Justice Story's formulation, but the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years.[82]

The Federal Circuit Court opinion continues by stating it is not the responsibility of either the courts or the patent office to consider whether a product is morally sound, i.e., that such responsibility tangentially falls within the purview of other entities such as the Food and Drug Administration, Environmental Protection Agency, and other regulatory agencies not known to exist when Justice Story was authoring opinions.[83] Indeed, the United States Supreme Court has stated, "[C]ongress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted."[84] The intent of the beneficial utility requirement is well-understood and settled law: the responsibility for moral analysis is in the hands of the legislative bodies, not the patent office or the courts.

Next, the complaint stated that Monsanto had "unjustly extended its period of patent exclusivity by duplicating its ownership of a field of invention already covered by other patents," alleging that Monsanto's patents should be declared invalid for violating the prohibition against double patenting.[85] Based on the language in the complaint, it appears that OSGATA asserted what is known as obviousness-type double patenting.[86] In plain terms, a company may not unreasonably rely upon a series of patents to indefinitely keep the technology under patent protection. For a double patenting claim to succeed, a party must show through clear and convincing evidence that the current patent claim is not patentably distinct from an already held patent.[87]

The next basis for challenging Monsanto's patents was made pursuant to 35 U.S.C. § 102, alleging prior art exists that anticipates or

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[82] *Id.*
[83] *Id. at 1368.*
[84] *Id. (quoting Webber v. Virginia, 103 U.S. 344, 347-48 (1880)).*
[85] *Complaint at 39, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[86] *Id.*
[87] *See generally Eli Lilly & Co. v. Barr Laboratories, Inc., 251 F.3d 955, 962 (Fed. Cir. 2001); United States Surgical Corp. v. Ethicon Inc., 103 F. 3d 1554, 1563 (Fed. Cir. 1997); In re Longi, 759 F.2d 887 (Fed. Cir. 1985).*

renders obvious each of Monsanto's claims.[88] Historically, when evaluating a claim of prior art that involves § 102(a), courts have considered: "(1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and (4) objective evidence of nonobviousness if any."[89] Furthermore,

> A patent is invalid if an alleged infringer proves, by clear and convincing evidence, that the difference between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art.[90]

The last statutory challenge was made pursuant to 35 U.S.C. § 112, claiming Monsanto's patents are invalid because each patent fails to satisfy any of the requirements of written description, enablement, or best mode.[91] It is generally understood that in order to satisfy the requirements of written description, an inventor must include enough information to enable someone skilled in the art to recreate the invention.[92] The Federal Circuit Court of Appeals stated that an "adequate written description of genetic material requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed invention."[93] Enablement requires the inventor to describe her invention clearly enough so as to prevent a skilled artisan from having to undertake a great deal of experimentation to reproduce the claimed invention.[94] When evaluating a claim of enablement, courts often seek to determine whether or not undue experimentation would be required to recreate the patented article by addressing:

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[88] *Complaint, Organic Seed Growers & Trade Ass'n, 851 F. Supp. 2d 544 at 39, 44; 35 U.S.C.A. § 102 (2013).*
[89] *In re Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009); See Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966).*
[90] *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc., 678 F.3d 1280, 1290 (Fed. Cir. 2012) cert. denied, (2013); See 35 U.S.C.A. § 103 (2013).*
[91] *Complaint, Organic Seed Growers & Trade Ass'n, 851 F. Supp. 2d 544 at 44; 35 U.S.C.A. § 112 (2013).*
[92] *Merges, supra note 52, at 303.*
[93] *Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (quoting Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir. 1993)).*
[94] *Merges, supra note 52, at 262.*

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[95]

Although somewhat similar, the Federal Circuit Court of Appeals has noted the requirement of written description is separate and distinct from enablement.[96] The purpose of enablement is to ensure that the patented article is communicated to the public in a meaningful way, in hopes of furthering creativity and development, while the purpose of written description is that an inventor adequately describes the article to which she is laying patent claim.[97] In regards to the third requirement found in § 112, known as the "best mode requirement," the law does speak of how "an inventor must tell the public the best mode she knows for practicing the claimed invention."[98] Essentially this means an inventor must disclose what she believes to be the most commercially attractive way to apply the patented technology.

After itemizing each claim for invalidity presented in the complaint, it is doubtful OSGATA had the substantial evidence necessary to overcome the clear and convincing evidence standard for each and every claim of all of Monsanto's patents. Indeed, such a broad spectrum of patent invalidity claims against such a large number of patents without detail is atypical in traditional patent litigation. Of course, due to plaintiff's lack of standing, the efficacy of the invalidity claims is effectively unknown.

B. Patent Unenforceability

The next attack in the complaint was directed to claims of patent unenforceability, which are different from claims of patent invalidity.[99] Unenforceability claims accept the validity of a patent but are actionable where a patentee has acted egregiously and therefore should not be able to enforce the patent rights.[100] OSGATA claimed

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[95] *In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).*
[96] *Enzo Biochem, Inc., 323 F.3d at 963.*
[97] *Merges, supra note 52, at 262.*
[98] *Id. at 263.*
[99] *Complaint at 40-43, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[100] *Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1233-34 (Fed. Cir. 2008).*

Monsanto's patents should be declared unenforceable based upon theories of exhaustion, misuse, estoppel, and trespass.[101]

1. Patent Exhaustion

Beginning with the theory of patent exhaustion, OSGATA alleged that the doctrine of patent exhaustion prevented Monsanto from enforcing its rights because Monsanto's patent rights legally exhausted upon the first sale by Monsanto of the GMO technology to its customers.[102] Historically, the doctrine of patent exhaustion limits the rights of a patentee after the initial authorized sale of a patented item, i.e., the initial authorized sale of a patented item terminates all patent rights to that item, and the sale confers on the purchaser, or any subsequent owner, the right to use or sell the thing as he sees fit.[103] This means that once a patentee has received a just return from the sale of a patented article, the law does not allow for the patentee to have the power to restrict a subsequent use or sale of that particular thing.[104] However, the patentee may prevent the purchaser or subsequent owner from making new copies of the item. The purchaser of the patented machine does not acquire any right to construct another machine either for his own use or to be vended to another.[105] In other words, once a person buys a patented wrench at the hardware store, she is free to use the wrench however she sees fit without further payment to the patent holder. In this example, the first buyer can even resell the patented wrench to a second buyer without any additional obligation of further royalty to the patentee.

Unfortunately for OSGATA, the patent exhaustion argument does not hold water as it relates to self-replicating plants and seeds, because the United States Supreme Court in *Bowman v. Monsanto* effectively denied the applicability of the patent exhaustion doctrine to seed reproducibility.[106] The facts of the case illustrate the distinction for self-replicating technologies. Vernon Hugh Bowman had purchased and used Monsanto's GMO Roundup Ready soybeans to plant his

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[101] *Complaint, Organic Seed Growers & Trade Ass'n, 851 F. Supp. 2d 544 at 40-43.*
[102] *Id. at 45.*
[103] *Bowman v. Monsanto Co.,133 S. Ct. 1761, 1766 (2013).*
[104] *Id.*
[105] *Id.*
[106] *Bowman, 133 S.Ct. at 1769.*

soybean crop.[107] For his late season planting, Bowman elected to purchase soybean-harvested grain from his local grain elevator.[108] He then planted and cultivated the elevator-sourced soybeans with full anticipation that the substantial majority of those soybeans would carry the Roundup Ready technology because Monsanto's technology is pervasive.[109] Bowman thereafter saved the harvest from the elevator-sourced soybeans for his subsequent year's crop.[110] He continued this practice for eight years.[111] Monsanto eventually sued Bowman and his singular defense was that Monsanto's patent rights were exhausted by virtue of already having sold the item in the past.[112] Bowman argued the downstream purchase of a patented article through a third party served to cut off the patent holder's rights to that article, specifically that Monsanto's sale of its first generation seeds effectively exhausted Monsanto's rights to subsequent generations because the subsequent generations were embodied in the first.[113]

In May 2013, the United States Supreme Court held the doctrine of patent exhaustion for self-replicating technology "applies only to the particular item sold, and not reproductions."[114] A farmer may sell or consume the seeds that result from the original crop but cannot create reproductions of said seeds.[115] The Court did not address the role that intent to exploit Monsanto's technology played in the Bowman fact pattern.[116] Justice Kagan noted that, in Bowman's fact pattern, human intervention was the cause of infringement, not the self-replicating nature of the technology.[117] The Court cautiously stated the opinion did not apply to every case involving a self-replicating product.[118]

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[107] *Id. at 1765.*
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] *Id.*
[113] *Id.*
[114] *Id. at 1768.*
[115] *Id. at 1766.*
[116] *Id. at 1769.*
[117] *Id. at1769.*
[118] *Id.*

2. Patent Misuse

OSGATA's complaint sought a declaration Monsanto's patents were patent unenforceable because Monsanto had misused the patents.[119] A patent misuse affirmative defense guards against the possibility that a patentee might abuse the right to hold exclusive rights to the patented article. One of the first cases on patent misuse, *Morton v. G.S. Suppiger Co.*, held that a patent could not be used to restrain competition in the marketing of unpatented items.[120] In that case, the Suppiger Company had developed and patented a machine that made salt tablets that were, at the time, necessary for canning foods.[121] To increase profits, the Suppiger Company would then require a purchaser of the patented machine to enter a licensing agreement that mandated all companies to purchase all salt exclusively from Suppiger.[122] Morton, desiring a share of the market, sold similar machines.[123] Suppiger sued Morton for patent infringement.[124] In defense, Morton claimed that Suppiger's patent was unenforceable because Suppiger had impermissibly extended the patent rights to nonpatented items, the salt tablets.[125] The United States Supreme Court affirmed the finding of unenforceability, and the doctrine of patent misuse was thus established.[126] The Court reasoned that Suppiger was using its patent rights to the patented machine as a means to impermissibly restrain competition of an unpatented article, salt tablets, in hopes of extending a limited monopoly.[127]

Likewise, in the complaint, OSGATA asserted Monsanto had likewise misused its patents on transgenic seed to achieve dominance and maintain anticompetitive benefit.[128] Monsanto is alleged to have used this dominance to diminish innovation, and as a result, OSGATA

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[119] *Complaint at 40-41, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*
[120] *Morton Salt Co. v. G. S. Suppiger Co., 314 U.S. 488 (1942), abrogated by Illinois Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, (2006).*
[121] *Id at 489.*
[122] *Id. at 491.*
[123] *Id.*
[124] *Id. at 489.*
[125] *Id at 490.*
[126] *Id. at 494.*
[127] *Id.*
[128] *Complaint at 40-41, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*

pointed to a dramatic rise in seed prices.[129] Furthermore, the complaint alleged Monsanto sought to enhance its dominant market power through abusive litigation practices and anticompetitive licensing agreements.[130]

These allegations must be viewed in context of current trends. For example in *Princo v. International Trade Commission and U.S. Phillips Corp.*, an *en banc* Federal Circuit Court of Appeals stated,

> [T]he doctrine of patent misuse is . . . . grounded in the policy-based desire to 'prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right. It follows that the key inquiry under the patent misuse doctrine is whether, by imposing the condition in question the patentee has impermissibly broadened the . . . . scope of the patent grant and has done so in a manner that has anticompetitive effects. Where the patentee has not leveraged its patent beyond the scope of rights granted by the Patent Act, misuse has not been found . . . . Recognizing the narrow scope of the doctrine, we have emphasized that the defense of patent misuse is not available to a presumptive infringer simply because a patentee engages in some kind of wrongful commercial conduct, even conduct that may have anticompetitive effects.[131]

Ultimately, due to the plaintiff's lack of standing, the weight of the misuse assertions in OSGATA's complaint were never put to the test. Interestingly, the complaint's language tracked well with a dissenting opinion of *Princo*.[132] The dissent in *Princo* noted that the United States Supreme Court "made clear that patent misuse occurs when patent licensing agreements are used to control conduct by the licensee not embraced in the patent monopoly."[133] Additionally, the dissent noted "the use of license agreements to fix prices and suppress competition from alternative technologies constituted patent misuse."[134] Even so, it would appear OSGATA's assertion of misuse would be unlikely to succeed due to the Federal Circuit Court of Appeal's narrow application of the misuse doctrine.[135]

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[129] *Id. at 40.*
[130] *Id. at 40-41.*
[131] *Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318, 1328-29 (Fed. Cir. 2010) (en banc) (internal citations omitted).*
[132] *Id. at 1341.*
[133] *Id. at 1346 (quoting Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 456–57 (1940)).*
[134] *Id. (quoting United States v. United States Gypsum, 333 U.S. 364 (1948)).*
[135] *Id. at 1328-29.*

3. Trespass

OSGATA also devoted some allegations language in the complaint to the common law theory of trespass, stating that, "Monsanto commits trespass when its genetic seed contaminates another's."[136] Incidents of pesticide drift have been litigated using a trespass claim; however, there has not yet been a published case of pollen drift involving GMOs.[137] The question of whether an intentional tort claim may lie in the context of pollen and pesticide drift from GMO crops is largely unanswered.[138] Some legal theorists argue that producers of GMO crops owe a duty to owners of adjacent fields containing non-GMO crops since most agriculturists would agree that seed companies and growers alike understand the pollen-drift potential of GMO crops, but "whether mere knowledge alone is sufficient to establish an intentional trespass claim is a question that the legal system has not yet addressed."[139] At least one author believes that because the typical farmer reasonably knows that pollen drift occurs, "a farmer who plants GM crops in the vicinity of organic farms would be substantially certain that GM pollen will drift onto those organic farms."[140] However, it is wholly unclear whether OSGATA would have succeeded on this claim, especially in the light of the fact that not one of the named plaintiffs had been contaminated.

On denial of a trespass claim, some courts have held that there are more appropriate remedies to address unwanted drift. For example, in a 2012 Minnesota Supreme Court case involving an organic farm that lost ten acres of crops and years of work due to pesticide spray drift from a nearby farm, the court ruled that the torts of negligence or nuisance were more appropriate remedies.[141] The court held that

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[136] *Complaint at 4, Organic Seed Growers & Trade Ass'n v. Monsanto Co., 851 F. Supp. 2d 544 (S.D.N.Y. 2012).*

[137] *Roger A. McEowen, Legal Issues Related to the Use and Ownership Of Genetically Modified Organisms, 43 Washburn L.J. 611, 619 (2004).*

[138] *Id.*

[139] *Id. In an interesting comparative analysis of GMOs to noxious weeds, Roger McEowen notes that, "an open question at the present time is whether the legal system will treat GMOs similarly to noxious weeds. While that outcome is unlikely, it is entirely possible that the planting of GMO crops with malicious intent to harm a neighbors non-GMO crops could give rise to liability." Id.*

[140] *Student Carie-Megan Flood, Pollen Drift and Potential Causes of Action, 28 J. Corp. L. 473, 482 (2003).*

[141] *Johnson v. Paynesville Farmers Union Co-op. Oil Co., 817 N.W.2d 693, 705 (Minn. 2012) cert. denied, 133 S. Ct. 1249 (2013).*

nuisance was more appropriate because an action for trespass involves tangible interferences with the right to exclusive possession of land, while nuisance deals with indirect or intangible interference with an owner's use and enjoyment of land.[142]

VI. A LOOK AT PATENT INVALIDITY THROUGH THE EYES OF EXPIRATION

The success of OSGATA's patent claims against Monsanto is unclear. Regardless, invalidating Monsanto's patents, while understandable, would not only have been in direct opposition to the stated goals of many of the plaintiffs and the organic industry as a whole, but also would have logically increased the one thing that the plaintiffs were trying to stop – genetic contamination. Furthermore, protecting OSGATA from patent infringement would be only a limited short-term remedy. Invalidation of all of Monsanto's relevant patents would have certainly prevented Monsanto from asserting its patent rights against the stated plaintiffs, but it is shortsighted for the analysis to stop there. Patent invalidation is not an appropriate strategy to protect the organic industry by stopping genetic contamination because the technology has already overwhelmed the marketplace farming practices. Furthermore, as will be shown via patent expiration, the potential negative consequences of invalidating Monsanto's patents tips the scales in favor of letting be Monsanto's patents and pursuing other routes such as injunctions, legislative action, or stricter regulation.

A. Patent Expiration

On its face, patent expiration is a fairly simple process. Upon expiration, the patent owner's exclusive rights expire and the general public and competitors are permitted to recreate and sell the copy without obligation to the patent owner. This is a general rule, but agricultural law has a few minefields, i.e., even absent patent protection there are other regulatory concerns that would not allow

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[142] *Id. However, the Minnesota Supreme Court notes a "review of cases from other jurisdictions reveals that courts have abandoned the distinction between trespass and nuisance, at least in part, because courts generally favor allowing parties to vindicate wrongs and, in many jurisdictions, actions for trespass have a longer statute of limitations than actions for nuisance." Id at 705.*

unrestricted use of the previously patented technology. Take for example, Monsanto's proprietary RR1 technology.

Monsanto first began patenting its RR1 technology in the mid 90's.[143] Throughout its history, many patents have been a part of what is known as the RR1 family of patents, most notably, the '605' patent, which Monsanto has premised suit on multiple times.[144] The '605' patent expired in 2011, but other key patents still remain and are set to expire in 2014, thus confirming the RR1 technology will be completely off patent. These patents are: U.S. Patent No. 5,717,084; 5,728,925; and RE 39247.[145] Theoretically, upon expiration, farmers and competitor seed companies will be able to make, use, and sell the Roundup Ready technology without paying Monsanto the royalties previously owed. Theoretical possibilities aside, in many situations, the expiration of a patent does not always produce a free-for-all commercialization opportunity. There are still many other rules and regulations regarding use and re-creation of biotechnology that may prevent a party from doing so, e.g., PVPA certificate protection, licensing agreements, and domestic and international regulatory biotechnology requirements.

B. Monsanto's International Regulatory Approvals

International regulatory approvals are the backbone of American agriculture – the infrastructure that allows American farmers to export their crops and capitalize on needy global markets. Indeed, global exporting of genetically modified crops accounts "for over $40 billion annually, making the United States the largest producer and exporter

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[143] U.S. Patent No. 5,352, 605 (issued Oct. 4, 1994), available at http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=5,352,605.PN.&OS=PN/5,352,605&RS=PN/5,352,605.

[144] See generally Bowman v. Monsanto Co.,133 S.Ct. 1761 (2013); Monsanto Co. v. David, 516 F.3d 1009 (Fed. Cir. 2008); Monsanto Co. v. Scruggs, 459 F.3d 1328 (Fed. Cir. 2006); Monsanto Co. v. McFarling, 302 F.3d 1291 (Fed. Cir. 2002).

[145] Product Patents, MONSANTO, http://www.monsanto.com/products/Pages/product-patents.aspx (last visited July 24, 2103); Dennis Crouch, When Monsanto's Patents Expire, PATENTLY O BLOG (July 24, 2013), http://www.patentlyo.com/patent/2011/09/when-monsantos-patents-expire.html; Roundup Ready® Soybean Patent Expiration, MONSANTO NEWS & VIEWS, http://www.monsanto.com/newsviews/pages/roundup-ready-patent-expiration.aspx (last visited July 22, 2013).

of crops and grain derived from biotechnology globally."[146] Because most genetically modified crops are heavily regulated in the European and Asian markets, United States farmers rely on the body of international regulatory approvals that govern the export of genetically engineered crops.[147] By granting regulatory approval, countries are recognizing that the product is safe for consumption and therefore can be imported. Already having international regulatory approvals in place allows farmers to plant, harvest, and ship their product around the world without disruption. Without these prior approvals, farmers would have fewer markets in which to sell grain. As such, companies like Monsanto have significant economic incentive to secure international regulatory approval for their patented products. Arguably, if stripped of patent protection by means of invalidation, a company such as Monsanto would have had little direct economic incentive to obtain, yet alone maintain, the necessary international regulatory approvals to allow export of the genetically engineered crop. Thus, should a company like Monsanto decide to stop servicing the regulatory regime, the consequences could be dire for American agriculture market. Invalidation aside, expiration is an equally as tricky proposition, especially considering that Monsanto's RR1 technology is the first of these biotechnology events to go off patent, the development of generic international regulatory approvals is a new concept, and to date there has been no preexisting industry framework structure to govern the management of international regulatory approvals post patent expiration. Thankfully, there are developments in the private sector to help foster the transition between patented international regulatory approvals and generic international regulatory approvals.

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[146] *The Accord, AG ACCORD FACT SHEET, http://www.agaccord.org/include/facts.pdf (last visited July 24, 2013).*

[147] *See generally Roger McEowen, Expiration of Biotech Crop Patents – Issues For Growers, IOWA STATE UNIVERSITY CENTER FOR AGRICULTURAL LAW AND TAXATION (July 24, 2013), available at, http://www.calt.iastate.edu/briefs/CALT%20Legal%20Brief%20-%20Expiration%20of%20Biotech%20Crop%20Patents%20-%20Issues%20for%20Growers.pdf; K. Sauer, Soybean Post-Patent Regulatory Commitment Extended through 2021, MONSANTO NEWS & VIEWS, http://www.monsanto.com/newsviews/Pages/Roundup-Ready-Soybean-Post-Patent-Commitment-Extended-through-2021.aspx (last visited July 22, 2013).*

C. The Accord Agreement: GEMAA and DUCA

A collaborative effort between the American Seed Trade Association ("ASTA") and the Biotechnology Industry Organization ("BIO") has resulted in the formation of the Accord Agreement.[148] The Accord Agreement seeks to establish international regulatory and stewardship responsibilities that define the responsibilities for signatories involved in "commercializing biotechnology seed products containing off-patent biotechnology events."[149] The Agreement has two parts: the Generic Event Marketability and Access Agreement ("GEMAA") and the Data Use and Compensation Agreement ("DUCA").

Under the GEMAA, companies like Monsanto are required to provide notice of patent expiration three years before the last patent on the biotechnology event expires.[150] At the point of the notice of patent expiration, a GEMAA signee has a choice to: (1) independently maintain regulatory responsibility for the event at no cost to users of the generic event; (2) seek to share regulatory responsibility; (3) discontinue regulatory responsibility.[151]

The primary focus of DUCA is to provide data access while addressing "some of the more complicated regulatory issues associated with stacked products."[152] DUCA will become operational once three parties that are current proprietary regulatory property holders or have petitioned the U.S. Department of Agriculture for non-regulated status for an event have signed, and three parties that are not covered by the above, for example seed companies that are not proprietary regulatory property holders or national farm organizations, have signed.[153]

Upon expiration of the RR1 technology, as a signatory of the Accord Agreement, Monsanto has committed to independently maintain regulatory responsibility until 2021.[154] However, as stated previously,

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[148] *The Accord, supra note 146.*
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] *Meghan Grebner, An Update on the Accord, BROWNFIELD AG NEWS, http://brownfieldagnews.com/2013/06/24/an-update-on-the-accord/ (last visited July 24, 2013).*
[153] *About the AgAccord, THE AG ACCORD, http://www.agaccord.org/?p=about, (last visited Jan. 2, 2014).*
[154] *Generic Event Marketability and Access Agreement, THE AG ACCORD, http://www.agaccord.org/?p=GEMAA, http://www.agaccord.org/?p=GEMAA, (last visited July 23, 2013); Sauer, supra note 147.*

if Monsanto were to be divested of all its patents it would likely be very unwilling to maintain the necessary approvals, and under the GEMAA, Monsanto would likely opt to defer this responsibility to would be generic producers. This is a significant fiscal responsibility, considering that Monsanto purports that it spends $1-1.5 million per year to maintain the necessary international regulatory approvals.[155]

D. Monsanto's Domestic Regulatory Approvals

The Monsanto RR1 Technology was one of the first genetically modified plants and seeds to be regulated in the United States.[156] Over time, the federal government has created an interconnected framework of agencies and oversight, comprised primarily of three federal agencies: the United States Food & Drug Administration ("FDA"), Environmental Protection Agency ("EPA"), and the Animal and Plant Health Inspection Service ("APHIS").[157] The FDA is responsible for regulating GM crops that are consumed by either humans or animals, and while the EPA does not directly regulate the crops themselves, they do greatly affect the pesticides that are used in conjunction with the Roundup Ready Technology.[158] Finally, APHIS, as a part of the United States Department of Agriculture ("USDA"), is tasked with regulating the development and testing of genetically modified crops; in particular, USDA-APHIS "regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic

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[155] *Sauer, supra note 147.*
[156] *See F.Owen Fields, Biotechnology Consultation Memorandum of Conference BNF NO.000001, FDA (Sept. 19, 1994), http://www.fda.gov/Food/FoodScienceResearch/BiotechnologySubmissions/ucm161129.htm; Letter from Alan M. Rulis, Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition to Diana Re, Regulatory Affairs, Monsanto (January 27, 1995), available at http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm161129.htm.*
[157] *Coordinated Framework for the Regulation of Biotechnology, APHIS BIOTECHNOLOGY & BRS REGULATIONS, http://www.aphis.usda.gov/biotechnology/regulations.shtml, (last visited July 15, 2013).*
[158] *See Id.*

engineering."[159] Although all three organizations have foreseeable regulatory authority over Monsanto's Generation 1 Roundup Ready Soybean Technology, primary domestic regulation resides in the hands of the FDA and APHIS.[160]

1. FDA Regulatory Approval Process

The FDA has regulated genetic modification techniques for the development of new foods for several decades now.[161] The FDA derives its regulatory authority from the Federal Food, Drug, and Cosmetic Act, relying primarily on sections 402(a)(1) and 409 of the Act.[162] Section 409 of the Act considers those substances that are intentionally added to food to be food additives unless the substance is generally recognized as safe or GRAS.[163] Section 409 permits the FDA "to require premarket review of any substances intentionally introduced via bioengineering that are not generally recognized as safe."[164] However, the FDA acknowledges that most food additives are "well characterized proteins, fats, and carbohydrates that are . . . . generally recognized as safe."[165] Aside from its statutory regulatory authority, the FDA also has a self-imposed regulatory policy created in

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[159] *Roles of US Agencies in the Coordinated Framework of Biotechnology, APHIS, http://www.aphis.usda.gov/biotechnology/framework_roles.shtml (last visited July 12, 2013).*
[160] *Coordinated Framework for the Regulation of Biotechnology, supra note 157; Roles of US Agencies in the Coordinated Framework of Biotechnology, supra note 159.*
[161] *Genetically Engineered Foods: Hearing on FDA Regulation of Foods Derived from Genetically Engineered Varieties Before the House Committee on Science, 106th Cong. 1 (1999) (statement of James H. Maryanski, Biotechnology Coordinator, Center for Food Safety and Applied Nutrition, Food and Drug Administration), available at http://www.fda.gov/newsevents/testimony/ucm115032.htm.*
[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] *Id.*

1992.[166] This 1992 policy has been the primary guiding policy for the Agency's review of biotechnology since.[167]

> The 1992 policy clarified the agency's interpretation of the application of the Federal Food, Drug, and Cosmetic Act with respect to human food and animal feeds derived from new plant varieties and provided guidance to the industry on scientific and regulatory issues related to these foods . . . including those developed using recombinant deoxyribonucleic acid (rDNA) technology.[168]

The FDA approval process for a genetically modified plant or seed utilizes a twofold process: (1) they utilize their authority under the Act to require that manufacturers ensure the safety and efficacy of the particular product, and (2) they utilize their 1992 policy to encourage those manufactures to participate in a voluntary consultation process to help ensure compliance with the Act.[169] All genetically engineered crops currently on the market have gone through this voluntary consultation process.[170] The FDA's submission process is relatively informal. The FDA asks that a would-be marketer inform the Agency when they have completed what is a called a safety and nutritional assessment summary.[171] This summary typically includes information used by Agency scientists to determine "whether any unresolved issues exist, regarding the food variety that would necessitate legal action by the Agency if the product were introduced into commerce."[172]

Monsanto sought FDA advisement for its Generation 1 Roundup Ready Technology in late 1994 and received conformation in early 1995.[173] Utilizing the data provided by Monsanto, the FDA reasoned that because Monsanto "concluded that the new soybean variety is not

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[166] *The FDA's policy, "Statement of Policy: Food Derived from New Plant Varieties" was published in the Federal Register on May 29, 1992 as 57 FR 22984. Genetically Engineered Plants for Food and Feed, FDA, http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/default.htm (last updated May 31, 2013).*

[167] *Id.*

[168] *Id.*

[169] *Roles of US Agencies in the Coordinated Framework of Biotechnology, supra note 159.*

[170] *Id.*

[171] *Genetically Engineered Foods, supra note 161.*

[172] *Id.*

[173] *See Letter from Alan M. Rulis to Diana Re, supra note 156; Fields, supra note 156.*

materially different in composition, safety, or any other relevant parameter from soybean varieties currently on the market," it would not require premarket review or approval.[174] Upon consultation, the FDA considered several factors when reviewing Monsanto's data: the intended effect and food/feed use, the mechanism of the intended effect, the molecular alterations and characterization, the safety of the expressed protein, compositional analysis, and wholesomeness studies.[175]

2. APHIS Regulatory Approval Process

Under the authority of the Plant Protection Act, APHIS, through its Biotechnology Regulatory Services ("BRS") program, regulates genetically modified organisms that pose a risk to plant health.[176] The USDA-APHIS regulations provide a petition process for a regulated article to obtain a non-regulated status.[177] As part of the petition process, "the petitioner must supply information such as the biology of the recipient plant, experimental data and publications, genotypic and phenotypic descriptions of the genetically engineered organism, and field test reports."[178] Upon approval of deregulated status, the genetically modified organism is not required to undergo any further APHIS regulatory oversight.[179] Monsanto's Generation 1 Roundup Ready Soybean Technology gained unregulated status in May of 1994.[180]

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[174] *Letter from Alan M. Rulis, Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition to Ms. Diana Re, Regulatory Affairs, Monsanto, supra note 156.*
[175] *Fields, supra note 156.*
[176] *Roles of US Agencies in the Coordinated Framework of Biotechnology, supra note 159.*
[177] *Regulated Article Letters of Inquiry, APHIS BIOTECHNOLOGY & BRS REGULATIONS, http://www.aphis.usda.gov/biotechnology/am_i_reg.shtml (last visited July 15, 2013); Roles of US Agencies in the Coordinated Framework of Biotechnology, supra note 159.*
[178] *Roles of US Agencies in the Coordinated Framework of Biotechnology, supra note 159.*
[179] *Permits, Notifications, & Petitions, APHIS, http://www.aphis.usda.gov/biotechnology/submissions.shtml (last visited July 15, 2013).*
[180] *USDA/APHIS Response to Monsanto Petition 06-178-01p, http://www.aphis.usda.gov/brs/aphisdocs/06_17801p_pea.pdf (last visited July 12, 2013).*

VII. CONCLUSION

In the past, PUBPAT has successfully championed the public interest by invalidating the patent rights of big corporate interests. In those instances, PUBPAT challenged patent protection in hopes of promoting unrestricted use of the technology. Unfortunately, this strategy was ill applied, in cookie cutter fashion, to *OSGATA v. Monsanto*.

First, had PUBPAT believed they possessed the appropriate strategy and necessary evidence to actually invalidate Monsanto's patents, why not choose a group of plaintiffs that had clear legal standing? Were PUBPAT to have the necessary clear and convincing evidence to invalidate Monsanto's patents, it would be expected to step forward and work alongside producers who are already involved in litigation with Monsanto. This point cannot have been a mere lapse, especially since part of OSGATA's argument in hoping to preserve standing was that Monsanto aggressively asserts its patents. Necessary standing aside, there does not appear to be a substantial likelihood of success for OSGATA's patent invalidity claims, judging from the pleadings as filed. In its complaint OSGATA threw everything but the proverbial patent kitchen sink at Monsanto: utility, double patenting, prior art, written description, enablement, best mode, and exhaustion, misuse, estoppel, and trespass. The likelihood of success on these claims is either unlikely or unclear.

Second, invalidating the whole of Monsanto's patents is certainly not consistent with an organic industry that has long sought to limit use of genetically modified plants and seeds, especially when considering the goal of patent invalidation - unrestricted use of the putative technology. Admittedly, the equation is infinitely more complex, i.e., invalidation does not necessarily equate to unrestricted use by all. However, one thing is clear, invalidation of Monsanto's patents by OSGATA is logically inconsistent, and arguably the least effective means by which to restrict the spread of genetically modified plants and seeds.

Finally, albeit unfortunate for many organic growers, it appears, at least for the time being, Monsanto's genetically modified seed technologies are here to stay. Roundup Ready Technology and its kin are firmly entrenched in American agriculture. Furthermore, considering the weight and complexity of the regulatory burden on the GMO crop market, were the delicate balance of Monsanto's patented technology be upset with one fell swoop, the economic consequences

could be devastating to industry which relies heavily on Monsanto's commitment to fund and maintain the necessary foreign and domestic regulatory approvals – a commitment that Monsanto might not be so ready to maintain should they find themselves with a handful of invalidated patents.

Still though, the fight is not over. OSGATA v. Monsanto, and the growing body of similar cases, makes it very clear that litigation over genetic contamination is here to stay. As such, the courts are beginning to recognize the tension between the advantages of genetically modified agricultural methods and the associated burdens and risks. Hopefully, future cases will begin to tease out a body of principles that will both reward the economic monopolies of the patent system and the advances in technology that can bring, as well as, protect a growing organic market and the concerns of its consumers.

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