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Europe's Biotech Patent Landscape: Conditions and Recent Developments

Tade Matthias Spranger*

INTRODUCTION**

After ten years of discussions and disputes,¹ on July 30, 1998 the European Community's ("EC") "Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions"² ("Directive") came into effect. Until then, ethical considerations had protracted the enactment of the Directive as a legal framework for biotech patents. Critics from among the European Parliament ("EP") referred to the "non-patentability of nature," especially with regard to patents on human DNA and gene sequences.³ As a result, in 1995 the EP rejected the Commission's⁴ first draft of the Directive from 1988.⁵ Fearing

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** All translations by the author.

1. See N. R. Scott-Ram & A. G. Sheard, *The Rise and Fall of the EU Patent Directive*, 13 *BIO/TECHNOLOGY* 734, 734 (1995).

2. 1998 O.J. (L 213) 13 [hereinafter Directive]. The first portion of the Directive contains a list of recitals. The recitals are not legally binding, but clarify the intent of the drafters and provide guidance in interpreting the provisions of the Directive itself.

3. 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, 12.

4. The Commission of the EC is made of twenty "Commissioners." The Commission nearly always initiates the legislative process in the EC by submitting a proposal. In addition, the Commission has executive powers in various fields and has the power to initiate infringement suits against a Member State that fails to meet its obligations under EC law.

that the United States would consolidate its lead in the biotechnological field, the Commission submitted a second draft to the EP and the Council⁶ just a few months later. The second draft then served as the basis for the Directive's final wording. The Directive is expected to guarantee legal uniformity and certainty in providing patent protection for biotechnological inventions.

According to Art. 15 paragraph 1 of the Directive, Member States shall bring into force the laws, regulations, and administrative provisions necessary to comply with the Directive no later than July 30, 2000.⁷ Shortly after the Directive's enactment, several Member States sought its annulment.⁸ After the Advocate General gave his opinion in favor of the Directive's legal validity on June 14, 2001,⁹ the Court of Justice of the European Communities declared the Directive legal on October 9, 2001.¹⁰ However, many Member States have still failed to discharge their obligations. Only Ireland¹¹ and Denmark¹² have transformed the Directive into national law, while other Member States are attempting to do so.

In view of legal uncertainty in the field of patents on biotechnological inventions, the rejection of the Dutch request is an important step toward an adequate protection of intellectual property in the EC. However, the Advocate

5. 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, 12.

6. The Council is the EC's institution with the greatest legislative power. It consists of representatives of the Member States drawn from the governments of those states.

7. Directive, *supra* note 2 art. 5, ¶ 1, at 18.

8. See Case C-377/98, Kingdom of the Netherlands v. European Parliament and Council of the European Union, Op. Advoc. Gen. ¶ 1 (2001), available at http://europa.eu.int/eur-lex/en/recent/index_2001.html [hereinafter Op. Advoc. Gen.].

9. See *id.*

10. See Case C-377/98, Kingdom of the Netherlands v. European Parliament and Council of the European Union (2001), available at <http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&docquire=alldocs&numaff=C377%2F98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>.

11. See European Communities (Legal Protection of Biotechnological Inventions) Regulations, 2000 (Ir.).

12. Lov nr. 412 af 31 maj 2000 [Law No. 412 of 31 May 2000]; Bekendtgørelse om ændring af bekendtgørelse om patenter og supplerende beskyttelsescertifikater. Ref: Bekendtgørelse nr. 1086 af 11/2000 (Den.).

General's final observations concerning the relationship between ethical aspects and patent law are insufficient. Regardless of the ratio of socio-economic aspects, vague ethical considerations have deleterious effects on patent law's neutrality. In addition, the EC's efforts to increase the role of ethics in biotechnology law¹³ conflict with WTO law, which aims to restrict the influence of socio-economic considerations in trade-related decisions.

I. THE APPEAL TO THE COURT OF JUSTICE

At the end of 1998, the Netherlands' Lower House of Parliament rejected a proposal to adopt the Directive into Dutch law, arguing that the Directive's content violates a number of fundamental rights.¹⁴ Eventually, the Dutch government took its complaint to the European Court of Justice seeking the Directive's rescission.¹⁵ In particular, it brought an action under Art. 173 of the EC Treaty (after amendment, Art. 230 EC) seeking annulment of the Directive.¹⁶ Italy and Norway, a non-Member State of the EC, supported the Dutch action.¹⁷

The Court of Justice dismissed the Dutch application for interim measures on July 25, 2000.¹⁸ In his subsequent advisory opinion, Advocate General Jacobs also rejected the

13. See Tade Matthias Spranger, *What is Wrong About Human Reproductive Cloning? A Legal Perspective*, 11 EUBIOS J. OF ASIAN AND INT'L BIOETHICS, 101, 101-2 (2001); Tade Matthias Spranger, *The Ethics and Deliberate Release of GMOs*, 11 EUBIOS J. OF ASIAN AND INT'L BIOETHICS, 144, 144-46 (2001).

14. See ALFRED MÜLLER, ET AL., ERNST & YOUNG'S EUROPEAN LIFE SCIENCES 99, SIXTH ANNUAL REPORT, COMMUNICATING VALUE 65 (Mike Ward ed. 1999); see also Geertrui van Overwalle, *Octrooien vor planten onder de EG-Biotechnologierichtlijn van 6 juli 1998 [Patents for Plants Under the EC Biotechnology Directive of 6 July 1998]*, 7 AGRARISCH RECHT 111, 124 (1999).

15. See Op. Advoc. Gen., *supra* note 8, ¶ 15.

16. See *id.* ¶ 1.

17. See *id.* ¶ 13. France refused to implement the Directive on ethical grounds as well. See Sabine Louët, *French Refuse to Implement Biotech Patent Directive*, 18 NAT. BIOTECH. 820, 820 (2000). The United Kingdom is reported to believe that no amendment to the UK Patents Act is needed. See Robin Nott, *Text of the EC Directive on Biotechnology, with introduction and comment*, 2 BIO-SCIENCE L. REV. 113, 119 (1998). The German government's draft of an Act on the implementation of the Directive is a word-for-word transmission of the Directive's provisions and, therefore, similarly fails to put the framework of European Law into concrete terms.

18. See Op. Advoc. Gen., *supra* note 8, ¶ 15.

material request on June 14, 2001.¹⁹ Although the Court is not bound by the Advocate General's opinion, it traditionally serves as a guideline for the Court's deliberations. Often, the Court reaches the Advocate General's conclusion for the same reasons.²⁰ If the Court does not follow the opinion of the Advocate General, it presents legal arguments supporting its opposing position in much the same way as dissenting judges in other judicial systems.²¹ On October 9, 2001, the Court followed the Advocate General's lead and dismissed the action,²² holding that the Directive complies with EC law. The Advocate General's opinion provides a well-balanced analysis of the legal aspects of the case.²³

The Advocate General rejected the grounds for annulment cited by the Dutch:

The grounds invoked for the annulment of the Directive were that it (i) is incorrectly based on Art. 100a of the Treaty; (ii) is contrary to the principle of subsidiarity; (iii) infringes the principle of legal certainty; (iv) is incompatible with international obligations; (v) breaches fundamental rights; and (vi) was not properly adopted since the definitive version of the proposal submitted to the Parliament and the Council was not decided on by the college of Commissioners.²⁴

Although all the grounds advanced by the Dutch were rejected, the action may not have been fruitless, as it may have demonstrated that the concerns submitted by the Dutch Government can and should be allayed. As the Advocate General stressed in his opinion, within the Directive's

19. *See id.*

20. *See* GEORGE A. BERMAN ET AL., EUROPEAN COMMUNITY LAW 72 (1993).

21. *See* HENRY G. SCHERMERS & DENIS F. WAELEBROECK, JUDICIAL PROTECTION IN THE EUROPEAN COMMUNITIES § 783 (5th ed. 1992).

22. *See* Case C-377/98, Kingdom of the Netherlands v. European Parliament and Council of the European Union (2001), available at <http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&docquire=alldocs&numaff=C377%2F98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100>. *See generally* Tade Matthias Spranger, *Urteilsanmerkung [Case Note on Case C-377/98, Kingdom of the Netherlands v. European Parliament and Council of the European Union, Judgment of 9 October 2001]*, 50 GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT INTERNATIONALER TEIL 1047 (2001).

23. *See* Schermers & Waelbroeck, *supra* note 21, § 782.

24. *Op. Advoc. Gen.*, *supra* note 8, ¶ 11.

framework "there are adequate moral safeguards going, in some respects, beyond mere application of the existing criteria for patentability."²⁵ Furthermore, he stated that "the fact that the ethical criteria for patentability is not exhaustively defined . . . enhances it since future developments will continue to be governed by those criteria even if not currently foreseeable."²⁶

II. THE DIRECTIVE'S MAIN OBJECTIVES

Following longstanding unemployment in Europe, the European Community ("EC") realized the importance of protecting biotechnology intellectual property rights for its economic development, due to biotechnology's potential for creating jobs. Understanding that national differences in the legal protection of biotechnological inventions could "create barriers to trade and hence impede the proper functioning of the internal market,"²⁷ the EC created a legal framework on its own. Within this framework, the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions. The EC's legal standards are limited to establishing certain principles for applying national laws to the patentability of biological material as such.

A. PATENTS ON HUMAN DNA AND GENE SEQUENCES

The most important part of the Directive ensures the patentability of human DNA or gene sequences, which is also guaranteed by World Trade Organization ("WTO") law. For example, Art. 27 paragraph 1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") demands that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they meet the general requirements of novelty, inventive step, and capability of industrial application."²⁸

25. *Id.* ¶ 227.

26. *Id.*

27. Directive, *supra* note 2, recital 5, at 13.

28. Agreement on Trade-related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 27, ¶ 1, Marrakesh Agreement Establishing the World Trade Organization, 319, 331 [hereinafter TRIPS]. See generally Hans-Jürgen Schulze-Steinen, *Patents*, in INTELLECTUAL PROPERTY & INTERNATIONAL TRADE 47, 48 (International Chamber of Commerce 1996).

Before the Directive's promulgation, the EC and some of its Member States neglected their obligation to enforce this standard.²⁹ The European Patent Convention of 1973, an intergovernmental instrument that led to the establishment of the European Patent Office ("EPO"), had been unable to fill this gap, failing to provide clear standards for patents on biotechnological inventions.³⁰ Now, the Directive explicitly points out the need to assimilate the EC's intellectual property rights regarding biotechnological inventions to TRIPS' requirements.³¹

Article 3 paragraph 1 of the Directive states that inventions "shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used."³² According to paragraph 2, "biological material, which is isolated from its natural environment or produced by means of a technical process, may be the subject of an invention even if it previously occurred in nature."³³ The antagonists of biotechnology patents consider Art. 3 illegal, as it allows the granting of "patents on life."³⁴ This assessment violates basic principles of patent law.

First, patent law does not aim at the protection of living organisms *in situ*, that is, as found in nature. Rather, "an element isolated from a substance occurring in nature or otherwise produced" is patentable since it is "the result of technical processes used to identify, purify and classify it and

29. See generally S. J. R. BOSTYN, ENABLING BIOTECHNOLOGICAL INVENTIONS IN EUROPE AND THE UNITED STATES (2001) (giving an overview of European and U.S. patent law).

30. See H.-R. JAENICHEN, THE EUROPEAN PATENT OFFICE'S CASE LAW ON THE PATENTABILITY OF BIOTECHNOLOGY INVENTIONS vii (2nd ed. 1997). See generally K. GOLDBACH ET AL., PROTECTION OF BIOTECHNOLOGICAL MATTER UNDER EUROPEAN AND GERMAN LAW (1997).

31. See Directive, *supra* note 2, recital 12, at 14, recital 36, at 16.

32. *Id.* art. 3, ¶ 1, at 18.

33. *Id.* art. 3, ¶ 2, at 18.

34. Den Leskien, *Genetechnologie und Patentrecht* [Genetic Engineering and Patent Law], 7 ZEITSCHRIFT FÜR UMWELTRECHT 299, 301 (1996). See generally Rainer Moufang, *Problems Related to the Protection of New Technologies: Biotechnological Inventions*, in EUROPEAN RESEARCH STRUCTURES – CHANGES AND CHALLENGES: THE ROLE AND FUNCTION OF INTELLECTUAL PROPERTY RIGHTS 178 (Max-Planck-Gesellschaft ed., 1994); Baljit Dhadda, *Patenting Human Genetic Information. Is Nothing Sacred?*, in PERSPECTIVES ON INTELLECTUAL PROPERTY: INTELLECTUAL PROPERTY AND ETHICS 89 (Lionel Bently & Spyros Maniatis eds., 1998).

reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.”³⁵

Second, the slogan “patents on life” creates the impression that patents confer property rights. However, a patent for an invention does not even authorize the holder to use the invention; it merely entitles him to prohibit third parties from exploring it for industrial and commercial purposes.³⁶ In addition, even if the argument that genes should not be “owned” because they exist in nature were well founded, it is really a philosophical argument that cannot easily fit into the grounds available for refusing a patent.³⁷

Third, “patents on life” have been granted for the last 160 years.³⁸ In *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, the U.S. Supreme Court upheld a patent granted to Chakrabarty, a microbiologist for General Electric Company, for oil-eating bacteria.³⁹ Contrary to popular belief, that was not the first patent to be granted for living matter.⁴⁰ Finland has been granting patent protection for living organisms since July 24, 1843.⁴¹ In addition, in 1873 Louis Pasteur was granted U.S. Patent No. 141,072, containing a claim to “yeast, free from organic germs of disease, as an article of manufacture.”⁴² Therefore, Art. 3 of the Directive is far less revolutionary than its opponents argue.

Regarding patents on parts of the human body, Art. 5 of the Directive clarifies the general principles described in Art. 3. Article 5 paragraphs 1 and 2 repeat the differentiation between

35. Directive, *supra* note 2, recital 21, at 15 (concerning patents on substances deriving from the human body).

36. See *id.* recital 14.

37. See R. Stephen Crespi, *Patents On Genes: Clarifying the Issues*, 18 NAT. BIOTECH. 683, 683 (2000).

38. See Tade Matthias Spranger, *Ethical Aspects of Patenting Human Genotypes According to EC Biotechnology Directive*, 31 INT'L REV. INDUS. PROP. COPYRIGHT L. 373, 376 (2000).

39. See *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty*, 447 U.S. 303, 303 (1980); see also 1 IVER P. COOPER, 1 BIOTECHNOLOGY AND THE LAW § 2.08 (2001 Revision); I. Jane Churchill, *Patenting Humanity: The Development of Property Rights in the Human Body and the Subsequent Evolution of Patentability of Living Things*, 8 INTELL. PROP. J. 249, 270-72 (1994).

40. See PHILIP W. GRUBB, *PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY* 258 (3rd ed. 1999).

41. See Spranger, *supra* note 38, at 376.

42. COOPER, *supra* note 39, § 2.02.

patentable inventions and non-patentable discoveries.⁴³ According to these provisions, neither the “human body, at the various stages of its formation and development, [nor] the simple discovery of one of its elements, including the sequence or partial sequence of a gene, . . . constitute patentable inventions.”⁴⁴ On the other hand, “an 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.”⁴⁵

Article 5 of the Directive raises the question of the patentability of ESTs, or Expressed Sequence Tags. ESTs circumscribe partial sequences of a clone that is picked at random from a cDNA⁴⁶ library and used in the identification of probably yet unknown genes found in a particular tissue.⁴⁷ According to some scholars’ assessments, ESTs do not constitute a patentable invention, but rather a mere discovery, since their extraction is automated.⁴⁸ However, the ESTs’ preparation is based on a technical procedure that does not occur in nature and for that reason may constitute an invention.⁴⁹

The crucial point is that Art. 5 paragraph 3 of the Directive demands that the “industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application” as filed.⁵⁰ Hence, the required industrial

43. See Directive, *supra* note 2, art. 5, ¶¶ 1-2, at 18.

44. *Id.* art. 5, ¶ 1, at 18.

45. *Id.* art. 5, ¶ 2, at 18.

46. cDNA stands for complementary DNA, which is synthesized from a messenger RNA (mRNA) template by reverse transcription. The single-stranded form is often used as a probe in physical mapping.

47. See Martin Grund & Volker Vossius, *Patentability of ESTs Under the EPC*, 2 *BIO-SCIENCE L. REV.* 106, 106 (1998).

48. See Andreas Oser, *Patentierung von (Teil-) Gensequenzen unter besonderer Berücksichtigung der EST-Problematik* [Patents on Partial Gene Sequences with Special Emphasis on ESTs], 47 *GEWERBLICHER RECHTSSCHUTZ UND URHEBERRECHT INTERNATIONALER TEIL* 648, 650 (1998); see also Christian Gugerell, *The European Experience*, in *LE GENIE GÉNÉTIQUE* [THE GENETIC GENIUS], *BIOTECHNOLOGY AND PATENT LAW* 87, 100-1 (Francois Dessemontet ed., 1996).

49. See Matthias Herdegen & Tade Matthias Spranger, *EC-Law/Comment, Directive 98/44/EC*, in *INTERNATIONALE PRAXIS GENTECHNIKRECHT* 1, 23 (Matthias Herdegen ed., 2001).

50. Directive, *supra* note 2, art. 5, ¶ 3, at 18.

application must be concrete.⁵¹ For that reason, ESTs without a specific function are not patentable under EC law.⁵² In addition, the concrete function requirement should also be the guiding principle for patents on so-called SNPs, or Single Nuclear Polymorphisms, which are single-base differences in a DNA sequence among individuals.⁵³

The Directive's Art. 6 establishes different criteria for the patentability of inventions that refer to the human body. Article 6 paragraph 1 refers to *ordre public* and morality as internationally accepted limits to patentability.⁵⁴ In addition, paragraph 2 provides a list of inventions that are excluded from patentability in order to provide national courts and patent offices with a general guide for interpreting the reference to *ordre public* and morality.⁵⁵ According to this provision, "processes for cloning human beings,"⁵⁶ "processes for modifying the germ line genetic identity of human beings,"⁵⁷ and "uses of human embryos for industrial or commercial purposes"⁵⁸ shall be considered unpatentable. It is important to stress that these restrictions have no effect on the patentability of stem cell procedures as stem cells can neither be considered clones nor present embryos for the purposes of Art. 6 paragraph 2(c).⁵⁹

51. See Herdegen & Spranger, *supra* note 49, at 23; see also Matthias Herdegen, *Patenting Human Genes and Other Parts of the Human Body Under EC Biotechnology Directive*, 3 BIO-SCIENCE L. REV. 102, 104 (2000/2001).

52. See Herdegen & Spranger, *supra* note 49, at 23.

53. See *id.*

54. See Directive, *supra* note 2, art. 6, ¶ 1, at 18.

55. See *id.* art. 6, ¶ 2, at 18; see also Clair Baldock & Oliver Kingsbury, *Where Did It Come from and Where Is It Going? The Biotechnology Directive and Its Relation to the EPC*, 19 BIOTECHNOLOGY L. REP. 7, 14 (2000).

56. Directive, *supra* note 2, art. 6, ¶ 2(a), at 18. Note that the Directive's Art. 6 paragraph 2(a) discusses only the prohibition on techniques designed for human reproductive cloning.

57. *Id.* art. 6, ¶ 2(b), at 18.

58. *Id.* art. 6, ¶ 2(c), at 18.

59. See Tade Matthias Spranger, *Patentability of Human Stem Cell Procedures in Accordance with EC Law*, 11 EUR. INTEL. PROP. REV. (forthcoming 2002) (manuscript at 8, on file with author). The scope of Art. 6 paragraph 2(c) is restricted to embryos which are capable of living in their natural environment, i.e., *in vivo*. The Directive explicitly contemplates "inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it." Directive, *supra* note 2, recital 42, at 16.

B. ETHICAL CONSIDERATIONS

Examining the ethical considerations of the granting of patents is a very difficult task. Until now, international patent law was free of ethical considerations. Although limitations for patentability result from *ordre public* and morality, these terms are used as strictly judicial conceptions.⁶⁰ Both concepts have a long and distinguished history as criteria for the lawfulness of the grant or exercise of intellectual property rights.⁶¹ For example, both the TRIPS Agreement⁶² and the European Patent Convention,⁶³ neither of which are a part of EC law but rather intergovernmental or international agreements, contain a reserve with regard to a patent's incompatibility with *ordre public* or morality. Nevertheless, the Directive's provisions create a new level of interaction between ethics and the law.

First, the Directive's Art. 7 states that "the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology."⁶⁴ This group may be consulted when biotechnology (including patents on biotechnological inventions) are to be evaluated at the level of basic ethical principles.⁶⁵ Notably, German and French scholars are demanding a strengthening of patent law's ethical provisions.⁶⁶ This call for additional ethical consideration seems to be superfluous as the Directive already contains a clause applying standards of ethics. According to Recital 39, "*ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State."⁶⁷ Such ethical or moral principles shall, regardless of the technical field of the invention, supplement the standard legal examinations under

60. See Spranger, *supra* note 38, at 377-80.

61. See Op. Advoc. Gen., *supra* note 8, ¶ 38.

62. See TRIPS, *supra* note 28, art. 27, at 331.

63. See Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, art. 53, § a.

64. Directive, *supra* note 2, art. 7, at 19.

65. See *id.* recital 44, at 16.

66. See Claus Luttermann, *Patentschutz für Biotechnologie* [Patent Protection for Biotechnology], 44 RECHT DER INTERNATIONALEN WIRTSCHAFT 916, 920 (1998); see also Andreas Fuchs, *Patentrecht und Humangenetik* [Patent Law and Human Genetics] 54 JURISTENZEITUNG 597, 598 (1999); DICTIONNAIRE PERMANENT BIOÉTHIQUE ET BIOTECHNOLOGIES, BULLETIN 66 [PERMANENT DICTIONARY ON BIOETHICS AND BIOTECHNOLOGY, BULLETIN 66] 8381, 8383 (1998).

67. Directive, *supra* note 2, recital 39, at 16.

patent law.⁶⁸ This hidden rule leads to serious consequences, which have gone almost unnoticed thus far: “ethical or moral principles” are put in the same category as the legal terms *ordre public* and morality. As a result, barriers between law and ethics are abolished. Recital 39 is more than a mere stylistic inaccuracy. Rather, the provision explicitly demands an ethical supplement to the standard legal examinations under patent law.

This regulation, notwithstanding the question of its compatibility with WTO law, blurs the barriers between law and ethics and is detrimental to patent law in that the influence of ethics often results in decisions in which the ethical perspective is not clearly distinguished from the legal assessment.⁶⁹ In contrast to ethics’ objective of philosophical reflection, the law’s intention is a practical one. The law does not “proclaim values that it cannot, within reason, also put into practice.”⁷⁰ Even if the rule of law rests on moral principles,⁷¹ law has to be readily ascertainable, distinct, and firm. Ethics, in contrast, does not meet these requirements.

C. FARMER’S PRIVILEGE

Another important question concerns the so-called farmer’s privilege.⁷² Article 11 of the Directive states:

the sale or other form of commercialization of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use, implies authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No. 2100/94.⁷³

68. *See id.*

69. *See* Paolo Zatti, *Towards a Law for Bioethics*, in A LEGAL FRAMEWORK FOR BIOETHICS 53, 59 (Cosimo Marco Mazzoni ed., 1998).

70. *Id.* at 60.

71. *See* Zeynep Davran, *The Ethical Foundations of the Rule of Law*, in ETHICS OF THE PROFESSIONS: MEDICINE, BUSINESS, MEDIA, LAW 117 (Ioanna Kuçuradi ed., 1999).

72. *See* Herdegen & Spranger, *supra* note 49, at 32-33. *See generally* Tade Matthias Spranger, *Landwirteprivileg bei Patentierung biotechnologischer Erfindungen nach der EG-Biotechnologierichtlinie [Farmers Privilege and Patents on Biotechnological Inventions Under EC Biotechnology Directive]* 29 AGRARRECHT 240 (1999).

73. Directive, *supra* note 2, art. 11, ¶ 1, at 19.

Article 11 paragraph 2 extends the privilege to animal reproductive material, stating:

the sale or any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not the sale within the framework or for the purpose of a commercial reproduction activity.⁷⁴

Article 11 turns out to be problematic for two reasons. First, paragraph 2 of Art. 11 corresponds with Art. 34 of TRIPS, which states:

For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

- (a) if the product obtained by the patented process is new;
- (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.⁷⁵

As a result, TRIPS Art. 34 imposes a reversal of the burden of proof to the detriment of the farmer. The farmer has to prove that he did not violate the rights of the holder of the patent. Is this the correct approach? Taking into account the possibility of self-sowing, the farmer's difficulty in proving his innocence is obvious. Although the Directive is indispensable for the justified protection of entrepreneurial interests, the reference to TRIPS Art. 34 turns out to be misguided.

The second problem refers to the extension of the farmer's privilege with regard to animals. Since the "sale within the framework or for the purpose of a commercial reproduction

74. *Id.* art. 11, ¶ 2, at 19.

75. TRIPS, *supra* note 28, art. 34, at 334.

activity”⁷⁶ is excluded from the farmer’s privilege, it is difficult to draw a bright line. What happens if the farmer has to sell a part of his livestock due to financial problems? Is this a sale within the framework or for the purpose of a commercial reproduction activity? In this regard, the wording of the Directive is absolutely insufficient.

D. COMPULSORY CROSS-LICENSING

In order to avoid a conflict between the holders of plant variety rights and patents, the Directive provides for compulsory cross-licensing of patent and plant variety rights.⁷⁷ Article 12 paragraph 1 states,

where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.⁷⁸

Where such a license is granted, “Member States shall provide that . . . the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.”⁷⁹ Conversely, Art. 12 paragraph 2 ensures that the holder of a patent may apply for a compulsory license for use of a protected plant variety, and the holder of the variety right will be entitled to a cross-license.⁸⁰ By this, the Directive acknowledges the fact that guaranteed access must be granted where the invention represents significant technical progress of considerable economic interest.⁸¹

The conditions for cross-licenses mandated by Art. 12 paragraph 3 have been the object of much criticism. To comply with this provision, applicants for cross-licenses must demonstrate that “they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence”⁸² and that “the plant variety or the

76. Directive, *supra* note 2, art. 11, ¶ 2, at 19.

77. See Baldock & Kingsbury, *supra* note 55, at 16.

78. Directive, *supra* note 2, art. 12, ¶ 1, at 19.

79. *Id.*

80. See *id.* art. 12, ¶ 2, at 19.

81. See *id.* recital 53, at 17.

82. *Id.* art. 12, ¶ 3(a), at 20.

invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.”⁸³ According to some scholars’ assessments, the absence of a definition of what “unsuccessfully” means violates the general principle of legal clarity:⁸⁴ does unsuccessfully mean that the applicant has been refused a license altogether or that the two parties simply could not agree on the contractual terms?⁸⁵ Arguably, the meaning of “unsuccessfully” cannot be generally defined, since its application is inevitably case specific. However, the assertion that the meaning of “unsuccessfully” is undetermined is not convincing, as TRIPS Art. 31(b) has already established an applicable definition. TRIPS Art. 31(b) concerns the use a patent without the authorization of the patent holder.⁸⁶ It states that

such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.⁸⁷

Although TRIPS Art. 31(b) does not explicitly define “unsuccessful,” it makes it clear that unsuccessful efforts are a central tenant of international patent law.

Article 12 paragraph 3(b) is also unclear as to what constitutes a significant technical progress of “considerable economic interest.” Obviously, an individual’s interest cannot constitute a considerable economic interest within the meaning of Art. 12. Requiring such a determination would thwart the purpose of patent law. Most scholars assume that it is the public’s economic interest, rather than that of an individual person or company, that would have to be evaluated.⁸⁸ However, the so-called “public’s economic interest” renders it even more difficult to implement Art. 12 paragraph 3(b): public interests are too varied and divergent to provide a legal

83. *Id.* art. 12, ¶ 3(b), at 20.

84. See generally Matthias Herdegen, *The Origins and Development of the General Principles of Community Law*, in GENERAL PRINCIPLES OF EUROPEAN COMMUNITY LAW 1 (U. Bernitz & J. Nergelius eds., 2000).

85. See J. Ardley, *Compulsory Cross-Licensing: An Examination of Article 12 of the Biotechnology Directive*, 2 BIO-SCIENCE L. REV. 135, 36 (1998/1999); see also Baldock & Kingsbury, *supra* note 55, at 16.

86. See TRIPS, *supra* note 28, art. 31(b), at 333.

87. *Id.*

88. See Ardley, *supra* note 85, at 136.

standard in any particular case. Instead, the “considerable economic interest” for the purposes of Art. 12 paragraph 3(b) should be assumed if the compulsory license would have a stimulating effect on a specific branch of industry.⁸⁹

CONCLUSION

The legal framework of the “Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions” seems to be defective and full of loopholes. In particular, it fails to expel ethical considerations from patent law. Nevertheless, it presents an important step toward the improvement of the patentability of biotechnological inventions in Europe, as it recognizes the need for an adequate protection of intellectual property. In view of the Directive’s implementation, the Member States should take the opportunity to redress the remaining incongruities.

89. See RICHARD FLAMMER, BIOTECHNOLOGISCHE ERFINDUNGEN IM PATENTRECHT [BIOTECHNOLOGICAL INVENTIONS IN THE FIELD OF PATENT LAW] 173 (1999).

