Journal of Environmental and Sustainability Law

Missouri Environmental Law and Policy Review
Volume 15
Issue 3 *Summer 2008*

Article 3

2008

Super Crops or a Super Problem? The Battle over Bt Corn. Monsanto Company v. Bayer Bioscience N.V.

Lee Stockhorst

Super Crops or a Super Problem? The Battle over Bt Corn

Monsanto Company v. Bayer Bioscience N.V.[1]

I. INTRODUCTION

In *Monsanto* the Court works its way through a technical analysis of patent law in order to determine which of two huge corporations has the right to market a Bt corn product[2]. The case itself strictly adheres to established precedent concerning the patentability of genetically modified organisms and the impact that inequitable conduct has on the enforceability of a patent. On the surface this case appears to be a bland interpretation on a worn-out subject, but under the surface lies a more complex issue. Every year more countries become reliant on genetically modified crops for both production and consumption. The United States alone plants approximately fifty-four million hectares of genetically modified plants each year.[3] As a result, there are billions of dollars to be made for the company that holds the patent rights to lucrative genetically modified organisms. What often gets lost in the corporate battle for patent rights are the potential environmental impacts resulting from increased exposure of indigenous plant and animal species to organisms that are modified genetically.

II. FACTS

At its most basic, this case concerns patent infringement of chimeric genes.[4] Monsanto brought a declaratory judgment action against

---

[1] 514 F.3d 1229 (C.A.Fed. Mo. 2008).

[2] Bacillus thuringiensis. Bacillus thuringiensis is a bacterium that parasitizes the caterpillars of some harmful moths and butterflies. *See*, Bio-Medicine, http://www.bio-medicine.org/biology-dictionary/Bacillus (last checked Aug. 11, 2008).

[3] *See* Friends of the Earth International, *Who benefits from the use of gm crops?: the rise of pesticide use* (January 2008), *available at* http://www.globalpolicy.org/socecon/trade/gmos/2008/01whobenefits.pdf (last checked April 12, 2008).

[4] An artificial gene constructed by juxtaposition of fragments of unrelated genes or other DNA segments, which may themselves have been altered. Merriam-Webster Dictionary, *available at* http://www.merriam-webster.com (last checked April 11, 2008).

Bayer Bioscience ("Bayer") claiming unenforceability of four Bayer patents, challenging the validity of the same four patents, and claiming the transgenic corn products[5] Monsanto marketed did not infringe upon the four Bayer patents in question.[6]

This story began in 1986 when Plant Genetic Systems, N.V.[7] obtained plants that expressed a truncated form of a specific Bt toxin. The truncated Bt toxin was created through transformation of the plants using a Bt toxin gene that encoded the first part of the toxin using Agrobacterium tumefaciens ("Agrobacterium").[8]

Monsanto sells genetically modified corn that expresses a Bt toxin with the same amino acid sequencing Bayer claims to have invented in 1986.[9] As a result Monsanto filed a declaratory judgment action seeking a finding that Monsanto's genetically modified corn product did not infringe upon Bayer patents '565, '372, '546, or '799[10], and that those patents were invalid and unenforceable.[11] The district court granted summary judgment in favor of Monsanto, holding all four patents unenforceable due to inequitable conduct.[12] The Court found certain patent claims invalid, and decided that the Monsanto corn product did not infringe on the '565 patent.[13]

Bayer appealed to the Federal Circuit Court of Missouri. The Court reversed as to construction of the term "Bt2 toxin" and vacated the

---

[5] "Transgenic" defined as "being or used to produce an organism or cell of one species into which one or more genes of another species have been incorporated." Merriam-Webster Dictionary, *available at* http://www.merriam-webster.com (last checked April 11, 2008).

[6] Friends of the Earth International, *Who benefits from the use of gm crops?: the rise of pesticide use* (January 2008), *available at* http://www.globalpolicy.org/socecon/trade/gmos/2008/01whobenefits.pdf (last checked April 12, 2008).

[7] Naamloze Vennootschap, a Dutch public limited-liability company.

[8] Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1232 (C.A.Fed. Mo. 2008).

[9] *Id.*

[10] U.S. Patent Nos. 5,545,565 ("the '565 patent"); 5,767,372 ("the '372 patent"); 6,107,546 ("the '546 patent"); and 5,254,799 ("the '799 patent"). *See Monsanto*, 514 F.3d at 1231.

[11] *Monsanto*, 514 F.3d at 1232.

[12] *Id.* at 1233.

[13] *Id.*

unenforceability and invalidity judgments.[14] The Court held that the summary judgment based on inequitable conduct during prosecution of the '799 patent "was improper because there were material facts in dispute, and . . . the district court erred in giving collateral estoppel effect to an earlier case between predecessors of the parties in this case and basing its invalidity findings on this estoppel".[15]

On remand Bayer dismissed its previous claims that the Monsanto corn product infringed on patent numbers '799, '372, and '546.[16] Therefore, the case proceeded to trial on the issue involving the infringement of the '565 patent. The jury found that Monsanto's genetically modified corn product did not infringe on patent '565 and that other claims relating to '565 were invalid for "obviousness and prior invention by Monsanto."[17] The district court conducted a four day trial finding that inequitable conduct made all four patents in question unenforceable.[18]

A. The Mariani Notes

During prosecution of the '565 patent, Bayer disclosed an abstract created by Dr. Wayne Barnes, prepared in 1985, for a scientific conference. At that conference, Barnes made a presentation about the uses of the Bt toxin for insecticide and the applicable shortening process.[19] Bayer voluntarily disclosed this information during the prosecution, but failed to disclose notes taken by Bayer employee, Dr. Celestina Mariani, on the Barnes poster. Mariani's deposition explained that she made her notes while standing in front of the poster.[20] The notes even included copies of schemes contained in the poster.[21] The Court then discovered that the Mariani notes were widely distributed among members of Bayer's

---

[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.* at 1232.
[18] *Id.*
[19] *Id.* at 1235.
[20] *Id.*
[21] *Id.*

Bt research group.[22] In particular Dr. Wouter Meulemanns, an employee in the intellectual property department at Bayer, admitted to seeing Mariani's notes and talking to Mariani about the Barnes poster, but Meulemanns testified that Mariani could not remember anything specific about the presentation or poster.[23] Dr. Meulemann's testimony was unpersuasive and the court concluded that "Bayer had a duty of candor and good faith to disclose the Mariani notes and intentionally withheld the information from the United States Patent Office examiner in the prosecution of the '565 patent with intention to deceive the PTO[24] examiner."[25] The finding of intent to deceive was fatal to Bayer's claims of patent enforceability.

The Federal Circuit Court made three holdings in this case. First, the Court affirmed the district court's conclusion that the Mariani notes were material because the notes directly contradicted the arguments Bayer made to the Patent and Trademark Office in an effort to support patentability.[26] The Court reasoned that based on a "substantial likelihood that a reasonable examiner would have considered the Barnes notes important in deciding whether to allow the application to issue as a patent. . . ."[27] Second, the court concluded that Bayer's failure to disclose the Mariani notes during prosecution for patent '565 was not sufficient to prove inequitable conduct on its own, but that the district court did not err in finding that Bayer had the requisite intent to deceive the PTO.[28] Finally the district court had jurisdiction to review inequitable conduct.[29]

---

[22] *Id.* at 1236.
[23] *Id.*
[24] Patent & Trademark Office.
[25] *Monsanto*, 514 F.3d at 1236.
[26] *Id.* at 1240. Understanding the patent process is an important element for analysis of this case. The court glosses over the patent process requirements and moves directly into "inequitable conduct" analysis, but no patent is enforceable unless it complies with the requirements that the Patent & Trademark Office devises. *See id.*
[27] *Monsanto*, 514 F.3d at 1237.
[28] *Id.* at 1239-42.
[29] *Id.* at 1242-44.

III. LEGAL BACKGROUND

Three legal topics are essential to understanding the decision in *Monsanto*. First, it is important to know some of the ins-and-outs of patent law because the court did not explain the patent process in depth, assuming the parties understood patent law, even though the process and protocol for registering a patent is a pivotal issue in this case.[30] Second, the case deals almost entirely with making a determination of inequitable conduct. Therefore, case precedent establishing the guidelines for making a determination of "inequitable conduct" is critical both to the legal scholar and the court. Finally, being presented with information about previous influential patent law decisions involving genetically modified organisms sheds light on some of the prevailing precedent and policy concerns that went into this decision. Even though the court in *Monsanto* never mentions the impact genetically modified organisms can have on the environment, the continuing debate over the threat that such organisms can pose to the environment requires extensive consideration because such threats should be considered in any case involving genetically modified organisms.

A. *Registering a Patent*

When the United States Patent and Trademark Office ("PTO") issues a patent, a property right is granted to the inventor.[31] Patents grant "the right to exclude others from making, using, offering for sale, or selling" the invention in the United States or "importing" the invention into the United

[30] A critical issue in this case is the impact Bayer's failure to provide certain information to the Patent and Trademark Officer has on the validity and enforceability of the patent. Failure to disclose a material issue to the Patent and Trademark Officer during the prosecution of a patent is a key element of "inequitable conduct." *See Monsanto*, 514 F.3d 1229 (C.A.Fed. Mo, 2008).

[31] U.S. Patent & Trademark Office, *General Information Concerning Patents* (January 2005), http://www.uspto.gov/web/offices/pac/doc/general/index.html (last checked February 29, 2008). Patents generally last 20 years from the date the application for patent is filed in the United States. *Id.* In special cases the term of the patent begins on the date that an earlier related patent application was filed. *Id.*

States.[32] The right is basically the right to exclude other people or corporations from "making, using, offering for sale, selling or importing the invention."[33] After a patent is issued the task of enforcement falls to the patent holder.[34]

Three types of patents are recognized: utility patents, design patents, and plant patents.[35] Utility patents involve machine, article of manufacture, or composition of any matter, or any new and useful improvement thereof."[36] Design patents are granted to anyone inventing "new, original, and ornamental design for an article of manufacture."[37] Finally, plant patents grant rights "to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant."[38]

---

[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.* While common sense may dictate that genetically modified organisms should receive a plant patent such organisms are actually patentable under a utility patent. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).
[36] U.S. Patent & Trademark Office, *A Guide to Filing a Non-Provisional (Utility) Patent Application* (June, 2005), http://www.uspto.gov/web/offices/pac/utility/utility.htm (last checked February 29, 2008).
[37] U.S. Patent & Trademark Office, *A Guide to Filing a Design Patent Application* (June, 2005), http://www.uspto.gov/web/offices/pac/design/index.html (last checked February 29, 2008).
[38] U.S. Patent & Trademark Office, *General Information About 35 U.S.C. 161 Plant Patents* (June 2005), http://www.uspto.gov/web/offices/pac/plant/index.html (last checked February 29, 2008).

Not every invention is patentable.[39] According to the PTO, "[i]f the invention has been described in a printed publication anywhere in the world, or if it was known or used by others in this country before the date that the applicant made her invention, a patent cannot be obtained."[40] A patent is not guaranteed just because the invention seeking a patent has differences from a nearly similar patented invention. The PTO demands "the subject matter sought to be patented must be sufficiently different from what has been used or described before that it may be said to be non-obvious to a person having ordinary skill in the area of technology related to the invention."[41]

Only an inventor can apply for a patent.[42] If someone other than the inventor applies for a patent, and the patent is obtained, the patent is invalid.[43] If a person falsely states that he is the inventor, he is subject to criminal penalties. Innocent mistakes in "erroneously omitting an inventor or in erroneously naming a person as an inventor" are correctable.[44]

B. Inequitable Conduct

---

[39] The power to enact patent laws is found in Article 1, section 8 of the United States Constitution. The section says "Congress shall have power...to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." U.S. CONST., Art. I., § 8. In 1952 patent laws were revised and codified in Title 35 of the United States Code. *See* U.S. Patent & Trademark Office, *General Information Concerning Patents* (January 2005), http://www.uspto.gov/web/offices/pac/doc/general/index.html (last checked February 29, 2008). In November of 1999 the American Inventors Protection Act ("AIPA") was enacted to further revise patent laws. U.S. Patent & Trademark Office, *General Information Concerning Patents* (January 2005), http://www.uspto.gov/web/offices/pac/doc/general/index.html (last checked February 29, 2008). If an applicant makes the request the amendments provide for the "continued examination of an application for a fee. 35 U.S.C. § 132 (2002).

[40] U.S. Patent & Trademark Office, General Information Concerning Patents (January 2005), http://www.uspto.gov/web/offices/pac/doc/general/index.html (last checked February 29, 2008).

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

In *Monsanto*, it was alleged that the Bayer patents were invalid and thus unenforceable due to inequitable conduct.[45] The appellate court agreed that patent '565 was unenforceable due to inequitable conduct; therefore, the appellate court focused review on the district court's inequitable conduct holdings.[46] The established standard of review for inequitable conduct determinations is to "review the district court's findings on the threshold issues of materiality and intent for clear error."[47] To find a patent unenforceable for inequitable conduct a court must find by clear and convincing evidence that "a patent applicant breached its duty of candor and good faith to the PTO by failing to disclose material information, or submitting false material information, with an intent to deceive the PTO."[48]

Precedent has established that information is material for inequitable conduct decisions if "a reasonable examiner would have considered such [information] important in deciding whether to allow the patent application."[49] Rule 56 defines materiality as:

> information that is not cumulative to information already of record or being made of record in the application, and that (1) establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2)...refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) asserting an argument of patentability.[50]

---

[45] Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1232-33 (C.A.Fed. Mo. 2008)..

[46] *Id.* at 1233 (citing eSpeed, Inc. v. Brokertec USA L.L.C., 480 F.3d 1129, 1138-1139 (Fed. Cir. 2007)).

[47] *Id.* (quoting Cargill, Inc. v. Cambra Foods, Ltd., 476 F.3d 1359, 1365 (Fed.Cir. 2007)).

[48] *Id.* at 1233-34 (citing Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348, 1351 (Fed.Cir. 2005)); *see also* Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed.Cir. 1988); *see also* Monsanto Co. v. Bayer Bioscience N.V., 363 F.3d 1235, 1239 (C.A. Fed. Mo. 2004) (explaining that inequitable conduct can be found when the "applicant omitted or misrepresented material facts with the intention of misleading or deceiving the patent examiner").

[49] *Monsanto*, 514 F.3d at 1236 (quoting Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314 (Fed.Cir. 2006)).

[50] 37 C.F.R. § 1.56 (2000).

A key element in a finding of inequitable conduct is the intent to deceive.[51] Absent a credible reason to explain withholding information, "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application."[52] Withholding information in good faith does not negate "an intent to manipulate the evidence when an applicant knows or obviously should know that information would be material to the examiner."[53]

Several factors contribute to ensuring the validity of a patent. First, the patent must meet the specifications the PTO laid out defining inventions eligible for patent. In the case of the genetically modified corn at issue here, the inventors were required to meet the specifications of a plant patent. Only after the inventors had established the patentability of the corn was a patent issued. Once the patent is issued, the validity and enforceability is challengeable on the basis of inequitable conduct. In order to prove inequitable conduct a challenger must prove three elements. First, that information was withheld from the PTO.[54] Second, that the information withheld from the PTO was material to the issuance of a patent.[55] Finally, the material information was withheld with the intent to deceive the PTO.[56] The court in *Monsanto* considered each of these factors

---

[51] *Monsanto*, 514 F.3d at 1234 (citing Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348, 1351 (Fed.Cir. 2005)); *see also* Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed.Cir. 1988); *see also Monsanto I*, 363 F.3d at 1239 (explaining that inequitable conduct can be found when the "applicant omitted or misrepresented material facts with the intention of misleading or deceiving the patent examiner").

[52] *Monsanto*, 514 F.3d at 1241 (citing *Bruno Indep. Living Aids*, 394 F.3d at 1354 (holding that an "inference of deceptive intent may fairly be drawn in the absence of a credible explanation for the non-disclosure.")).

[53] Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1368 (Fed.Cir. 2007).

[54] U.S. Patent & Trademark Office, *General Information About 35 U.S.C. 161 Plant Patents*, http://www.uspto.gov/web/offices/pac/plant/index.html#1 (last checked February 29, 2008).

[55] 37 C.F.R. § 1.56 (2000).

[56] *Monsanto*, 514 F.3d at 1233 (citing Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348, 1351 (Fed.Cir. 2005)); *see also* Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed.Cir. 1988); *see also Monsanto I*, 363 F.3d at 1239 (explaining that inequitable conduct can be found when the "applicant omitted or

in making the determination that the Bayer patents were unenforceable for inequitable conduct.

C. Notable GMO Patent Cases

Several cases have developed strong support for the patentability of genetically modified organisms. *Diamond v. Chakrabarty*[57] is one such case. At over twenty years old, the United States Supreme Court's decision that living organisms were not outside the scope of patentability[58] still stands and continues to influence all cases involving genetically modified organism patents.[59] In 1972, Charkrabarty filed a patent application for the invention of a bacterium.[60] The engineered bacterium was capable of breaking down multiple components of crude oil.[61] In its analysis the Court determined that 35 U.S.C. § 101, which outlined the realm of patentability, was very broad.[62] The Court concluded that the engineered bacterium was patentable because the claim "[was] not ...unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter – a product of human ingenuity "having a distinctive name, character [and] use."[63] This holding opened the door to the future of genetically modified organisms by providing protection to companies with an interest in creating such organisms.

J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.[64] is another notable case. Pioneer brought an action alleging infringement of patents involving plants and seed for varieties of hybrid and inbred corn. J.E.M.[65] bought patented hybrid seeds from Pioneer in bags that bore a

---

misrepresented material facts with the intention of misleading or deceiving the patent examiner").

[57] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[58] *Id.*

[59] The court in Monsanto never discussed the issue of whether the Bt Corn gene, or the resulting product, were patentable because case precedent has clearly established the patentability of such products.

[60] *Diamond*, 447 U.S. at 304-05.

[61] *Id.*

[62] *Diamond*, 447 U.S. at 309-10.

[63] *Id.*

[64] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc , 534 U.S. 124 (2001).

[65] J.E.M. was doing business as "Farm Advantage, Inc." *Id.* at 128.

license agreement restricting use of the seed for propagation.[66] J.E.M. subsequently resold these bags in violation of the licensing agreement. The case is important for two reasons. First, the court agreed with the reasoning in *Chakrabarty* that 35 U.S.C. § 101[67] has broad scope and applicability.[68] Second, with the broad scope in mind, the Court held that utility patents can be issued for plants.[69] Specifically, that newly developed plant breeds are included in the terms of § 101.[70] After finding that plants could receive a utility patent, the Court went on to find that J.E.M. infringed on the Pioneer-held patent by re-selling the seed product.[71] The real importance of this decision is that, in validating the patentability of newly developed plant breeds, the Court indirectly encouraged the growth and development of researching and creating genetically modified organisms.

IV. INSTANT DECISION

The Federal Circuit Court focused on two specific areas of interest: the materiality of the Mariani notes and the district court credibility finding.

A. *Materiality of Mariani Notes*

Three guidelines dominated the Court's decision on the materiality of the Mariani notes. First, information is material in an inequitable conduct determination "if a reasonable examiner would have considered

---

[66] *Id.* at 128. The label license read: "License is granted solely to produce grain and/or forage. *Id.* [The license] does not extend to the use of seed from such crop or the progeny thereof for propagation or seed multiplication. *Id.* The license also strictly prohibited the "use of such seed or the progeny thereof for propagation or seed multiplication or for production or development of a hybrid or different variety of seed." *Id.*

[67] § 101 reads: "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, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (2000).

[68] *J.E.M. Ag Supply, Inc.*, 534 U.S. at 131.

[69] *Id.* at 127.

[70] *Id.* at 145.

[71] *Id.* at 124 (2001).

such [information] important in deciding whether to allow the patent application."[72] Second, the court looked to the definition of material information as provided in PTO Rule 56.[73] Finally, the Court determined that "a misstatement or omission that is material under the Rule 56 standard "is considered material for the purposes of the inequitable conduct inquiry."[74]

Bayer maintained that the district court's findings, that the Mariani notes were material, were clearly erroneous because they were based on allegations that Barnes used identical species of Bt toxin as Bayer used.[75] Bayer claimed that without this "erroneous finding of fact, there can be no materiality."[76]

The court disagreed. While conceding that Bayer was correct in that nothing on the record supported a finding that the Bt toxin highlighted in the Barnes abstract was identical to the Bt toxin covered in the '565 patent, the court determined that the district court did not have to find Barnes used an identical Bt toxin. The Court posited six reasons in support of this conclusion.[77]

First, when the Examiner first rejected the '565 patent, Bayer was not limiting the patent claim to one species of Bt toxin, but was making claims to a specific chimeric gene encoding.[78] Therefore, any chimeric gene that Barnes created within this particular genus directly implicated Bayer's claims.[79] Second, neither the Examiner's rejections, nor any of Bayer's arguments to overcome those rejections, relied on the exact Bt toxin Barnes used.[80] The critical issue was whether the Barnes Abstract made the Bayer invention obvious absent unexpected results. Third, Bayer ignored the district court's materiality finding that the Mariani notes

[72] Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1237 (C.A.Fed. Mo. 2008) (citing Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1363 (Fed.Cir. 2006)).
[73] *Id.* (citing Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1129 (Fed.Cir. 2006)).
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.* at 1238-39.
[78] *Id.* at 1239.
[79] *Id.*
[80] *Id.*

showed the Barnes chimeric gene displayed toxicity when applied to plants.[81] Fifth, the district court clearly based its materiality on finding all the factual findings through the opinion, including Mariani's very specific testimony about the information included in the Barnes Abstract.[82] Finally the court focused on the discrepancies between the interpretation of the Barnes abstract posited by Bayer and the information that was actually contained in the Mariani notes.[83] The court concluded that the Mariani notes met the standard for materiality because they "clearly and convincingly refute . . ., or [were] inconsistent with a position the applicant took in opposing the Examiner's argument of unaptentability."[84]

B. *Determining Inequitable Conduct*

After accepting the district courts materiality finding, the Federal district court had only to apply the facts of the case to relevant case law regarding inequitable conduct. In the Court's opinion Bayers' failure to disclose the Mariani notes to the PTO was not enough to prove inequitable conduct. Instead "clear and convincing evidence" must also establish an intent to deceive the PTO.[85] To prove intent, "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive."[86] According to the Court, precedent established that "absent a credible reason for withholding the information intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application."[87]

The Court determined that the district court did not err in finding that the attempts made by Bayer to establish good faith were not persuasive and in concluding that Dr. Meulmanns intentionally withheld

---

[81] *Id.* This information could indicate that Bayer utilized ideas in the Barnes abstract to create its own Bt toxin. That would make the invention "similar" to the Barnes idea and, thus, the Bayer Bt toxin gene might lack patentability.
[82] *Id.*
[83] *Id.*
[84] *Id.* (citing 37 C.F.R. § 1.56(2)(i) (2000)).
[85] *Id.*
[86] *Id.*
[87] *Id.*

the Mariani notes in an attempt to deceive the PTO.[88] Affirmation of the district court's decision was further supported by the fact that explanations that Bayer provided concerning failure to divulge the Mariani notes were unconvincing in light of Mariani's thorough testimony.[89]

V. COMMENT

A decade or so ago you could not turn on the television or read the paper without seeing something about genetically modified organisms. As consumer goods produced from genetically modified organisms began to enter the marketplace, concern began to rise about the health and safety of both consuming and producing such organisms.

A. Environmental Impact of G.M.O.'s

One of the main areas of concern surrounding the development, utilization, and consumption of genetically modified organisms involved the potential impact of such organisms on the environment.

Several negatives result from genetically modified organisms. One concern is a reported increase in the overall use of pesticides, especially in the United States, which is accompanied by increasing development of super weeds that are resistant to herbicides.[90] One particular study indicated that between 1996 and 2004, the United States saw a use of 122 million more pounds of pesticides than would have been applied if GM crops had not been introduced.[91] The use of so much pesticide has led to increasing occurrences of herbicide resistant weeds. In an effort to contain the resistant weeds, instances of mechanical tillage of increased contributing to soil erosion and global warming gas emissions.[92]

---

[88] *Id.*
[89] *Id.*
[90] *See* Friends of the Earth International, *Who benefits from the use of gm crops?: the rise of pesticide use* (January 2008), *available at* http://www.globalpolicy.org/socecon/trade/gmos/2008/01whobenefits.pdf (last checked April 12, 2008).
[91] *Id.* at 7.
[92] *Id.*

Another environmental concern arises from the basic idea of how some G.M.O.'s, particularly Bt products, work on a basic level. If ingested, Bt toxin will cause mortality in insects.[93] The toxins dissolve in the gut of the insect and then punch a hole in the lining of the insect's gut cells.[94] The Bt will then spill out of the gut into the insect resulting in death of the insect within a few days.[95] While Bt products are created to target specific crop-destroying insects, there is nothing to say that other, non-target insects, will not ingest the Bt toxin.[96] This process could threaten the survival of hundreds of insect species, not to mention the potential unbalance in the ecosystem that could result from an insect species being eradicated in a particular area.

However, not everything about genetically modified organisms is negative. Despite the possible negative impacts on the environment, the increased use of such organisms can have positive results. Today there are more than 840 million people in the world who are malnourished.[97] More than 153 million of those people are children under the age of five.[98] Many supporters of genetically modified organisms believe that G.M.O.'s that are engineered for drought resistance, pest resistance, and to possess particular vitamins are the answer to the world hunger problem.[99]

---

[93] University of California, Bacillus thuringiensis, *How does bt work?*, *available at* http://www.bt.ucsd.edu/how_bt_work.html (last checked April 12, 2008).

[94] *Id.*

[95] *Id.*

[96] Several years ago there was controversy concerning the impact that Bt toxins were having on Monarch Butterfly populations. A two-year study eventually indicated that the impact on the butterflies was negligible. *See* Mark K. Sears et al., *Impact of Bt corn pollen on monarch butterfly populations: A risk assessment*, http://www.pnas.org/cgi/content/abstract/98/21/11937 (last checked April 12, 2008).

[97] *See* CARE, *Facts About Hunger*, http://www.care.org/campaigns/world-hunger/facts.asp (last checked April 12, 2008).

[98] *Id.*

[99] Golden Rice is one genetically modified food product that has been highly touted as an end to world hunger. This transgenic rice contains beta-carotene and could help end vitamin A deficiency around the world. *See*, Craig Holdrege & Steve Talbot, *Golden Genes and World Hunger: Let them Eat Transgenic Rice?*, http://online.sfsu.edu/~rone/GEessays/goldengenes.htm (last checked April 12, 2008).

B. The Question of Materiality & the Intent to Deceive

The court reviewed Bayer's actions, in obtaining the patents in question, for inequitable conduct.[100] Bayer neglected to inform the PTO that Dr. Celestina Mariani had viewed the Barnes poster and provided extensive notes on the contents of the poster to fellow Bayer scientists that were ultimately responsible for creating the "Bt2" technology at issue in these particular patents.[101] The Federal Circuit Court of Missouri determined that this was an omission of a material fact.[102] The Court established the intent to deceive the PTO required to find a patent unenforceable for inequitable conduct because there was no credible explanation for Bayer's failure to disclose this information.[103]

Based on the facts of the case as applied to the rules for determining inequitable conduct, it is difficult to attack the Federal District Court's decision. There is no new shocking outcome or surprising rewriting of patent law here. The formula for declaring unenforceability for inequitable conduct has long been established by case law.[104] However, the court incorrectly interpreted key facts resulting in an erroneous decision in favor of Monsanto.

The court wrongfully decided that the Mariani notes were material and a basis for a finding of inequitable conduct. Case precedent has established that information is material for inequitable conduct decisions if "a reasonable examiner would have considered such [information] important in deciding whether to allow the patent application."[105] First, the court incorrectly concluded that the Mariani notes included coding for the Bt toxin that was identical to the Bt toxin coding sequence presented in the

---

[100] Monsanto v. Bayer Bioscience N.V., 514 F.3d 1229 (C.A.Fed. Mo. 2008).
[101] *Id.*
[102] *Id.*
[103] *Monsanto*, 514 F.3d at 1241 (citing *Bruno Indep. Living Aids*, 394 F.3d at 1354 (holding that an "inference of deceptive intent may fairly be drawn in the absence of a credible explanation for the non-disclosure.")).
[104] *See* Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348, 1351 (Fed.Cir. 2005); *see also* Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed.Cir. 1988); *see also* Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314 (Fed.Cir. 2006).
[105] *Monsanto*, 514 F.3d at 1237 (quoting Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314 (Fed.Cir. 2006)).

Barnes abstract. While the Mariani notes contained code for the same toxic protein that Bayer wanted to claim, it was not the same code as was contained in the Barnes abstract. Monsanto never produced evidence or testimony indicating that the toxin sequence code in the Mariani notes was identical to the code in the Barnes abstract, but the court operates under the assumption that the coding was "similar" enough to warrant the disclosure of the notes to the PTO.[106]

Second, if the Court was correct in its finding that the Mariani notes were material because the notes mentioned the coding for the toxin, the notes are still immaterial because they became cumulative and cumulative references are not considered material.[107] The earlier court decision in *Monsanto*,[108] as well as the brief submitted to the court, establish that the Patent and Trademark Officer had the Barnes abstract and other supplemental material that contained information on coding for the toxin.[109] It is also indicated that at one point the Patent Officer argued the unenforceability of the '565 patent based on the information in the Barnes abstract and other supplemental information. Therefore, release of the Mariani notes provided nothing new for the Patent and Trademark Office to consider. The notes simply supplemented the information that the Office already had before it which renders the notes cumulative. As cumulative information, the notes can neither be deemed material nor serve as the basis for a finding of inequitable conduct.

Third, without materiality, the inequitable conduct count fails and the conjectures of Dr. Meulman's intent should not have been considered. But even if the notes were actually material, the requisite intent was not present. The intent to deceive "may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application," without a credible

---

[106] *See* Monsanto v. Bayer Bioscience, 514 F.3d 1229 (C.A.Fed. Mo. 2008).

[107] Digital Control, Inc. v. The Charles Machine Works, 437 F.3d 1209, 1319 (Fed.Cir. 2006) (stating that "a withheld otherwise material prior art reference is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner.").

[108] Monsanto v. Bayer Bioscience N.V., 514 F.3d 1229, (C.A. Fed. Mo. 1008).

[109] Monsanto Co. v. Bayer Bioscience N.V., 363 F.3d 1235, 1239 (C.A. Fed. Mo. 2004); *see also* Reply Brief of Defendant-Appellant Bayer Bioscience N.V., Monsanto v. Bayer Bioscience N.V., 514 F.3d 1229, (C.A. Fed. Mo. 1008) (No. 2007-1109).

reason explaining the withholding of information.[110] Nothing in the record proves that Dr. Meulemanns had any knowledge of the contents of the Mariani notes. Dr. Meulemanns testified that Mariani told him she could remember nothing about the abstract and that there was nothing important in the notes on the Barnes abstract.[111] There is no reason for the court to doubt Dr. Meulemanns intent, especially in light of the fact that Mariani never told him any important information was contained in the notes.[112]

C. Missouri Case Law in the Wake of Monsanto

The *Monsanto* decision does not appear to have affected Missouri's approach to determining inequitable conduct. The court followed clearly established precedent in making its determination that the patents in question were unenforceable due to inequitable conduct. The fact that the Court came to the incorrect conclusion was not due to incorrect application of established law, but instead came from an ineffective interpretation of the facts of the case. The process for determining materiality and the requisite intent is subjective and gives the court broad discretion in interpreting the facts of a given case and coming to a decision on inequitable conduct. Therefore, it is arguable that the court did not come to the wrong conclusion in *Monsanto* per se. It came to the correct conclusion for the facts as the court chose to view them. However, since the court viewed the facts incorrectly the conclusion of inequitable conduct was tainted and invalid.

D. The United States Response to G.M.O.'s

Countries around the world have adopted various approaches to handling the production, consumption and sale of genetically altered products. The United States adopted the Coordinated Framework for Regulation of Biotechnology ("Framework") in an attempt to guarantee

---

[110] (110) *Monsanto*, 514 F.3d at 1241 (citing Bruno Indep. Living Aids, 394 F.3d at 1354 (holding that an "inference of deceptive intent may fairly be drawn in the absence of a credible explanation for the non-disclosure")).

[111] *Monsanto*, 514 F.3d at 1236.

[112] *See* Monsanto v. Bayer Bioscience, 514 F.3d 1229 (C.A.Fed._Mo. 2008).

the safety of G.M.O.'s.[113] The Framework "instituted a "comprehensive federal regulatory policy for...biotechnology research and products."[114] It established that the laws and regulations already in existence at the time were sufficient to evaluate biotechnology products.[115] Under the Framework the Food and Drug Administration ("FDA"), Environmental Protection Agency ("EPA"), and the United States Department of Agriculture ("USDA") monitored G.M.O.'s.[116] The FDA is generally responsible for food safety involving transgenic crop and animal food products while the EPA monitors any health and environmental effects that arise from "pest-protected plants," such as the Bt corn being fought over in this patent case.[117] The USDA focuses regulation on the effect of G.M.O.'s, particularly genetically modified plants, on the other plants and animals in an agricultural setting.[118]

In response to concerns about environmental safety, the Environmental Protection Agency ("EPA") released information indicating that Bt products are safe for use in the environment and with mammals.[119] The EPA has not found any human health hazards and has gone so far as to exempt Bt from food residue tolerances, groundwater restrictions, endangered species labeling, and special review requirements.[120] In fact, according to the EPA in the 50-year history of Bt-

---

[113] Gregory N. Mandel, *Toward Rational Regulation of Genetically Modified Foods*, 4 Santa Clara J. Int'l L. 21 (2006). The Framework was developed by the White House Office of Science and Technology Policy in 1986. *Id.* at 21.

[114] *Id.* (citing Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23, 302 (June 26, 1986).

[115] Mandel, *supra* note 113, at 21. The decision to regulate biotechnology products under the controlling regulatory scheme in 1986 was largely influenced by the popularly held belief that biotechnology was not risky in itself, so only the products resulting from biotechnology required monitoring. *Id.*

[116] *Id.*

[117] *Id.* at 21.

[118] *Id.* Agency regulation generally occurs through application of statutes such as the Federal Food, Drug, and Cosmetics Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Animal and Plant Health Inspection Service (APHIS). *See id.*; *see also* Doug Farquhar, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439 (2007).

[119] *See* Bacillus Thuringiensis, *Animal Safety*, http://www.bt.ucsd.edu/bt_safety.html (last checked April 12, 2008).

[120] *Id.*

based products, only two incidents of human allergic reaction have been reported.[121] The EPA also requires farmers planting transgenic crops, such as the Bt corn involved in this case, to follow resistance management requirements to help reduce the build-up of insect and pest resistance to synthetic pesticides.[122] However, the EPA admits that Bt can cause adverse allergic reactions in some mammals such as rabbits.[123]

Some individual States within the United States have taken action beyond the Federal Coordinated Framework, though many States "feel that the primary responsibility for health and safety of biotechnology should remain with the federal government."[124] The States that have decided to attack the G.M.O. problem have generally done one of two things. The State either provides funds or tax credits to support the development of biotechnology development or the State bans G.M.O.'s and their products outright.[125]

The State of North Dakota provides an interesting example of a State that chose to fund biotechnology and support G.M.O.'s and then considered banning certain genetically modified plants outright. In 2001 North Dakota proposed a ban on genetically modified wheat within the state. The proposition was due largely to the fact that Japan, the main purchaser of North Dakota wheat, had a ban on genetically modified foods.[126]

The conundrum faced by North Dakota legislatures highlights a second arena where the concerns of G.M.O.'s play out. Many G.M.O.'s, and their products, are approved for consumption in European Union member countries, but very few genetically modified crops have been approved for cultivation.[127] Starting in the early 1990s the EU developed

---

[121] *Id.* In one instance the person was found to be suffering from a previous disease that exacerbated the reaction and in the second case the individual had a history of life threatening food allergies. *Id.*

[122] *Id.*

[123] *Id.* The reaction was reported to be a mild irritation of the area around the eyes. *Id.*

[124] Farquhar, *supra* note 118, at 458. The reason for this sentiment is likely due to the fact that many States do not have the resources or the availability to experts to replicate federal studies. *Id.*

[125] *Id.* at 459-60.

[126] *Id.* at 460-61.

[127] Margaret Rosso Grossman, *The Coexistence of GM and Other Crops in the European Union*, 16 KAN. J.L. & PUB. POL'Y 324 (2007).

a process requiring case-by-case authorization of G.M.O.'s, which included components for traceability and labeling of GMO products.[128] Many EU countries now practice "coexistence" which "focuses on practices used to minimize adventitious presences."[129]

E. Missouri Response to GMO's

Missouri is a heavily focused agricultural state. There are over 100,000 farms in Missouri averaging 287 acres, comprising over 30 million acres of the state's land mass.[130] Many of those farms produce corn, soybeans, wheat and other agricultural products. With the growing preference for genetically modified crops, the environmental concerns surrounding G.M.O.'s undeniably affects Missouri's environment.[131]

In the last two years, bills have been introduced to both the Missouri Senate and House of Representatives concerning pre-emption of Missouri laws involving genetically modified crops and products.[132] Most of the bills have failed to pass.[133] However, in August 2007 Missouri Governor Matt Blunt signed the Missouri Rice Certification Act into law.[134] The Act regulates the production, transportation and handling of

---

[128] *Id.* at 333.

[129] *Id.* at 329-30. "Adventitious presence" is the "unavoidable variability in seed, grain, and food" that occurs naturally over a long period of time in order to give a plant an advantage for survival. *Id.* at 328-29.

[130] *See* United States Department of Agriculture, *Missouri State Agriculture Overview-2006, available at* http://www.nass.usda.gov/Statistics_by_State/Ag_Overview/AgOverview_MO.pdf (last checked April 12, 2008).

[131] The United States is one of the biggest producers of genetically modified crops in the world, producing over 50% of genetically modified crops alone. *See*, Friends of the Earth International, *Who benefits from the use of gm crops?: the rise of pesticide use*, at 5-6 (January 2008*), available at* http://www.globalpolicy.org/socecon/trade/gmos/2008/01whobenefits.pdf (last checked April 12, 2008).

[132] *See* Environmental Commons, *2007 Food Democracy Legislation Tracker*, http://environmentalcommons.org/tracker2007.html (last checked April 12, 2008).

[133] *Id.*

[134] *See* Governor's Office, *Blunt Discusses Agricultural Innovation and Technology at Delta Center Field Day* (August 2007), http://governor.mo.gov/press_Aug2007.htm

specific rice varieties.[135] The Act was proposed after it was discovered in 2006 that U.S. rice crops were contaminated by a strain produced by Bayer CropScience. As a result, the U.S. lost the European Union rice market.[136] Though no statutory regulations exist in Missouri that apply specifically to genetically modified organisms, the common law tort of public nuisance is still available to farmers whose crops are altered by cross-pollinating drift.[137] The enactment of the Missouri Rice Protection Act illustrates the concern that genetically modified organisms will have a negative impact on native and non-native plant species.

It is clear that at this time, while Missouri acknowledges the potential negative impacts of G.M.O.'s, that the state legislature still believes that the benefits outweigh the costs. However, as more states sign preemption statutes into law, impose greater restrictions on growing and marketing genetically modified organisms, and enact liability statutes for farmers who's crops cross-pollinate with non-genetically modified crops, Missouri is likely to begin enacting more legislation that acknowledges the potential threat such crops pose to Missouri's natural environment.

VI. CONCLUSION

Monsanto is not a groundbreaking decision that alters decades of well-established case law. It is not the result of a highly publicized corporate struggle over the cure for cancer. It does not possess a "sexy" fact pattern that keeps the reader glued to the material. It is not a lot of things, but the *Monsanto* decision is one thing – it is a reminder that genetically modified organisms are still an important legal, political,

---

(follow "Blunt Discusses Agricultural Innovation and Technology at Delta Center Field Day" hyperlink) (last checked April 12, 2008).

[135] Rob Mayer, Missouri Senate, *Missouri Rice Certification Act Protects Farmers from GMOs* (Feb. 19, 2007), *available at* http://www.senate.mo.gov/07info/members/newsrel/d25/022207.pdf (last checked April 12, 2008).

[136] *Id.*

[137] *See* Stephen M. Scanlon, *Should Missouri Farmers of Genetically Modified Crops be Held Liable for Genetic Drift and Cross-Pollination?*, 10 MO. ENVTL. L. & POL'Y REV. 1, 2 (2003) (citing Tichenor v. Vore, 953 S.W.2d 171, 176 (Mo. App. S.D. 1997)).

economic, and environmental issue that Missouri, and the United States, will grapple with for years to come.

LEE STOCKHORST