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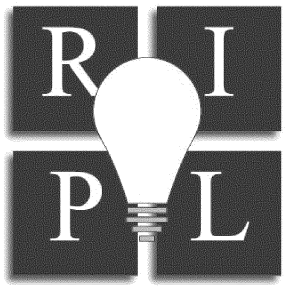

BIOTECH PATENT INFRINGEMENT IN EUROPE: THE "FUNCTIONALITY" GATEKEEPER

VID MOHAN-RAM, RICHARD PEET & PHILIPPE VLAEMMINCK

ABSTRACT

The Court of Justice of the European Union recently concluded in *Monsanto Technology LLC v. Cefetra BV* that a patent with claims drawn to isolated DNA, or transgenic products containing that sequence, cannot be infringed if the DNA is not functional at the time of the alleged infringement. This paper discusses how the *Cefetra* judgment may unintentionally inflict serious economic harm on the European biotechnology industry because countless biotechnology products may no longer be protected by what are otherwise valid and enforceable patent claims. After *Cefetra*, an accused infringer may deny infringement by simply asserting that the patented sequence does not perform its function at the time of alleged infringement because many genes are only temporarily functional or only functional in certain tissues and organs. Further, the judgment may extend far beyond the biotechnology industry. The *Cefetra* decision may very well change the landscape of gene patents in Europe if seen as a sister case to the *Myriad Genetics* case in the U.S. The *Myriad* Court held that "isolated DNA" is not patent eligible because it is not "markedly different" from native, endogenous DNA. *Cefetra* is surprising because the court relied on Article 9 of Directive 98/44/EC which was intended to define patentable subject matter of living and replicating organisms, rather than the scope of enforceable rights in patent infringement. In this paper, the authors assert that a claim should be infringed so long as the patented genetic information is present in a commercial product regardless of activity and function at the time of the alleged infringement. The paper concludes by discussing the best practices for biotechnology companies seeking protection in Europe, such as: (1) providing careful attention to obtaining Plant Breeder's Rights protection pursuant to the International Convention for the Protection of New Varieties of Plants; (2) using product-by-process claims in utility patents; and (3) claiming the product's characteristics and traits without reference to the genetic material responsible.

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INTRODUCTION

The Court of Justice of the European Union recently concluded that a patent with claims drawn to isolated DNA, or to transgenic products that contain the patented DNA, cannot be infringed if the DNA is not functional at the time of alleged infringement.[1] This judgment in the underlying case, *Monsanto Technology LLC v. Cefetra BV*,[2] may now unintentionally inflict serious economic harm on the European biotechnology industry. Countless biotechnology products, for instance, may now not be protected by what are otherwise valid and enforceable patent claims. An accused infringer, for example, could deny infringement by simply asserting that the patented polynucleotide or gene does not perform its function at the time of alleged infringement.[3] Because many genes are only temporarily functional, functional only in some tissues or organs, or have many functions, this defense may have merit.[4] Furthermore, the judgment's impact may extend far beyond a narrow conception of the biotechnology industry. For example, the viability of patents claiming isolated DNA or RNA sequences used as reagents—including reagents used in diagnostic

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[1] Case C-428/08, Monsanto Tech. LLC v. Cefetra, 2010 ECJ EUR-Lex LEXIS 396 (Jul. 6, 2010) ¶ 1 [hereinafter *Cefetra II*].

> [T]he legal protection of biotechnological inventions 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.

Id.

[2] *Id.*

[3] *Id.* ¶ 32.

[4] *See generally* EVELYN FOX KELLER, THE CENTURY OF THE GENE 57–96 (2d prtg. 2001) (stating that genes can be expressed or not, some can encode a number of proteins that "reaches into the hundreds," and that triggering the "eyeless" gene in a fruit-fly can "create full-fledged eyes in fly wings, legs, antennae, and a variety of other tissues that don't normally produce eyes").

methods such as gene tests and DNA chips—are now in jeopardy.[5] If seen as a kind of sister case to *Association for Molecular Pathology v. U.S. Patent and Trademark Office* (the "*Myriad Genetics*" case) in the United States ("U.S."),[6] where the District Court held that "isolated DNA" is not even eligible for patenting because it is not "markedly different" from native, endogenous DNA,[7] the *Cefetra* decision could very well change the landscape of "gene patents" in Europe.

The Court of Justice of the European Union ("ECJ") judgment is surprising because Article 9 of Directive 98/44/EC (the "Directive"),[8] which was an important basis for the ECJ's ruling,[9] was intended to define what constitutes patentable subject matter when the claims in question cover living and replicating organisms.[10] Article 9 was not intended to define the scope of enforceable rights in the context of alleged patent infringement.[11] In the context of patent infringement, so long as the patented genetic information is present in the commercial product, its activity and function at the time of commercialization is immaterial.[12]

I. THE BACK STORY: ARGENTINEAN SOYBEANS IN EUROPE

The dispute underlying the ECJ's judgment and its interpretation of Directive 98/44/EC arose from importation into Europe of soybean meal made from Argentinean plants engineered to express the herbicide resistance gene 5-enolpyruvylshikimate-3-phosphate synthase ("EPSPS").[13] Monsanto had obtained patent protection for this herbicide resistance gene in Europe, but did not have patent protection in Argentina.[14]

After harvest, soybean oil was solvent-extracted from the seeds at high temperatures.[15] The remaining solid matter, the soybean meal, was then imported

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[5] *See, e.g.*, Aleksandra Adomas et al., *Comparative Analysis of Transcript Abundance in* Pinus sylvestris *After Challenge with a Saprotrophic, Pathogenic or Mutualistic Fungus*, 28 TREE PHYSIOLOGY 885, 886–87 (2008) (preparing microarrays of complimentary DNA for the targeted sequences which remain wholly inactive until test samples are applied to the arrays).

[6] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[7] *Id.* at 232.

[8] Council Directive 98/44/EC, 1998 O.J. (L 213) 13 (EC) [hereinafter Directive 98/44], *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF.

[9] *See Cefetra II, supra* note 1, ¶¶ 1, 32(1)–(2).

[10] *See* Directive 98/44, *supra* note 8, at 14, 18, 19; *see also* Daya Shanker, *Argentina-US Mutually Agreed Solution, Economic Crisis in Argentina and Failure of the WTO Dispute Settlement System*, 44 IDEA 565, 610 (2004) (stating that Articles 5(2) and 9 of the Directive apply to patentability of a gene).

[11] *See* Convention on the Grant of European Patents arts. 64(2)–(3), 69(2), Oct. 5, 1973, 1065 U.N.T.S. 255 [hereinafter EPC], *available at* http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/$FILE/EPC_14th_edition.pdf.

[12] *See id.*

[13] *Cefetra II, supra* note 1, ¶¶ 17, 19, 21.

[14] *Id.* ¶¶ 15, 18.

[15] *See* Rb' s-Gravenhage 19 maart 2008, 249983 / HA ZA 05-2885, ¶¶ 2.2.3–2.2.4 (Monsanto Tech., LLC/Cefetra B.V.) (Neth.) [hereinafter *Cefetra I*]; Rb 's-Gravenhage 19 maart 2008, 270268 / HA ZA 06-2576 (Monsanto Tech., LLC / Vopak Agencies Rotterdam B.V.) (Neth.). This case was joined with *Cefetra I*.

into Europe.[16] Due to the harsh conditions used in the solvent-extraction process, soybean meal does not contain living plant cells.[17] It does, however, contain protein, DNA, and other cellular components.[18] Thus, if the imported soybean meal was made from glyphosate-tolerant soybeans, the claimed herbicide-resistance gene may be detectable in the imported soybean meal.[19]

The herbicide glyphosate is sold by Monsanto as Roundup®, which is widely used to kill numerous weeds, grasses, and woody plants.[20] In 1996, Monsanto obtained a European patent covering methods of making plants resistant to glyphosate by making plant cells express the EPSPS gene.[21] That patent, EP 0 546 090 ("the 090 patent"),[22] describes the original isolation and cloning of DNA that encodes the EPSPS protein from bacteria and describes how to transform plant cells with the EPSPS gene to make glyphosate-tolerant plant cells and plants.[23] Monsanto's patent gave them proprietary 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.[24] Importantly, the 090 patent did not expressly contain claims directed to a method of making soybean meal from glyphosate-tolerant plants.[25]

The activity underlying Monsanto's infringement actions was the importation of soybean meal from Argentina and into Europe, which Monsanto alleged infringed these patents.[26] Because Monsanto had no patent rights to its EPSPS glyphosate tolerance technology in Argentina, the company decided to enforce the 090 patent in Europe.[27] Monsanto sued European importers of soybean meal coming from Argentina in Spain,[28] the United Kingdom,[29] Denmark,[30] and Holland.[31] The Danish case has not been decided.[32]

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[16] *Cefetra I*, ¶¶ 2.7–2.8.

[17] *Id.* ¶ 4.15.2.

[18] *Cefetra II*, *supra* note 1, ¶ 21.

[19] *Cefetra I*, *supra* note 15, ¶ 3.1.1.

[20] MONSANTO, HISTORY OF MONSANTO'S GLYPHOSATE HERBICIDES 1 (June 2005), http://www.monsanto.com/products/Documents/glyphosate-background-materials/back_history.pdf.

[21] Glyphosate Tolerant 5-enolpyruvylshikimate-3-phosphate Synthases, Eur. Patent No. EP 0 546 090 at 63 l. 58–64 l. 32 (filed Aug. 28, 1991).

[22] EP 0 546 090 at 63 l. 58–64 l. 32.

[23] EP 0 546 090 at 2 l. 48–3 l. 18.

[24] EP 0 546 090 at 62 ll. 46–49, 63 ll. 19–21, 63 ll. 29–40, 63 l. 58–64 l. 18, 64 l. 33, 64 l. 43, 64 l. 53–65 l. 13.

[25] *See* EP 0 546 090 at 62 l. 44–65 l. 28.

[26] *Cefetra II*, *supra* note 1, ¶ 21 ("Following the tests, which revealed the presence of CP4-EPSPS in the soy meal and the DNA sequence encoding it, Monsanto applied for injunctions against Cefetra . . . .").

[27] *Id.* ¶¶ 18, 21 (suing "on the basis of Article 16 of Regulation No. 1383/2003, and for a prohibition of infringement of the European patent in all countries in which the patent is valid" because "there is no patent protection [in Argentina]").

[28] S. Juz. Prim., Jul. 27, 2007 (No. 488/07) (Spain) [hereinafter *Sesostris I*], *available at* http://jurisprudencia.vlex.es/vid/-38074056; *see also*, Gareth Morgan, Matthew Royle & Simon Cohen, *Expert Analysis of Recent European Developments:* Cargill vs. Monsanto, 27 BIOTECH. L.

A. In Spain: Directive 98/44/EC Applies

Monsanto sued Sesostris SAE for patent infringement in Spain alleging that the importation from Argentina of soybean meal containing the EPSPS gene infringed claims in a Spanish patent based on the 090 patent.[33] In 2007, the Commercial Court in Madrid held there was no patent infringement.[34] The Spanish Court concluded that Directive 98/44/EC was applicable.[35]

Furthermore, the Spanish Court held that pursuant to provisions of Directive 98/44/EC, including Article 9,[36] a product does not infringe a patent claiming genetic material even if the accused product contains the patented genetic material, as long as the genetic material does not have the capacity to perform its intended function in the accused product.[37] The Commercial Court held that the invention is not the DNA sequence, but the function it performs.[38] Monsanto subsequently appealed the decision of the Commercial Court in Madrid.[39]

B. In the United Kingdom: Directive 98/44/EC Does Not Apply

In the United Kingdom ("UK"), Monsanto sued Cargill for patent infringement, alleging that Cargill's importation of soybean meal containing the EPSPS gene from Argentina infringed claims in a UK patent based on the 090 patent.[40]

In contrast to the Spanish Commercial Court, the High Court of Justice held that Directive 98/44/EC was not applicable to the 090 patent's UK counterpart

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REP'T 109, 110 (2008) (stating that Monsanto has filed suit in the United Kingdom, Denmark, The Netherlands, and Spain).

[29] Monsanto Tech. LLC v. Cargill Int'l. SA, [2007] EWHC (Pat) 2257, [1]–[2] (Eng.) [hereinafter *Cargill I*]; *see also*, Morgan, *supra* note 28, at 110 (stating that Monsanto has filed suit in the United Kingdom, Denmark, The Netherlands, and Spain).

[30] Morgan, *supra* note 28, at 110.

[31] *Cefetra I*, *supra* note 15; *see also*, Morgan, *supra* note 28, at 110.

[32] *See* Morgan, *supra* note 28, at 110.

[33] *Sesostris I*, *supra* note 28, at Primero.

[34] *Id.* at Quinto (dismissing the complaint and awarding fees to Defendant).

[35] *Id.* at Tercero (interpreting various paragraphs and articles of Directive 98/44).

[36] Directive 98/44, *supra* note 8, at 19. Article 9 of Directive 98/44/EC provides that "[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 in [sic] incorporated and in which the genetic information is contained and performs its function." *Id.* Article 5(1) states that "[t]he human body, at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. *Id.* at 18. However, Article 5(2) provides that '[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element." *Id.*

[37] *Sesostris I*, *supra* note 28, at Tercero.

[38] *Id.* In the words of the Spanish Court, "la invención no consiste en la secuencia de ADN, sino en la función que desempeña." *Id.* Translated, the Court stated: "the invention does not consist of the sequence of DNA, but the role."

[39] S. A.P., Mar. 10, 2009 (No. 55/2009) (Spain) (affirming the lower court and dismissing the appeal with costs).

[40] *Cargill I*, *supra* note 29, at [1]–[2].

because the patent application was filed before July 28, 2000.[41] The High Court of Justice also held that there was no infringement of claims to the isolated DNA encoding the EPSPS gene because the gene had been inserted into the plant's chromosomal DNA.[42]

It was the corresponding Dutch litigation, however, that created the present controversy, as discussed in more detail below.

C. And then Came the Dutch

Monsanto sued both Cefetra et al. and Alfred C. Toepfer International GmbH ("ACTI") for patent infringement in the first instance court (Rechtbank) in The Hague.[43] The two cases were joined.[44] Following its established pattern, Monsanto alleged that import from Argentina of soybean meal containing the EPSPS gene infringed claims in a Dutch patent based on the 090 patent.[45]

The Dutch court adopted the reasoning of the UK High Court of Justice and held soybean meal containing the EPSPS gene did not infringe patent claims directed to "isolated" DNA encoding the EPSPS gene.[46] Furthermore, the court held that claims directed to a "method of producing genetically transformed plants which are tolerant toward glyphosate herbicide" were not infringed because the substantial additional steps of crushing, extraction, and treatment to make soybean meal resulted in a product that was not directly obtained from the patented method.[47]

The parties to the Dutch litigation disagreed about the scope and interpretation of Directive 98/44/EC and, in particular, whether Article 9 was applicable.[48] Because a procedural question arose concerning how to interpret Article 9 of Directive 98/44/EC, the court stayed the patent infringement litigation and referred these four questions to the ECJ.[49]

> **Question 1:** Must Article 9 of [Directive 98/44] . . . be interpreted as meaning that the protection provided under that article can be invoked even in a situation such as that in the present proceedings, in which the product (the DNA sequence) forms part of a material imported into the European Union (soy meal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be

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[41] Michael A. Kock, *Purpose-Bound Protection for DNA Sequences: In Through the Back Door?*, 5 J. INTELL. PROP. L. & PRACT. 495, 496 (2010) (discussing that in the UK, the Directive applies only to patents filed on or after July 28, 2000).

[42] *Cargill I*, *supra* note 29, at [77], [88].

[43] *Cefetra I*, *supra* note 15.

[44] *Id.* ¶¶ 1.1–1.3.

[45] *Id.* ¶¶ 2.3, 2.7–2.8, 3.1.4.

[46] *Id.* ¶ 4.4.

[47] *Id.* ¶¶ 2.3, 4.5.

[48] *Id.* ¶¶ 4.16–4.16.2, 4.17–4.17.3.

[49] *Id.* ¶¶ 4.30, 5.

able to perform its function after it has been isolated from that material and inserted into the cell of an organism?[50]

Question 2: Proceeding on the basis that the DNA sequence described in claim 6 of patent no[.] EP 0 546 090 is present in the soy meal imported into the Community by Cefetra and ACTI, and that the DNA is incorporated in the soy meal for the purposes of Article 9 of Directive 98/44 and that it does not perform its function therein: does the protection of a patent on biological material as provided for by Directive 98/44, in particular Article 9, preclude the national patent legislation from offering (in parallel) absolute protection to the product (the DNA) as such, regardless of whether that DNA performs its function, and must the protection as provided under Article 9 of the Directive therefore be deemed to be exhaustive in the situation referred to in that article, in which the product consists of genetic information or contains such information, and the product is incorporated in material which contains the genetic information?[51]

Question 3: Does it make any difference for the purpose of answering the previous question, that the patent was applied for and granted (on 19 June 1996) prior to the adoption of Directive 98/44 and that such absolute product protection was granted under national patent legislation prior to adoption of that directive?[52]

Question 4: Is it possible, in answering the previous questions, to take into consideration the TRIPS Agreement, in particular Articles 27 and 30 thereof?[53]

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[50] Case C-428/08, Monsanto Tech. LLC v. Cefetra BV, 2008 O.J. (C 313) 16, 17, *available at* http://curia.europa.eu/jcms/jcms/j_6/ (search for "C-428/08" in the "Case no." field; then select the hyperlink for "OJ C 313 of 06.12.2008, p.16") (June 12, 2008) (footnote omitted).

[51] *Id.* at 17.

[52] *Id.*

[53] *Id.* *See also* Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, Apr. 15, 1994, 33 I.L.M. 1125, 1869 U.N.T.S. 299 (1994) [hereinafter TRIPS Agreement]. Article 27 of the TRIPS Agreement addressed patentable subject matter and provides:

> (1) Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents 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.
>
> (2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.

D. The ECJ's "Answers"

With regard to Question 1, the ECJ held that under the system established by Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, the protection for a patent relating to a DNA sequence is limited to situations in which the genetic information is currently performing the functions described in the patent.[54] That holds true both as regards the protection of the genetic information as such and as regards the protection of the materials in which that genetic information is contained.[55]

Accordingly, the ECJ interpreted the Directive as effectively incorporating an extraneous functionality element into patent claims to genetic information and products containing that genetic information when infringement of the claims is being determined.[56]

With regard to Question 2, the ECJ held that Directive 98/44/EC precludes national legislation from offering, in relation to biotechnological inventions, patent protection wider than that provided for under that directive.[57] The ECJ-imposed functionality requirement, therefore, applies to patent infringement claims in all Member States.[58]

With regard to Questions 3 and 4, the ECJ held that the patent grant date does not impact the answers to Questions 1 and 2 and that Articles 27 and 30 of the TRIPS Agreement do not affect the aforementioned interpretation.[59]

> (3) Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of human or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination therefore. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

TRIPS Agreement, *supra* at art. 27 (footnote omitted). Article 30 of the TRIPS Agreement places exceptions on the rights conferred and provides:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Id. at art. 30.

[54] *See Cefetra II*, *supra* note 1, ¶ 50.

[55] *Id.* ¶¶ 48–49.

[56] *See id.* ¶ 50 (holding that "Article 9 of the Directive must be interpreted as not conferring patent right protection in circumstances . . . where [the product] does not perform the function for which it was patented, but did perform that function previously . . . or would possibly again be able to perform that function").

[57] *Id.* ¶ 63 (stating that "[Article 9] precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.").

[58] Consolidated Version of the Treaty on the Function of the European Union, arts. 218, 267, 280, Sept. 5, 2008, 2008 O.J. (C 115) 49, 146, 164, 176 (2008).

[59] *Cefetra II*, *supra* note 1, ¶¶ 69, 77.

II. THE ECJ'S POSITION ON THE DIRECTIVE CONFLICTS WITH ITS LEGISLATIVE HISTORY

The ECJ's interpretation of the Directive is inconsistent with the Directive's legislative history. The Directive's drafters were concerned about securing patent protection for biotechnology inventions, including self-replicating living organisms.[60] In particular, the drafters were concerned about patent exhaustion—the effective relinquishment of patent rights after the commercial sale of a single patented product.[61] The Directive provides that a patent right is not exhausted if the patented product is used to multiply the biological material.[62] To that end, the Directive's drafters included Article 8(1) which provides that: "The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics."[63]

On the other hand, Article 9 of the Directive was intended to limit the scope of the patent right to progeny "in which the genetic information is contained and performs its function."[64]

Because patented genetic information may be a regulatory element or some other non-coding sequence rather than a gene, the drafters used the phrase "performs its function" to more broadly encompass gene expression control technology.[65] The drafters likely knew that genetic information introduced into a transgenic organism might be lost during propagation and not be present in subsequent generations.[66] For example, the transgenic organism might be an open-pollinated plant, in which case some progeny would be expected not to contain the claimed genetic information.[67] Article 9 was intended to limit the scope of patent

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[60] Directive 98/44, *supra* note 8, at 13–14; *see also Commission of the European Communities, Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions*, at 3, 29–30, COM (1995) 661 final (Dec. 13, 1995) [hereinafter *European Communities Proposal*] (defining biological material, in part, as "capable of self-reproduction" and explaining the interests of protectable and non-protectable material); *see* Opinion of the Economic and Social Committee on the "Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions," 1996 O.J. (C 295) 11, ¶¶ 1.2–1.3, 2.2, 3.4–3.4.2, 4.5.1 (describing that one of the primary concerns behind the proposed legislation was the drastic rise in U.S. biotechnological patents, and its negative effect on the European biotechnological industry).

[61] Directive 98/44, *supra* note 8, at 19; *see also European Communities Proposal*, *supra* note 60, at 19, 32 (adding and redrafting provisions related to compulsory and implied licenses available for farmers).

[62] Directive 98/44, *supra* note 8, at 16–17.

[63] *Id.* at 19.

[64] *Id.*

[65] Kock, *supra* note 41, at 499–500.

[66] *Id.*; *see also European Communities Proposal*, *supra* note 60, at 19 (noting that patent protection would apply to "biological material derived . . . through multiplication or propagation in an identical or different form").

[67] *See* Hae-Woon Choi, Xiao-Hong Yu, Peggy G Lemaux & Myeong-Je Cho, *Stability and Inheritance of Endosperm-Specific Expression of Two Transgenes in Progeny from Crossing Independently Transformed Barley Plants*, 28 PLANT CELL REPROD. 1265, 1266 (2009).

protection to subsequent generations that contain the introduced genetic information.

III. THE QUESTION SHOULD BE "IS IT THERE?" NOT, "DOES IT WORK?"

The ECJ's interpretation of Article 9 in the context of the Monsanto litigation is contrary to the intent of the Directive. In the context of patent infringement, 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.

Now, however, enforcing patent rights for biotechnology inventions involving nucleic acids may prove futile if the patentee shoulders the burden of presenting evidence that the particular DNA, gene, or polynucleotide is "functioning" in the accused product. But many genes are only expressed for a limited time period or in specific tissues in a living organism.[68] The commercial product produced by the transgenic organism may contain the helpful and desired trait conferred by the transgene, such as herbicide resistance, but that gene may not be expressed at the time of the alleged infringing act.

Under the ECJ's interpretation of the Directive, a patent claiming a potato plant transformed with a novel gene that provides resistance to the devastating late blight fungus may be granted and valid, but may not be infringed by importing the claimed potato into Europe.[69] Although the potato that is shipped into Europe contains the patented resistance gene, it is not performing the function described in the patent when the tuber reaches a European port because the potato plant was not planted or growing.[70] It is exceedingly unlikely that the Directive's drafters intended this counter-intuitive result.

IV. VIOLATING TRIPS?

Article 27 of the TRIPS Agreement provides in relevant part that "patent rights shall be available and patent rights enjoyable without discrimination . . . to the field of technology and whether products are imported or locally produced."[71] Yet, as described above, the ECJ's interpretation of Directive 98/44/EC may weaken patent enforcement for many biotechnology inventions. Most genes do not perform their

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[68] Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 420 (2002) (noting that genes may differ as to their functions both over time and with respect to different sites).

[69] *See, e.g.*, *Cefetra II*, *supra* note 1, ¶¶ 36–38 (holding that Article 9 protection "is not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived").

[70] *Id.* ¶ 40 ("allow[ing] protection under Article 9 of the Directive on the ground that the genetic information performed its function previously in the material containing it or that it could possibly perform that function again in another material would amount to depriving the provision interpreted of its effectiveness, since one or other of those situations could, in principle, always be relied on").

[71] TRIPS Agreement, *supra* note 53, at art. 27.

function all the time and in all tissues.[72] Furthermore, many genes have many "functions."[73] Thus, denying infringement of a valid claim because a particular activity is not functional at the time of the alleged infringing act significantly undermines the ability of biotechnology companies to enjoy and enforce patent rights. In this regard, therefore, the ECJ's ruling undermines patent enforcement for a field of technology, biotechnology, in contravention to Article 27 of TRIPS.[74] Furthermore, the types of patent claims made difficult to enforce by the ruling, are not included among the inventions that member states may legitimately exclude from patenting according to Articles 27 and 30 of TRIPS.[75]

V. WHAT TO DO?

Biotechnology companies should immediately undertake a careful review of their options and intellectual property protection strategies.

Plant biotechnology companies should give careful attention to obtaining Plant Breeder's Rights protection pursuant to the International Convention for the Protection of New Varieties of Plants ("UPOV").[76] Some countries have adopted UPOV provisions which extend the plant breeder's rights to harvested material and products made from harvested material. Article 14.2 of the 1991 UPOV Convention extends the plant breeder's rights to harvested material obtained from the protected variety;[77] and Article 14.3 extends the rights to "products made directly from harvested material of the protected variety . . . unless the breeder has had a reasonable opportunity to exercise his right in relation to the said harvested material."[78] Soybeans and soybean meal would fall within the protection provided by Articles 14.2 and 14.3, respectively.[79]

Biotechnology companies also should review utility patent claim strategies. The ECJ's judgment increases the importance of claims directed to methods of making a product. For example, a method of making soybean meal comprising the steps of harvesting seed from a glyphosate-tolerant plant transformed with the EPSPS gene, extracting oil from said seed, and recovering the soybean meal would have been very useful in Monsanto's effort to prevent import of soybean meal made from seed

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[72] *See* Demaine, *supra* note 68, at 327 n.112, 420 n.516.

[73] *See id.*; Letter from Wylie Burke et al., Nat'l Advisory Council for Human Genome Research, Nat'l Insts. of Health, to the Comm'r of the U.S. Patent and Trademark Office (Mar. 21, 2000), http://www.uspto.gov/web/offices/com/sol/comments/utilguide/nih.pdf.

[74] *Compare* TRIPS Agreement, *supra* note 53, at arts. 27, 30 (allowing members to deny patent eligibility for "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes"), *with Cefetra II*, *supra* note 1, ¶ 76 (stating that the implementation of a functionality requirement for infringement actions did not unreasonably prejudice patents, which is the requirement under Article 30 of the TRIPS Agreement).

[75] *See supra* note 53, and accompanying text.

[76] *See generally* International Convention for the Protection of New Varieties of Plants, Act of 1991, ch. V, Mar. 19, 1991, 66 U.S.T. 2703, T.I.A.S. 10199 [hereinafter UPOV] (discussing the rights of plant breeders).

[77] *Id.* at art. 14(2).

[78] *Id.* at art. 14(3).

[79] *Id.* at art. 1(vi).

produced by glyphosate tolerant plants in Argentina. Furthermore, special attention should be given to how the function(s) of any claimed polynucleotides are described in a patent application to increase the likelihood of enforcement.

The ECJ's ruling increases the importance of claims directed to a product that recites the product's unique characteristics and traits without reference to the genetic material that confers those characteristics.[80] A conventional transgenic product claim might recite a tomato fruit transformed with a gene X which confers trait Y.[81] If gene X is not expressed in the fruit, import of the fruit into an EU member state would not constitute an infringing act according to the ECJ.[82] If a claim to a tomato fruit comprising trait Y is patentable, import of tomato fruit comprising trait Y would constitute an infringing act, even if the gene which controls the trait is not expressed in the fruit.

The enforceability of patent claims directed to isolated nucleotides used as reagents, such as reagents in diagnostic methods, are also put at significant risk by the ECJ's opinion. These nucleotides do not perform their function in a reagent vial or kit.[83] Thus, patent claims directed to this subject matter may not be enforceable in view of the ECJ's judgment.[84] Method claims such as claims to use of a nucleotide in a diagnostic method, have increased importance in view of the opinion.

The U.S. biotechnology industry may want to urge the U.S. government to take action at the WTO because the Directive, as interpreted by the ECJ, now makes it very difficult to effectively enforce patent claims for biotechnology inventions in the EU. In fact, this interpretation seems to undermine the intent of the Directive's drafters and violates Article 27 and/or 30 of the TRIPS Agreement.

Before *Cefetra*, a patentee could legitimately assert that the accused product contained his patented nucleic acid, and therefore making or selling the product, or importing it into a country with patent protection, constituted infringing activities.[85] Now, however, that patentee has to prove the nucleic acid is functioning, or is capable of functioning, in that infringing product. Not only will this drive up litigation costs, and burden the plaintiff's case, but the weakening of enforcement rights could encourage others to continue their infringing activities in Europe without fear of serious consequences. After *Cefetra*, therefore, proving the functionality of DNA in the accused product must become a paramount concern of all patentees.

Science and the evolution of complex and sophisticated insights into molecular mechanisms of DNA, the genome, diagnostics, and crop development direct the commercialization of many areas, but none so more importantly than in the Biotech,

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[80] *See* EP 0 546 090.

[81] *See, e.g.*, U.S. Patent No. 5,538,880 at col. 23 ll. 12–19 (filed May 26, 1994) (claiming "[a] process for producing a fertile transgenic *Zea mays* plant comprising the steps of (i) bombarding intact regenerable *Zea mays* cells with DNA-coated microprojectiles, (ii) identifying or selecting a population of transformed cells, and (iii) regenerating a fertile transgenic plant therefrom, wherein said DNA is transmitted through a complete sexual cycle of said transgenic plant to its progeny, wherein the DNA imparts insect resistance thereto").

[82] *Cefetra II*, *supra* note 1, ¶ 50 (finding no infringement where the patented genetic material was not performing its function within a processed product).

[83] *See, e.g.*, Adomas, *supra* note 5 (preparing microarrays of complimentary DNA for the targeted sequences which remain wholly inactive until test samples are applied to the arrays).

[84] *See Cefetra II*, *supra* note 1, ¶ 50.

[85] *See id.* ¶¶ 17, 19, 21.

Medicine, and Agricultural Industries. Government-induced incentives and protections for bringing important inventions into these critical industries in Europe could now be jeopardized.