

2010

Seeds of Doubt: The European Court of Justice's Decision in *Monsanto v. Cefetra* and the Effect on European Biotechnology Patent Law

Craig C. Carpenter

Recommended Citation

Craig C. Carpenter, *Seeds of Doubt: The European Court of Justice's Decision in Monsanto v. Cefetra and the Effect on European Biotechnology Patent Law*, 44 INT'L L. 1189 (2010)
<https://scholar.smu.edu/til/vol44/iss4/7>

This Case Note is brought to you for free and open access by the Law Journals at SMU Scholar. It has been accepted for inclusion in International Lawyer by an authorized administrator of SMU Scholar. For more information, please visit <http://digitalrepository.smu.edu>.

Seeds of Doubt: The European Court of Justice's Decision in *Monsanto v. Cefetra* and the Effect on European Biotechnology Patent Law

CRAIG C. CARPENTER*

I. Introduction

*Monsanto Technology LLC v. Cefetra BV*¹ was the first European Court of Justice (ECJ) interpretation of the twelve-year-old European Union Biotechnology Directive (Directive 98/44/EG), which established the foundation for patenting genetic material in member countries.² The ECJ's decision effectively limited the scope of the directive, and consequently, European biotechnology patent protection by determining that genetic patents are only effective when the patented gene "perform[s] the function for which it is patented[.]"³ The first part of this paper will discuss the history of the parties in dispute and the industry that is becoming familiar to this kind of dispute. The second and third parts will focus on the specific case that is the focus of this paper, and the final portion will analyze the effect this case had and will continue to have on patent law, particularly in the European Union and Argentina.

II. Background

Monsanto, the world's biggest seed company,⁴ provides agricultural products for farmers in the United States and internationally.⁵ Monsanto is a major player in global biotechnology innovation and business through its involvement in genetically modified seed crea-

* Craig C. Carpenter, 2012 Candidate for Juris Doctor, SMU Dedman School of Law.

1. Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.R. 7, available at http://curia.europa.eu/jcms/jcms/j_6/.

2. Richard Van Noorden, *DNA Patent Ruling Hinders Monsanto*, NATURE, July 9, 2010, <http://www.nature.com/news/2010/100709/full/news.2010.345.html>.

3. Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.R. 7.

4. Stephanie Bodoni, *Monsanto May Lose Bid to Halt Argentinean Soy Imports*, BUS. WEEK, Mar. 9, 2010, <http://www.businessweek.com/news/2010-03-09/monsanto-may-lose-bid-to-halt-argentinean-soy-imports-update1-.html>.

5. *Monsanto Co.*, YAHOO FIN., <http://finance.yahoo.com/q/pr?s=MON> (last visited Feb. 16, 2011).

tion. The company sells genetically modified seeds to farmers worldwide and also licenses the beneficial genes that it uses to modify the seeds to other seed producers.⁶ To protect and profit from its innovation, Monsanto seeks patents on the seeds, methods of producing the seeds, and the genetic traits within the modified seeds.

In 2005 and 2006, Monsanto sued European importers of Argentine soybean meal in Spain, the United Kingdom, Denmark, and Holland, for infringing on three of its European biotechnology patents.⁷ According to Monsanto, the imported soy meal was derived from soy beans produced by soy plants that were modified with a gene developed by Monsanto.⁸ The patents at issue relate to a gene (known as EPSPS) that, when added into the soy genome, confers resistance to the herbicide glyphosate, commonly known as "Roundup."⁹ This trait allows farmers to use the herbicide to eliminate weeds while permitting the soy plant to grow unharmed.¹⁰ Specifically, the patent awarded Monsanto:

[P]roprietary exclusivity over (1) isolated DNA encoding EPSPS, (2) a method of producing a genetically transformed plant which tolerates the herbicide glyphosate by making a transgenic plant cell containing the EPSPS gene, (3) glyphosate-tolerant plant cells and plants, and (4) a method of controlling weeds in a field by applying glyphosate to a crop and weeds in a field containing a crop that has been transformed with the EPSPS gene and is therefore glyphosate-tolerant.¹¹

Monsanto alleged that the plants contained traces of the DNA from its patented gene, which indicated that the soy meal was produced from soy plants grown from its patented seeds.¹² The suit alleged that the presence of this DNA in the soy meal violated Monsanto's patent rights in three ways: (1) infringement of Monsanto's patent claim of the isolated gene, (2) infringement of Monsanto's patent claim of the method of producing resistant plants using the gene, and (3) infringement of Monsanto's patent claim of the DNA sequence itself.¹³ Monsanto elected to enforce its patent in Europe because it did not have patent protection in Argentina, where the patent was rejected for procedural reasons,¹⁴ and thus Monsanto was not able to take action against Argentine farmers using the seeds without consent.¹⁵

6. *Id.*

7. Gareth Morgan et al., *Expert Analysis of Recent European Developments Cargill vs. Monsanto*, 27 BIOTECHNOLOGY L. REP. 109, 110 (2008).

8. *Id.*

9. *Id.* at 109.

10. Press Release, Court of Just. of the European Union, *Monsanto Cannot Prohibit the Marketing in the EU of Soy Meal Containing, in a Residual State, a DNA Sequence Patented by It* (July 6, 2010), available at <http://curia.europa.eu/jcms/upload/docs/application/pdf/2010-07/cp100073en.pdf>.

11. Richard Peet et al., *The Future of Biotechnology Patents in the European Union*, INTELL. PROP. WATCH, Aug. 17, 2010, <http://www.ip-watch.org/weblog/2010/08/17/the-future-of-biotechnology-patents-in-the-european-union/>.

12. *Id.*

13. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.) (Neth.). For an English translation, see <http://holmancm.googlepages.com/CefetraEUBiotechDirective.pdf>.

14. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.).

15. *Id.*; see also Andrew Turley, *DNA Must Do Its Job for Patent Protection*, CHEMISTRY WORLD, July 8, 2010, <http://www.rsc.org/chemistryworld/News/2010/July/08071001.asp> ("Farmers in Argentina can grow

III. The Dutch Case

In June 2005 and March 2006, shipments of soybean meal from Argentina arrived in harbors in the Netherlands intended for Cefetra Futures BV.¹⁶ The cargo was detained by customs on the grounds of the Anti-Piracy Regulation (E.U. Regulation number 1383/2003), and Monsanto took samples of the product to determine if the soy meal originated from its patented genetically modified soybeans.¹⁷ Monsanto found DNA matching that of its patented trait, and sued the importers (Cefetra and others) for patent infringement based on its European patent (the “patent”) granted June 19, 1996, under number EP0 546 090 relating to glyphosate tolerant 5-enolpyruvylshikimate-3 phosphate synthesis.¹⁸ The European Patent Office granted the patent, which was valid in Austria, Belgium, Switzerland, Germany, France, the United Kingdom, Italy, Lichtenstein, Luxemburg, the Netherlands, and Sweden.¹⁹ Cefetra and the government of Argentina, a major exportation country of soy products, joined to dispute Monsanto’s infringement claims.

The Dutch court, sitting in The Hague, heard the case in 2008.²⁰ The decision concurred with the earlier decision by the United Kingdom High Court of Justice.²¹ In response to Monsanto’s claimed infringement on the isolated DNA, the Dutch court and British court both held that “there can be no question of breach of these claims [for infringement of the isolated DNA patent] as the DNA is not present as isolated matter but is incorporated in the soy meal.”²² In so finding, the court reasoned that, even though the DNA was outside of its normal environment (the bacterial chromosome) and put into the plant cell, “[t]he average person skilled in the art would understand the term isolated DNA as DNA that has been retrieved from the cell (core) of an organism for further treatment in a manner as is usual in the relevant profession.”²³ The Dutch court was equally skeptical of Monsanto’s second argument and rejected the theory “that the soy meal can be regarded as a directly obtained product by application of the claimed methods[.]”²⁴ The court reasoned that “[i]t can be accepted that the soy plant and soy bean have been directly obtained by the method,” but that “[b]y means of the previously described crushing process, the beans are then separated, in a number of treatment stages, and worked into different components with a new identity. This process is too drastic to still assume a direct relationship between the method and the soy meal.”²⁵ Thus, the

Roundup Ready soya beans because Monsanto does not have patent protection in the country. Monsanto said in a recent statement that: ‘Approximately 95 per cent of the soybeans grown in Argentina contain the Roundup Ready trait.’”)

16. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.).

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*; Peet et al., *supra* note 11.

21. Peet et al., *supra* note 11.

22. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.).

23. *Id.*

24. *Id.*

25. *Id.*

product (soy meal) was not “directly obtained” by the patented method (growing herbicide resistant soy plants)²⁶ and was not protected under the patent.

Monsanto’s third infringement argument prompted the most discussion by the court and led to the present controversy. In this argument Monsanto claimed infringement of its patent claims that relate to the DNA sequence per se, without restrictions for isolation or method.²⁷ The court dismissed Cefetra’s argument that the DNA present in the soy meal was overly fragmented and in de minimus quantity to support infringement, finding that:

[e]ven should it have to be assumed that the DNA sequence is only present in the soy meal in minimal quantity, this does not deter from the fact that there is a breach of the Monsanto patent, if and to the extent that the scope of protection extends to the product, the DNA, as such[.]²⁸

However, as the court noted, the question still remained as to whether the law even covers the DNA at issue. An interpretation of the applicable patent standard would be outcome determinative in this case: if the law does apply to the DNA per se, then Monsanto’s patent was infringed upon; however, if the law does not apply to the DNA per se, then there was no infringement.²⁹

The court first grappled with the applicable law; specifically, whether to apply the national (Dutch) patent law or the E.U. directive.³⁰ Article 9 of the E.U. Directive states: “[t]he protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and *in which the genetic information is contained and performs its function.*”³¹ Monsanto first argued that Article 9 of the Directive should not apply because soy meal was not a biological material.³² Monsanto also stated that the directive was created to expand patent protection to biotechnological inventions and not to limit it, and therefore set a minimum standard of protection for biotechnological inventions, which could be strengthened by the absolute protection of national law.³³ Monsanto supports

26. Peet et al., *supra* note 11.

27. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.). See also Chris Holman, *Limitations on the scope of DNA Patent Claims in Europe: Monsanto Struggles in Its Attempt to Block Importation of Soy Meal Containing Patented DNA*, HOLMAN’S BIOTECH IP BLOG, (May 4, 2008, 9:28 EST) <http://holmansbiotechblog.blogspot.com/2008/05/limitations-on-scope-of-dna-patent.html> (explaining “whether claims directed to the DNA sequence per se, without any limitation to ‘isolated DNA,’ are infringed by the soy meal”).

28. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.).

29. *Id.*

30. *Id.*

31. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, art. 1 (emphasis added), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>.

32. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.).

33. Rijksoctrooiwet [Patents Act of the Kingdom] 1995, art. 53 (Neth.), available at <http://www.ivir.nl/legislation/nl/patentact1995.html> (“a patent shall confer on its owner the exclusive right: a. to make, use, put on the market or resell, hire out or deliver the patented product, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes”); Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.); Holman, *supra* note 27.

this argument by adding that “[s]uch a limitation . . . is not compatible with Article 27 of the [Trade-Related Aspects of Intellectual Property Rights (TRIPS)] Treaty[.]”³⁴ Further, Monsanto argued that regardless of the use of Article 9 of the Directive, “the product[] is incorporated in the soy meal and expresses its function.”³⁵ Monsanto reasoned that:

the requirement that the DNA expresses its function means that it is sufficient that the DNA has exercised its function (namely the provision of resistance to glyphosate in the soy plant) or that the DNA, should it be isolated from the soy meal, can be incorporated in a cell in a soy plant and can then (once again) exercise its function.³⁶

Cefetra cited a Spanish case and an English case, which applied the purpose/function limitation to patent protection for DNA as well as supplemental language from different sources from the E.U.³⁷ Noting that the decision in this case turns on the interpretation and scope of Article 9 of the E.U. Directive (a transnational doctrine), the Dutch court decided that such matters would be better suited to the ECJ. Thus, the Dutch court referred the following three questions to the ECJ for clarification:

1. Should Article 9 of the Directive be understood such that the protection meant in this Article can also be relied upon in a situation such as in these proceedings whereby the product (the DNA) is present in a materials and does not express its function at the time of the stated breach but has indeed expressed its function or possibly, following the isolation from the material and its incorporation in the cell of an organism, could once again express its function?
2. Proceeding from the presence of the DNA sequence as described in claim 6 of the patent in soy meal imported into the European Community by Cefetra and ACTI and assuming that DNA is incorporated in the soy meal as meant in Article 9 of the Directive and that it therein no longer expresses its function: Does the provided protection of a patent for biological material in the Directive, specifically in Article 9, stand in the way for the national patent legislation to (additionally) allow absolute protection for the product (the DNA) as such, whether or not the DNA expresses its function and must the protection provided by Article 9 therefore be considered exhaustive?
3. Does it make any difference to the answer to the previous question that the patent was applied for and granted (on 19 June 1996) prior to the Directive being adopted? Can you, on answering the previous questions, take into consideration the TRIPS Treaty, specifically the Articles 27 and 30?³⁸

34. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.); Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S. 299, available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (“[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”).

35. Ktr. The Hague Maart 19, 2008, 249983/HA ZA 05/2885 m.nt (Monsanto Technology LLC/Cefetra B.V.).

36. *Id.*

37. *Id.* (“Cefetra, Argentina and ACTI have submitted a decision by the Spanish judge . . . in the case of Monsanto-Sesostris S.A.E. . . . [they have] also submitted an opinion on the same lines by Professor Dr. Dres. h.c. Joseph Strauss [and]. . . a decision by the English High Court of Justice dated 10 October 2007 was submitted in respect of the case Monsanto–Cargill.”).

38. *Id.*

IV. THE ECJ DECISION

On July 6, 2010, the ECJ made the final decision on *Monsanto Tech. LLC v. Cefetra BV*—a sweeping blow against Monsanto.³⁹ In response to the first question proposed by the Dutch Court, the ECJ held that:

[a]rticle 9 of Directive 98/44/EC of the European Parliament . . . is to be interpreted as not conferring patent right protection in circumstances such as those of the case in the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it is patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.⁴⁰

The court likewise answered the second question against Monsanto stating that “[a]rticle 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such. . . .”⁴¹

Finally, to complete its rejection of Monsanto’s arguments, the court held that:

[a]rticle 9 of the Directive precludes the holder of a patent issued prior to the adoption of that directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable. . . . Articles 27 and 30 of the . . . [TRIPS] do not affect the interpretation given of Article 9 of the Directive.⁴²

With this decision, the Court chose sides and definitively answered a debate that has occupied European biotechnology scholars for some time. For the purposes of the Dutch litigation (and much to Cefetra and Argentina’s delight), the court held that there could not be infringement because the DNA was in dead material (the soy meal) and thus could not possibly be performing its patented function (resisting herbicide).⁴³ However, this decision had no effect on the Dutch litigation because the parties settled outside of court prior to the ECJ decision.⁴⁴ Settlement or no settlement, the ECJ, possibly sensing the urgency for clarification on its stance regarding the Directive, felt compelled to give a decision. This urgency likely spawned from the fact that the biotechnology industry is a controversial, \$80-billion-dollar and growing industry.⁴⁵ Europe has been slow to warm up to the industry and has instead allowed the United States and Canada to take the driver’s seat with regards to biotechnology policy.⁴⁶

39. Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.R. 7.

40. *Id.*

41. *Id.*

42. *Id.*

43. Turley, *supra* note 15.

44. *Id.*

45. Glen T. Giovannetti et al., *Beyond Borders Global Biotechnology Report 2010*, ERNST & YOUNG, 54 (2010), [http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2010/\\$FILE/Beyond_borders_2010.pdf](http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2010/$FILE/Beyond_borders_2010.pdf).

46. For a discussion on the history of biotechnology in Europe and the beginnings of the Directive, see Terence P. Stewart & David S. Johanson, *Policy in Flux: the European Union’s Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243 (1999); Lydia Nenow, *To Patent or Not to*

V. Effects of the Ruling

The implications for this decision are widespread, and its merits are heavily debated. This decision, which cannot be appealed and is retroactively applicable in all twenty-seven European Union Member States,⁴⁷ essentially makes European gene patents “purpose bound”⁴⁸ in that the patent “can only be relied on [when it] actually performs the function for which it is patented.”⁴⁹ Many commentators agree that this interpretation significantly narrows the protection offered by E.U. patents;⁵⁰ however, as noted below, there is much disagreement as to how this will affect the industry as a whole.

The Court refused the argument that gene patents should be “product-based” like other machine or chemical patents, which are granted per se protection that allows the owner to restrict any infringing use.⁵¹ In choosing this path, the court has carved out an exception to patent law that treats genetic patents differently than machines and other patentable material.⁵² Opponents argue that this interpretation of the directive is troublesome and would severely undermine patent enforcement for many biotechnology inventions.⁵³ It is argued that this treatment of genetic patents is counterintuitive to and inconsistent with the way typical patent laws would approach this kind of infringement—under which, “so long as the genetic information is present and *capable of performing its function*, it should not matter whether the genetic information is active at the time of the alleged infringing act, unless some other claim element requires it[.]”⁵⁴ This argument has teeth when applied to this case. Monsanto’s patented material was found in the imported soy meal, and it can be said that the soy meal could not have existed were it not for Monsanto’s patented material—under traditional patent law this could be a fairly straightforward infringement. In this vein, problems also arise because “[m]any genes are only expressed for a limited time period or in specific tissues in a living organism.”⁵⁵

Some commentators claim that this ruling allows for a lucrative loophole for patent infringement because growers could potentially “circumvent gene patents used to protect genetically modified crops by growing the crops in a country where the gene is not patented, such as Argentina in this case, . . . and then importing the product into a European Union member wherein the patent is in force with impunity.”⁵⁶ This is an important global argument. From a business standpoint, biotech companies rely on the limited mo-

Patent: The European Union’s New Biotech Directive, 23 HOUS. J. INT’L L. 569 (2001); Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AIPLA Q.J. 193 (2007).

47. Jeremy Phillips, *Monsanto: Court Makes a Meal of Soya Ruling*, IPKAT BLOG, (July 6, 2010), <http://ipkitten.blogspot.com/2010/07/monsanto-court-makes-meal-of-soya.html>.

48. Morgan et al., *supra* note 7, at 112.

49. *Agriculture: EU Court Rejects Monsanto Demand for EU Ban on Argentine Soya Imports*, 27 INT’L TRADE REP. (BNA) No. 1034 (July 8, 2010).

50. Van Noorden, *supra* note 2.

51. Morgan et al., *supra* note 7, at 112.

52. Turley, *supra* note 15.

53. Peet et al., *supra* note 11.

54. *Id.* (emphasis added).

55. *Id.*

56. Chris Holman, *Monsanto v. Cefetra: EU Court of Justice Limits Scope of Patent Protection Available to Gene Sequences*, HOLMAN’S BIOTECH IP BLOG, (July 9, 2010, 16:37 EST), <http://holmansbiotechblog.blogspot.com/2010/07/monsanto-v-cefetra-eu-court-of-justice.html>.

nopolies granted by patents to offset the huge research and development costs commonly found in scientific fields. Additionally, as developing countries like Argentina⁵⁷ continue to grow their agricultural export markets,⁵⁸ genetically-modified-organism patent protection will be of great concern to international companies. The potential loophole created by the ruling in this case could have an expensive impact on companies like Monsanto and undermine the efforts for global intellectual harmonization.⁵⁹ Because of this ruling, future action to reconcile this kind of “infringement” will have to focus on the court systems in the agricultural countries like Argentina, instead of patent protection in export destinations.⁶⁰ Many commentators stress that, so far, Argentine intellectual property protection has come up short of expectations from the rest of the intellectual property world.⁶¹

However, there is also strong support for the court’s decision. Many countries in Europe have expressly or implicitly showed skepticism toward product-based patent protection for genetic information,⁶² including the United Kingdom, which has held that “while it may be true to say . . . that [the DNA] lay ‘at the heart of the invention’, it was not the invention. An invention is a practical product or process, not information about the natural world.”⁶³ In that sense, this ruling harmonizes the E.U.’s stance on gene patents with that of some of the individual European countries.⁶⁴ Proponents (the Argentina government included) find the limits imposed by this ruling necessary to prevent overly broad protection, even concluding that “[i]f the court decided that Monsanto can invoke its rights in the EU against soy meal originating from Argentina, nothing could stop it to then use its rights against soy meal coming from other countries[.]”⁶⁵ Others do not see this situation becoming as much of a catastrophe, arguing that:

[a]lthough lawyers will have to be careful about how they file patents for products containing genetic material, most . . . feel that the ruling will probably not dampen innovation or investment in the European biotech industry as a whole. If anything

57. Argentina is one of the world’s top exporters of soy-bean products. *Balance of Trade: Argentine Exports Up 15 Percent to Record \$46.57 Billion in 2006*, 24 INT’L TRADE REP. (BNA) NO. 176 (Feb. 1, 2007) (“Among [Argentine] exports, \$8.86 billion came from soybean and soy byproducts, according to Indec. Argentina is the world’s top exporter of soybean oil and the third largest exporter of soy beans.”).

58. *See id.*

59. *41st World Intellectual Property Congress A Resounding Success*, BUS. WIRE, Sept. 26, 2008, available at http://findarticles.com/p/articles/mi_m0EIN/is_2008_Sept_26/ai_n29462689/.

60. *EU Court Ruling Favours Argentina in Dispute With Monsanto Over Soy-Seed Patent*, MERCOPRESS, July 8, 2010, <http://en.mercopress.com/2010/07/08/eu-court-ruling-favours-argentina-in-dispute-with-monsanto-over-soy-seed-patent> (noting that, in anticipation of this ruling, the dispute between the two major players in the litigation, Monsanto and Cefetra, was settled outside of court and Monsanto is pursuing its options in Argentina, stating that Argentina was “the correct place for a resolution in these matters” and that “it will continue to work on a fair solution”).

61. *Protection of Biotechnological Inventions in Argentina*, APLF PATENT L. UPDATE, May 15, 2007, <http://www.aplf.org/protection-of-biotechnological-inventions-in-argentina/>.

62. Morgan et al., *supra* note 7, at 112 (“It is worth noting that in implementing the Biotechnology Directive, Germany, France, and Luxembourg have all expressly barred gene sequences from product-based protection.”).

63. *Kirin-Angen Inc. v. Hoechst Marion Roussel Ltd*, [2004] UKHL 46 (appeal taken from EWCA) (Eng.).

64. Morgan et al., *supra* note 7, at 112.

65. Bodoni, *supra* note 4.

. . . the court decision shows that DNA patents are acceptable in Europe, even if their scope is quite narrow.⁶⁶

Some of these commentators put more faith in the patent-seeking companies and export countries, rationalizing Monsanto's current dilemma as an unfortunate mistake because "Monsanto's lack of patent protection in Argentina is anomalous. In most cases, if your claim is in Argentina, you'd be able to stop them in Argentina. . . . Biotechnology companies with 'good coverage' are unlikely to be worried."⁶⁷ Additionally, all hope for the protection sought by Monsanto is not lost—patents can be prepared (by a prudent author) with other claims that could be used to enforce protection on products containing genetic material without relying on a claim for the DNA sequence, which was ineffective for Monsanto in this case.⁶⁸ Inventors seeking patent protection for genetic information and the products created by such innovation will need to be aware of the "purpose-bound" distinction and creatively work around it in the patent claims to create optimal protection for their products.

VI. Conclusion

The ECJ's analysis of the twelve-year-old European Union Biotechnology Directive in the ruling in *Monsanto Technology LLC v. Cefetra BV* marks an important and definitive interpretation of European patent law. The finding that European Union patent protection of genetic material is "purpose-bound" helps clarify a murky area of patent law but places a significant limitation on biotechnology patents in Europe and may cause many holders of such patents to reconsider their comfort level with their patent portfolio. This insecurity reigns over the biotech industry as a whole; even countries that have shown early support for the biotech industry (like the United States) are struggling with application of patent law to this cutting-edge industry.⁶⁹ While the total effect of this interpretation of biotechnology patent law on the related industries remains to be seen, it is clear that, for Monsanto and other genetically modified organism innovators, the battlefield will shift from major import countries like those in Europe to the agricultural export countries, such as Argentina (where they may be met with courts immature in patent experience). As the biotechnology industry continues to expand, both in scope and controversy, legislation will have to hustle to keep up with the science.

66. Van Noorden, *supra* note 2.

67. Turley, *supra* note 15 (internal quotation marks omitted).

68. Van Noorden, *supra* note 2.

69. See e.g., Andrew Pollack, *U.S. Says Genes Should Not Be Eligible for Patents*, N.Y. TIMES, Oct. 30, 2010, at B1 (noting that recent litigation has the United States possibly on the cusp of revising its longstanding policy towards patents for isolated genes), available at http://www.nytimes.com/2010/10/30/business/30drug.html?_r=1&scp=2&sq=andrew%20pollack&st=cse.

