

TO PATENT OR NOT TO PATENT: THE EUROPEAN UNION'S NEW BIOTECH DIRECTIVE

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I. INTRODUCTION

After centuries of fusing, melting, forging, and burning inorganic materials to create useful things, we have come to a time in mankind's development when we are splicing, recombining, and transforming living material into commercial goods. Biotechnology is already used in a variety of business fields—agriculture, animal husbandry, pharmaceuticals, and medicine.¹ Scientists are mapping the genomes of many creatures, from bacteria to yeast to human beings,² and creating a huge genetic library for commercial exploitation. The deciphering, systematizing, and utilizing of the vast amount of genetic information is made possible only by the coming together of powerful computers and advanced life sciences.³ Information technology and life sciences are merging into a single, powerful, technological and economic force that will constitute the foundation of a new era in the industrial development of mankind: the era of life sciences and biotechnology-based products.⁴

While biotechnology has the potential to positively affect

1 See discussion *infra* Part II.

2 See, e.g., Martin Chalfie, *The Worm Revealed*, 396 NATURE 620 (1998) (reporting the completion of the genome sequence for the yeast *Saccharomyces cerevisiae*); Alison Abbott, *Annotation Competition Spurs Drosophila Sequencing Efforts*, 400 NATURE 699 (1999) (stating that Berkeley *Drosophila* Genome Project scientists will team up with the biotechnology company Celera to complete the sequencing of the *Drosophila* genome by the end of 1999); Asako Saegusa, *US Firm's Bid to Sequence Rice Genome Causes Stir in Japan . . .*, 398 NATURE 545 (1999) (stating that researchers involved in the international rice genome project plan to complete the sequencing by the year 2008, while a U.S. company plans to complete the job much sooner); Meredith Wadman, *Human Genome Project Aims to Finish 'Working Draft' Next Year*, 398 NATURE 177 (1999) (reporting that the National Human Genome Research Institute announced that a complete "working draft" of the human genome will be ready by spring of 2000); Myrna E. Watanabe, *Feline Genome Research Advances*, SCIENTIST, July 24, 2000, at 14 (explaining that research on the feline genome is biologically important because cats and humans share noteworthy genetic defects); *Drosophila Genome Sequencing Finished*, 401 NATURE 204 (1999).

3 See *infra* notes 42–61 and accompanying text.

4 See John Carey et al., *The Biotech Century*, BUS. WK., Mar. 10, 1997, at 78, 79 (quoting 1996 Nobel prize-winning chemist Robert F. Curl's statement that "this was the century of physics and chemistry . . . [b]ut it is clear that the next century will be the century of biology").

many aspects of our lives—from what we eat to the way we have our babies and treat diseases—it is also an industry that requires the investment of enormous financial capital for the research and development of new products.⁵ This financial capital becomes tied up for prolonged periods of time and can often be lost because of the company's failure to render a marketable product.⁶ Biotechnology is a “risky business,”⁷ and therefore, patent protection is essential for life science companies if they are to risk financial resources and years of research and development to bring new and useful products to the market.

Since the early eighties, the Member States of the European Union⁸ have known that biotechnology is emerging as one of the most innovative and promising among technologies⁹ and that the

⁵ See Liz McRobb, *Patents Row Over Genetics Breakthrough*, SCOTSMAN, Mar. 12, 1997, at 26 (stating that “development costs are high with long lead times before significant commercial returns are achieved”); see also *The Harm of Patents*, ECONOMIST, Aug. 22, 1992, at 17 (recognizing biotechnology patents as an area where uncertainty can raise legal costs and confusion, and ultimately create a disincentive to innovation); Amy E. Carroll, *A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Comment: Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2476–77 (acknowledging that it takes a quarter of a billion dollars and four to seven years to bring a biotechnology-based pharmaceutical product to market); Lisa Buckingham, *Shock for Shares as Treatments Fail to Yield Hoped-For Dividends*, GUARDIAN, Apr. 28, 1998, at 3 (“A new drug costs about £250 million to develop and only once shares have topped £220 million a year is it likely to be regarded as a clear financial winner.”) [hereinafter Buckingham, *Shock for Shares*].

⁶ See Buckingham, *Shock for Shares*, *supra* note 5, at 3 (stating that Britain's twelve largest biotechnology companies each suffered a collapse of at least forty-eight percent in their share prices in 1997); see also Lisa Buckingham, *Rumours Leave British Biotech on the Ropes: Lisa Buckingham on the Predicament of a Leading British Drugs Company*, GUARDIAN, Apr. 28, 1998, at 3 (reporting that British Biotech's stock market value crashed from £1.9 billion to £370 million in only 18 months) [hereinafter Buckingham, *Rumours*]; Julia Flynn, *Touch of the Flu for British Biotech*, BUS. WK., May 1, 1995, at 27 (explaining that British Biotech PLC's market value fell \$110 million after the company announced that its abdominal cancer drug would not be launched for another year and that Cantab Pharmaceuticals PLC's stock fell forty percent after a clinical trial proved the company's anti-transplant rejection drug did not work).

⁷ See Flynn, *supra* note 6, at 27.

⁸ The Member States of the European Union are Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Denmark, Ireland, United Kingdom, Greece, Portugal, Spain, Austria, Finland and Sweden. See NEILL NUGENT, *THE GOVERNMENT AND POLITICS OF THE EUROPEAN UNION* xxiv (4th ed. 1999).

⁹ Opinion of the Economic and Social Committee on the ‘Proposal for a European

biotechnology market is dominated by the United States,¹⁰ where the level of investments is three times higher than in Europe.¹¹ The Member States have also realized that the protection of biotech inventions is of fundamental importance for the European Community's industrial development, and that adaptation of European intellectual property rights to recent technological changes and harmonization of the European patent law systems can improve legal certainty and help increase the research and development investment in European life science companies.¹²

There are three sources of law that govern patent grants in Europe—the agreements of the European Patent Convention¹³

Parliament and Council Directive on the Legal Protection of Biotechnological Inventions,' paras. 1.2.2–1.3.1, 1996 O.J. (C 295) 11 [hereinafter Opinion of the Economic and Social Committee].

As a result of intensive scientific research and major inventions over the last few years, biotechnology has emerged as one of the most innovative and promising of technologies, particularly in the medical and veterinary fields, stockbreeding and the agro-food sector. As a technique applicable to biological matter (cells, genetic information), biotechnology has enabled researchers to make significant progress in understanding the mechanisms of numerous illnesses such as cancer and Alzheimer's disease, in isolating certain bacterial and viral agents of infection (AIDS virus, hepatitis, etc.), and in finding weapons to fight against such diseases. Biotechnology is therefore a source of hope and progress It goes without saying that there are also . . . possibilities for job-creation.

Id. See also Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, COM(95)661 final para. 1 [hereinafter 1995 Commission Proposal].

10 See Opinion of the Economic and Social Committee, *supra* note 9, para. 1.3.1 (recognizing that in 1996, the United States had 1300 biotechnology firms compared to only 485 in the European Union and that the United States held sixty-five percent of the patents arising out of biotechnology research compared to only fifteen percent for the Member States of the European Union. In addition, for every ten genetically modified plants that the United States placed on the market there was, on average, only one in the European Union.); see also Craig Pickering, *Towards a More Venturesome Europe*, 401 NATURE 209, 209–10 (1999) (stating that in 1992, U.S. funds serving the early-stage market were about seven times greater than in the United Kingdom, compared with a six-to-one difference in gross national product. By 1996, the gap had hardly shrunk. In 1996, the U.S. economy spent £117.7 billion on research and development, whereas the four largest European Union States together spent £60.9 billion.).

11 See Opinion of the Economic and Social Committee, *supra* note 9, para. 1.3.2.

12 See *id.* paras. 1.1.1–1.3.2.

13 Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199

(“EPC”), Directive 98/44/EC of the European Parliament and the Council of the European Union on the Legal Protection of Biotechnological Inventions¹⁴ (“Biotech Directive”), and the national laws of the individual European states.¹⁵ The property rights of biotechnology interests are undermined by the lack of harmony among these three sources, the need for patent “morality” assessments by the European Patent Office (“EPO”), and the ability of concerned citizens and organizations to challenge a patent at any stage of its issuance.

Part Two of this Article provides some general definitions from the area of biotechnology and information about the present applications of life science products. Part Three presents an overview of the purpose and economics of a patent system. Part Four discusses the sources of law that govern patent grants in Europe in an attempt to resolve potential supremacy issues among them and to assess to what extent these laws can affect the European Community’s endeavor to advance Europe’s biotechnology industry to the level of its U.S. counterpart. Part Five presents the argument that patent issuers should not be forced to make ethical judgments as to the morality of exploiting a given invention. Part Six concludes that the current state of patent laws will probably prevent European countries from securing the capital necessary to advance Europe’s

[hereinafter European Patent Convention].

14 Council Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 [hereinafter Biotech Directive].

15 Discussion of the patent laws of the individual European countries is beyond the scope of this article. It is important to note that, in addition to the three enumerated sources of patent law, there is a fourth source—the Convention for the European Patent for the Common Market. See Convention for the European Patent for the Common Market, 1976 O.J. (L 17), 15 I.L.M. 5 (1976) [hereinafter Community Patent Convention]. The Community Patent Convention (“CPC”) was signed in Luxembourg on December 15, 1975, but is not yet in force. See Opinion of the Economic and Social Committee on “Promoting Innovation Through Patents: Green Paper on the Community Patent and the Patent System in Europe,” para. 1.3, 1998 O.J. (C 129) 8. The purpose of the CPC was to abolish the territorial aspects of national patent protection rights by establishing community patents of unitary character and creating a common system of European patent law. See Convention for the European Patent for the Common Market, pmbl., arts. 1–2, 15 I.L.M. 5–7. The community patents granted under the CPC would have had equal effect throughout the territories to which the CPC applies. See *id.* art. 2. The community patent could only be granted, transferred, revoked, or allowed to lapse with respect to all of the territories. *Id.*

biotechnology industry to a level comparable to that of the United States.

II. BIOTECHNOLOGY APPLICATIONS: A FEW EXAMPLES

Any technology that exploits the biochemical activities of living organisms or their products (e.g., isolated enzymes) is a biotechnology.¹⁶ Antibiotic production and brewing are among the long-established biotech industries.¹⁷ Since the development of recombinant DNA technology¹⁸ and the ability to transfer genes from one organism to another, the potential of biotechnology has expanded enormously. While people have been domesticating, breeding, and selecting plants and animals for thousands of years, their accomplishments have been restrained by the natural constraints imposed by species borders. However, genetic engineering bypasses species

16 The European Union Member States have adopted the following definition of biotechnology with respect to the Biotech Directive: "Biotechnology is understood to comprise all the techniques that use or cause organic changes in any biological material (such as animal and plant cells or cell lines, enzymes, plasmids and viruses), microorganisms, plants and animals; or that cause changes in inorganic material by biological means." See Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, COM(88)496 final at 7 [hereinafter 1988 Commission Proposal].

17 See *Biotechnology*, available at <http://www.bmb.leeds.ac.uk/courses/Biotech/htm> (last visited Feb. 25, 2001).

18 Deoxyribonucleic acid ("DNA") comprises the genetic information of most living organisms. BENJAMIN LEWIN, GENES VI 74 (1997). A related molecule, ribonucleic acid ("RNA") is involved in the translating of the genetic information contained in DNA. *Id.* at 154-77. Some viruses, such as the AIDS virus, utilize RNA, rather than DNA as their genetic material. *See id.* at 76. The sequence of the RNA or DNA molecule specifies the amino acid sequence of the proteins and polypeptides found in living organisms. *Id.* at 71-79. Recombinant DNA technology is an umbrella term for procedures that result in the predetermined alteration of DNA *in vitro*. *See generally id.* at 623-44. This ability to manipulate and alter DNA depends on the activity of purified enzymes that cut and rejoin DNA molecules in very precise and predictable ways. *See id.* at 624-29. The two most important classes of enzymes in recombinant DNA technology are the bacterial restriction enzymes and DNA ligase. *Id.* at 117-22, 624-29. Restriction enzymes cut double-stranded DNA molecules at specific recognition sequences. *Id.* at 624. In this way a predictable and reproducible set of DNA fragments is generated from a particular DNA molecule. *See id.* DNA ligase can be used to join selected restriction fragments from different sources. *Id.* at 627. More in depth discussion of the technical aspects of molecular biology and recombinant biotechnology can be found in BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL (Bruce Alberts et al. eds., 3rd. ed. 1994).

restraints altogether.¹⁹ With the help of recombinant DNA technology, manipulation occurs not at the species level but at the genetic level.²⁰ The working unit is no longer the organism but rather the gene. The implications are enormous and far-reaching. Scientists have already developed genetically modified sheep and pigs that grow faster than normal.²¹ They have also attempted to transplant genes into sheep to make their wool grow faster.²² Researchers have genetically altered brooding turkey hens by blocking the gene for the hormone prolactin, hoping to limit the natural brooding instinct.²³ This new breed of genetically engineered hens would not exhibit the mothering instinct, thus laying more eggs.²⁴

Much of the cutting-edge research in animal husbandry is occurring in the new field of "pharming." Researchers are transforming herds and flocks into bio-factories to produce pharmaceutical products.²⁵ In April 1996 Genzyme Transgenics announced the birth of Grace, a transgenic goat carrying the gene to produce BR-96, an experimental anti-cancer drug.²⁶ There are also transgenic pigs that produce human hemoglobin²⁷ and cows whose milk contains lactoferrin (for the treatment of gastrointestinal infections) or human serum albumin (for the treatment of trauma following a severe blood loss).²⁸

19 *See id.* at 624. The use of restriction enzymes and DNA ligase allows scientists to cut DNA from one organism and splice it into the DNA of another organism. *See LEWIN, supra* note 18, at 623. A good analogy is the film editing process. One can cut out scenes from a film, and put them into another film, or one can cut out scenes from many films and make a new film.

20 *See id.* at 624.

21 *See* Jane Ford, *This Little Pig Rushed to Market*, NEW SCIENTIST, Apr. 28, 1988, at 27 (describing genetically modified pigs and sheep that are 30% more efficient in converting food and are brought to market earlier than normal animals).

22 *See id.*

23 *See* Michelle Hoffman, *Building a Badder Mother*, 81 AM. SCIENTIST 329, 329-30 (1993).

24 *See id.*

25 *See* Ann Thayer, *Firms Boost Prospects for Transgenic Drugs*, CHEMICAL AND ENGINEERING NEWS, Aug. 26, 1996, at 23, 23-24.

26 *See id.* at 24; *see also* Laura Johannes, *Biotech Goat Is Created to Produce Drug*, WALL ST. J., Apr. 9, 1996, at B1.

27 Thayer, *supra* note 25, at 23.

28 *Id.* at 23-24.

Scientists in the chemical industry are talking about replacing petroleum, which for years has been the primary raw material for the production of plastics, with renewable resources produced by microorganisms and plants.²⁹ Researchers at the Carnegie Institute of Washington have inserted a plastic-making gene into a mustard plant.³⁰ The gene transforms the plant into a factory for plastics.³¹ Monsanto hopes to have the plastic-producing plant on the market by the year 2003.³² Researchers are also attempting to create environmentally friendly trees to make the papermaking process more efficient.³³ According to scientists from Calgene, boosting the gene for the enzyme controlling the formation of cellulose in plants could make it possible to create trees with much higher proportions of cellulose, the plant kingdom's structural fiber, and less than the normal amounts of other cell wall components.³⁴ It is these secondary components that create pollution in the papermaking industry.³⁵

Researchers have also engineered *Bt* crops—maize, cotton, and potatoes—to produce toxins made by the soil bacterium *Bacillus thuringiensis*.³⁶ These crops are environmentally friendly—the natural toxins are less harmful to farmers, do not bind in the digestive systems of animals, and are biodegradable.³⁷ Because plants produce carotenoids (vitamin A precursors) and tocopherols (vitamin E), they are looked at as ideal miniature factories for the production of vitamins A and E.³⁸ The agricultural enhancement of vitamins A and D provides an easy way to improve public health, especially in third-world

29 See Carey et al., *supra* note 4, at 80–81.

30 *Id.* at 88.

31 *Id.*

32 See *id.*

33 See *id.*

34 *Id.*

35 See *id.*

36 Ehsan Masood, *US Groups Sue Over Approval of Bt Crops . . . as UK Press Reports Come Under Fire*, 397 NATURE 636 (1999).

37 See *id.* (stating that millions of children each year go blind or die because of diets low in fresh fruit and vegetables).

38 See Barry A. Palevitz, *With GM Crops, Who Needs Vitamin Pills?*, THE SCIENTIST, Feb. 7, 2000, at 14.

countries.³⁹ There are already transgenic rice and canola seed varieties producing vitamin A⁴⁰ and *Arabidopsis* seeds producing vitamin E.⁴¹

When discussing developments in biotechnology, it becomes apparent that there is a correlation between the genetic and computer revolutions. This teamwork of computers and genes will forever alter our reality at the deepest level of human experience. From the beginning of the genetics revolution, computer languages provided the appropriate analogy for understanding the structure of biological entities and the mechanism of biological processes. Watson and Crick's studies of the molecular structure of DNA were described to the public through a computer metaphor: "cracking" the genetic code was akin to unraveling a computer program, and the discovery of the DNA molecule's double helix structure was like an explication of a computer's basic wiring diagram.⁴² In 1985, physicist Freeman Dyson brought together the information and life sciences in a simple conceptual framework with the concise observation that "[h]ardware processes information; software embodies information. These two components have their exact analogues in living cells; hardware is mainly protein and software is mainly nucleic acid."⁴³ Today, science textbooks are rewritten to reflect the influence of computers on biology. In the popular textbook, *Molecular Biology of the Cell*, the authors state that

[f]or cells as for computers, memory makes complex programs possible, and many cells together, each one stepping through its complex developmental control program, can generate a very complex adult body. . . . Thus the cells of the embryo can be likened to an array of little computers . . . operating in parallel and

39 See *id.*

40 See Xudong Ye et al., *Engineering the Provitamin A (β -Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*, 287 *SCIENCE* 303 (2000); see also Christine K. Shewmaker et al., *Seed-Specific Overexpression of Photoene Synthase: Increase in Carotenoids and Other Metabolic Effects*, 20 *PLANT J.* 401 (1999).

41 See David Shintani and Dean DellaPenna, *Elevating the Vitamin E Content of Plants Through Metabolic Engineering*, 282 *SCIENCE* 2098 (1998).

42 See JOSEPH WEIZENBAUM, *COMPUTER POWER AND HUMAN REASON: FROM JUDGEMENT TO CALCULATION* 154–56 (1976).

43 FREEMAN DYSON, *ORIGINS OF LIFE* 7 (1999).

exchanging information with one another.⁴⁴

The potential power of computers to decipher and manage genes became apparent in the early 1980s, when University of California at San Diego scientists made a significant biological discovery by merely reading computer printouts.⁴⁵ The researchers compared the DNA sequences of two proteins with the help of a computer.⁴⁶ One of these proteins was implicated in a type of cancer and the other in cellular growth.⁴⁷ From the computer printouts, the scientists found that the DNA sequences of both proteins were strikingly similar, thus revealing a correlation between cancer and abnormal growth in cells.⁴⁸ This pivotal scientific discovery came without the performance of a single biological experiment.⁴⁹

Information theory has become instrumental in deciphering and organizing, as well as in understanding the increasingly complex world of molecular biology and genetic engineering. Molecular biologists around the world are busily engaged in the most extensive data collection project in history, the Human Genome Project. This project has hastened the coming together of the computer and genetic sciences.⁵⁰ With the working draft of the human genome completed, scientists must decipher the genome's pattern, functions, and meaning.⁵¹ They will continue to use computer prediction to annotate the genome automatically, i.e., to predict genes' biological features based on similar, previously identified genes from humans or other organisms.⁵² Scientists hope the data derived from analyzing the

44 ALBERTS ET AL., *supra* note 18, at 1067.

45 See Russell F. Doolittle et al., *Simian Sarcoma Virus onc Gene, v-sis, is Derived From the Gene (or Genes) Encoding a Platelet-Derived Growth Factor*, 221 SCIENCE 275 (1983).

46 *See id.*

47 *See id.*

48 *See id.* at 275-76.

49 *See id.* at 275.

50 See Wadman, *supra* note 2, at 177 (noting that the pace of sequencing was increased when mapped clones were provided more quickly to sequencing machines because of the fingerprinting of entire libraries of bacterial artificial chromosomes).

51 See Arielle Emmett, *The Human Genome*, THE SCIENTIST, July 24, 2000, at 1, 17.

52 See Eugene Russo, *Reading the Human Genome*, THE SCIENTIST, July 24, 2000,

human genome will result in an understanding of how genes orchestrate the underlying chemical reactions occurring in the human body.⁵³ This knowledge could be the basis for engineering computers that would tailor cures for various diseases.⁵⁴

Scientists are currently using computers combined with molecular biology in the field of genetic screening.⁵⁵ A revolutionary new technology, DNA chips, will allow doctors to scan an individual's genetic makeup and provide a detailed readout of his or her genetic predispositions.⁵⁶ The chips will tag genetic differences, giving doctors a roadmap for sorting out an individual's existing and potential illnesses.⁵⁷ DNA chips closely resemble computer chips.⁵⁸ They are made up of thousands of different pieces of DNA placed on a silicon chip by the same technique used to make microprocessors—photolithography.⁵⁹ Like their predecessor, the computer chip, DNA chips are becoming even more information rich. Affymetrix's first prototype in 1994 held 20,000 DNA probes.⁶⁰ Today, its chips contain more than 400,000 probes.⁶¹

Scientists believe that biotechnology not only benefits from the development of information science, but will also impact electronics.⁶² The DNA helix contains millions of times more information than the densest microchip.⁶³ As a result, DNA

at 8, 24.

⁵³ See Ralph T. King, Jr., *Gene Machines: An Eclectic Scientist Gives Biotechnology a Fast Assembly Line*, WALL ST. J., May 30, 1995, at A1.

⁵⁴ See *id.*

⁵⁵ See Charis Eng & Jan Vijg, *Genetic Testing: The Problems and the Promise*, 115 NATURE BIOTECHNOLOGY 422, 425–26 (1997) (explaining that there is a technological gap between gene identification and large-scale genetic testing. However, the author predicts that once the DNA template preparation limitation is overcome, genetic testing will likely revolutionize our basic concepts of what medicine is and how we should go about developing drugs for the treatment of human disease.).

⁵⁶ See *DNA Privacy Safeguards Crucial*, L.A. TIMES, Mar. 20, 2000, at NB4.

⁵⁷ See *id.*

⁵⁸ See David Stipp, *Gene Chip Breakthrough*, FORTUNE, Mar. 31, 1997, at 56, available at 1997 WL 3108268.

⁵⁹ See *id.*

⁶⁰ *Id.*

⁶¹ See *id.*

⁶² See Carey et al., *supra* note 4, at 80–81.

⁶³ *Id.* at 90.

computers could theoretically perform 100 million billion tasks at once.⁶⁴ University of Southern California mathematician Leonard Adleman engineered a DNA computer in 1994.⁶⁵ Microsoft's Bill Gates has personally donated almost \$20 million to biotech drug discovery projects.⁶⁶ Gates sums up the new collaborative efforts between the information and life sciences by saying: "This is the information age, and biological information is probably the most interesting information we are deciphering and trying to decide to change. It's all a question of how, not if."⁶⁷

III. THE PURPOSE AND ECONOMICS OF A PATENT SYSTEM

The origins of definitive patent law date back to the fifteenth century.⁶⁸ In 1474 the Council of Venice enacted a statute granting an exclusive ten-year privilege to the inventor of any machine or process that expedited or improved silk production.⁶⁹ The statute also provided for a special council to review applications and provide for express remedies against the infringement of any exclusive privilege grant.⁷⁰ Centuries later, economist Adam Smith recognized the importance of patents to safeguarding intellectual property.⁷¹ Patents allow innovators to internalize the benefits of their investment by excluding benefits to others.⁷² They stimulate technological investment by creating

64 *See id.* at 90.

65 *See* Steven Levy, *Computers Go Bio: DNA Beats a Pentium Anyday*, NEWSWEEK, May 1, 1995, at 63.

66 *See* King, Jr., *supra* note 53, at A1.

67 *Id.*

68 David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 996 (1993).

69 *Id.*

70 *Id.*

71 *See* ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS 712 (Edwin Cannan ed., Random House 1937) (stating that the risk involved in establishing trade in a new market is similar to the risk involved in creating an invention. Adam Smith argues that the grant of a temporary trade monopoly to a company venturing into a new market, like the grant of patent to an inventor, is a way for the state to compensate innovators for "hazarding a dangerous and expensive experiment, of which the public is afterwards to reap the benefit.").

72 *See* Opinion of the Economic and Social Committee, *supra* note 9, para. 4.1.1 (explaining that a patent "only confers a negative right, i.e. the possibility of prohibiting third parties from using the invention without authorization, and not a positive right,

security because an efficient and predictable patent system attracts businesses in search of guarantees that they will benefit from their research and development investments.⁷³ By securing a return on investment, patents encourage technological innovation.⁷⁴ In addition, the disclosure of information prevents the duplication of research, frees resources for new endeavors, and allows newcomers to build on the knowledge of their predecessors.⁷⁵

Through the encouragement of technological innovation, patents stimulate the economy and, consequently, are extremely important to the economic welfare of a nation. Analysis demonstrates that from the three sources of economic growth—capital, labor, and technical progress—technical progress is by far the most important, accounting for more than seventy percent of the economic growth of France, Germany, and the United Kingdom.⁷⁶ In addition, technical progress is a capital-augmenting factor, meaning that the higher the level of the capital stock, the greater the benefits of technical progress.⁷⁷

A patent's full commercial value can be realized only when patents are enforced with predictable reliability. The inability to enforce a patent because of lack of clarity in the pertinent laws may result in the diminishing or complete elimination of a company's incentive to invest in the development of new products and processes. The protection of a predictable patent system is of particular importance to the biotechnology industry where success requires massive investment.⁷⁸ It takes a quarter of a billion dollars and four to seven years to bring a biotech-

i.e. the right of exploitation and commercialization"); *see also* HARVARD/Onco-Mouse, 1991 E.P.O.R. 525 ("A patent does not give a positive right to its proprietor to use the invention but rather only confers the right to exclude other [sic] from using the invention for a limited period of time.").

⁷³ *See* 1988 Commision Proposal, *supra* note 16, paras. 9–11.

⁷⁴ *See id.* para. 11.

⁷⁵ *See id.*

⁷⁶ *See* Michael J. Boskin and Lawrence J. Lau, *Capital, Technology, and Economic Growth*, in *TECHNOLOGY AND THE WEALTH OF NATIONS* 46–47 (Nathan Rosenberg et al. eds., 1992).

⁷⁷ *See id.* at 50.

⁷⁸ *See* McRobb, *supra* note 5 and accompanying text.

based pharmaceutical product to the market,⁷⁹ and an estimated ninety percent of biotechnology companies will have a drug that fails or is delayed.⁸⁰ Hence, it is easy to understand why many would be deterred from biotech experimentation if they are unable to recoup the sizable research and development costs. In addition, the uncertainty of patentability, or enforceability of a granted patent, also raises a biotechnology company's legal costs and may ultimately create a disincentive to innovation.

The value of the European Community is the creation of a common market, which enables European Community producers to exploit economies of scale by freely supplying goods and services to several nations, as opposed to only one.⁸¹ As early as 1985, the European Commission had noted that differences in the existing intellectual property laws were an obstacle to the development of the internal market.⁸² These differences were recognized as "caus[ing] . . . legal uncertainty for inventors . . . and consequently hamper[ing] the movement of products spawned by these inventions . . . and giv[ing] rise to additional costs for businesses."⁸³ Consequently, the logical alternative was to strengthen the protection of biotech invention through

79 See Carroll, *supra* note 5, at 2476-77.

80 Buckingham, *Shock for Shares*, *supra* note 5, at 3.

81 See TREATY ESTABLISHING THE EUROPEAN ECONOMIC COMMUNITY, Mar. 25, 1957, 298 U.N.T.S. 3, 14 [hereinafter EEC Treaty], available in WL I.E.L. V-A-1-b, as amended by the Single European Act, Feb. 17 & 28, 1986, O.J. (L 169) 1 (1987), [1987] 2 C.M.L.R. 741 (1987), reprinted in 25 I.L.M. 503, and the Treaty of Amsterdam, Oct. 2, 1997, 1997 O.J. (C340) 1, reprinted in 37 I.L.M. 56, and separately joined (as the European Union) by the TREATY ESTABLISHING THE EUROPEAN COMMUNITY (Maastricht Treaty), Feb. 7, 1992, O.J. (C 224) 1 (1992), [1992] 1 C.M.L.R. 573 (1992), reprinted in 37 I.L.M. 56, as amended by the Amsterdam Treaty. The Amsterdam Treaty was recently ratified on May 1, 1999. See *France Ratifies EU Amsterdam Treaty Amid Criticism*, AGENCE FRANCE-PRESSE, Mar. 3, 1999, available in 1999 WL 2556911. Consistent with basic economic theory, the European Community articulated the benefits of a common commercial policy in Article 110 of the EEC Treaty, which states in part that "[t]he common commercial policy shall take into account the favourable incidence which the abolition of customs duties as between Member States may have on the increase of the competitive strength of the enterprises in those states." See *id.* art. 110.

82 See Opinion of the Economic and Social Committee, *supra* note 9, para. 1.1.1; see also 1988 Commission Proposal, *supra* note 16, paras. 1-7 (noting that the "[d]ifferences in industrial property laws have a direct and negative impact on intra-Community trade").

83 Opinion of the Economic and Social Committee, *supra* note 9, para. 1.1.2.

harmonized patent law adapted to the recent changes in biotechnology.⁸⁴ Strong biotech patent protection would then attract new investments, which would strengthen the European Community's economy in the field of biotechnology and raise it to the level of development of the United States.

IV. PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS IN EUROPE

As mentioned earlier, three sources of law govern patent grants in Europe—the European Patent Convention, Directive 98/44/EC of the European Parliament and the Council of the European Union on the Legal Protection of Biotechnological Inventions, and the national laws of the individual European states.⁸⁵ This section discusses these sources of law in an attempt to resolve potential supremacy issues among them and to assess to what extent these laws can affect the European Community's endeavor to advance Europe's biotechnology industry to the level of the U. S. counterpart.

A. *The European Patent Convention*

The European Patent Convention was conceived in 1973 by Belgium, Denmark, Germany, Greece, Spain, France, Ireland, Italy, Yugoslavia, Liechtenstein, Luxembourg, Monaco, the Netherlands, Norway, Austria, Portugal, Switzerland, Finland, Sweden, Turkey, and the United Kingdom.⁸⁶ The EPC enables an applicant seeking patent rights in more than one European country to achieve this result with a single application to a

⁸⁴ See *id.* paras. 1.1.2, 1.3.2; see also 1988 Commission Proposal, *supra* note 16, para. 8 (stating that “the main purpose of this proposal for a Directive is to establish harmonised, clear and improved standards for protecting biotechnological inventions in order to foster the overall innovatory potential and competitiveness of Community science and industry in this important field of modern technology”).

⁸⁵ See *supra* notes 13–15 and accompanying text.

⁸⁶ See European Patent Convention, *supra* note 13, at 363–66. The current EPC members are Belgium, Denmark, Germany, Greece, Spain, France, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, the Netherlands, Austria, Portugal, Switzerland, Finland, Sweden, Turkey, Cyprus, and the United Kingdom. See European Patent Office Member States, available at <http://www.european-patent-office.org/epo/members.htm> (last modified Nov. 2, 2000). Albania, Lithuania, Latvia, Macedonia, Romania, and Slovenia are expected to become members in the future. *Id.*

central authority.⁸⁷ The EPC is a registration system, not a legislative body.⁸⁸ The issuance of a European patent instantly creates a bundle of national patents, the enforceability of which is governed by the independent laws of the various contracting states.⁸⁹ As a result, a European patent may be interpreted to represent varying degrees of protection. While the EPC provides a cost-effective and time-efficient way of filing a single application, it does not provide the most valuable element of a patent convention—the unification of property rights.

Patentable subject matter is set forth in EPC Article 52.⁹⁰ EPC Article 52(1) provides that “European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.”⁹¹ These requirements, which are defined in EPC Articles 57 (Industrial Application), 54 (Novelty), and 56 (Inventive Step),⁹² are parallel to the utility, novelty, and non-obviousness factors necessary to obtain a patent in the United States.⁹³ Hence, patent fundamentals in the EPC are essentially the same as those applicable in the United States.

EPC Article 53, entitled “Exceptions to Patentability,” asserts that patents shall not be granted for:

inventions the publication or exploitation of which would be contrary to *ordre public*⁹⁴ or morality, provided that the exploitation shall not be deemed so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or

87 See European Patent Convention, *supra* note 13, arts. 1–3.

88 See *id.* art. 4 (describing the institutional set-up of the EPC).

89 See *id.* art. 64.

90 *Id.* art. 52.

91 *Id.*

92 *Id.* arts. 54, 56–57.

93 See 35 U.S.C.A. §§ 101–103 (West 1984 & Supp. 2000). Section 101 sets forth which inventions are patentable, Section 102 enumerates novelty as a condition for patentability, and Section 102 requires the subject matter of a patent to be “non-obvious.” *Id.*

94 For the meaning of *ordre public*, see *infra* notes 97–99 and accompanying text.

the products thereof.⁹⁵

The patent laws of the United States likewise deny property rights in plant and animal varieties and basic biological processes.⁹⁶ However, the concepts of *ordre public* and morality are unique to the EPC.

The EPC does not define the meaning of *ordre public* and morality, nor does it define what type of subject matter is contrary to public morality. The European Patent Office (“EPO”) has interpreted *ordre public* as covering “the protection of public security and the physical integrity of individuals as part of society.”⁹⁷ This concept also includes protection of the environment.⁹⁸ Hence, inventions must be excluded from patentability as being contrary to *ordre public* if their exploitation is “likely to breach public peace or social order (for example, through acts of terrorism) or seriously to prejudice the environment”⁹⁹ However, the mere possibility that a biotech invention could be used in an improper way does not exclude this invention from patentability.

The concept of morality is

related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation.¹⁰⁰

If the exploitation of an invention does not conform to accepted European standards of conduct, then the invention should not be patented, being contrary to morality.¹⁰¹

The EPC provides an opportunity for concerned citizens to

95 European Patent Convention, *supra* note 13, art. 53.

96 *See, e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (holding that a mixture of bacteria was not patentable because the qualities of the bacteria were manifestations of natural phenomena).

97 Decision T356/93, Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace), 1995 E.O.P.R. 357, 366.

98 *Id.*

99 *Id.*

100 *Id.*

101 *See id.*

challenge a pending or previously issued European patent if the citizens believe that the patent does not abide to *ordre public* and morality criteria.¹⁰² Unlike their U.S. counterparts,¹⁰³ the citizens of the EPC member countries are allowed to employ the judicial process to shape the EPO's regulatory agenda in regard to biotechnologies.¹⁰⁴ Both the patent owner and his or her opponents are necessary parties to the adversary proceedings before the European Patent Office.¹⁰⁵ Depending on the decision of the Opposition Division, the patent can be amended or revoked.¹⁰⁶ As a result of the opposition, the inventor is subjected to additional costs¹⁰⁷ and a lengthy delay in gaining patent protection.¹⁰⁸ The danger of costly litigation of biotechnology patents against various opponents of biotechnology development constitutes an insurmountable impediment in Europe's attempt to attract investors in the life sciences sector. Part Five, *infra*, will present an argument that the morality exceptions should be abolished from the EPC.

EPC Article 53(b) presents further problems for inventors in the biotechnology sector stemming from the lack of definition of

102 See European Patent Convention, *supra* note 13, arts. 52, 99–100.

103 See *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 923–24 & nn.3–4 (Fed. Cir. 1991) (denying the Animal Legal Defense Fund and six other animal rights groups standing to challenge a declaration made by the U.S. Patent and Trademark Office that non-naturally occurring animals shall be patentable).

104 See European Patent Convention, *supra* note 13, arts. 99–100 (granting the right of any person to give notice of opposition and stating the proper grounds for opposition).

105 See *id.* art. 99.

106 See *id.* art. 102.

107 See *id.* art. 104 (stating that each party is responsible for his own costs, unless the Opposition Division orders a different apportionment).

108 See, e.g., Howard Florey/Relaxin (Opposition by Fraktion der Grunen Im Europaischen Parlament; Lannoye), 1995 E.P.O.R. 541, 543–46. The inventor filed a patent application with the EPO on December 12, 1983. *Id.* at 543. He obtained the patent (EP-B-112 149) some nine years later and a mention of the patent grant was published on April 10, 1991. *Id.* The patent was opposed by the Green Party of the European Parliament in January of 1992, a year after it was published. *Id.* at 544. Due to this opposition, the patent owner had to incur the expense to defend its invention before the Opposition Division of the EPO. See European Patent Convention, *supra* note 13, art. 104. It took two years before the EPO rejected the opponents' arguments. See *id.* at 541, 544, 553. The validity of the patent was finally upheld on December 8, 1994. See *id.* at 541, 553.

the terms “essentially biological” process and “microbiological process.”¹⁰⁹ The EPO observed that to determine whether a non-microbiological process can be considered “essentially biological,” the patent examiner must make a decision “on the basis of the essence of the invention taking into account the totality of human intervention and its impact on the results achieved.”¹¹⁰

According to the Board’s opinion,

the necessity for human intervention alone is not yet a sufficient criterion for its not being “essentially biological.” Human interference may only mean that the process is not a “purely biological” process, without contributing anything beyond a trivial level. It is further not a matter simply of whether such intervention is of quantitative or qualitative character.¹¹¹

It seems that according to the European Patent Office, a process not “essentially biological” requires one essential step that cannot be carried out without human intervention and that has a decisive impact on the final determination.¹¹²

Another potential problem for biotechnology inventors stems from the lack of legal definitions in the EPC for the terms “animal varieties” and “plant varieties.” With regard to animal varieties, the German, English, and French wordings of EPC Article 53(a) differ in meaning.¹¹³ While the English text uses the term “animal varieties,” the corresponding German wording is *tierarten* (translated “animal species”), and the French wording is *raças animales* (translated “animal breeds”).¹¹⁴ These three terms describe different animal groupings, but the German term *tierarten* is broader than both the English “animal variety” and the French *raças animales*.¹¹⁵

109 See European Patent Convention, *supra* note 13, art. 53(b).

110 Decision T320/87, Lubrizol/Hybrid Plants, 1988 E.P.O.R. 173, 178.

111 *Id.*

112 See *id.*; see also Decision T356/93, Plant Genetic Systems/Glutamine Synthetase Inhibitors, *supra* note 97, at 375–77.

113 See KLARA GOLDBACH ET AL., PROTECTION OF BIOTECHNOLOGICAL MATTER UNDER EUROPEAN AND GERMAN LAW: A HANDBOOK FOR APPLICANTS 43 (1997); see also HARVARD/Onco-Mouse, *supra* note 72, at 8 (noting the differing designations).

114 See GOLDBACH ET AL., *supra* note 113, at 43.

115 See *id.*; HARVARD/Onco-Mouse, *supra* note 72, at 526-28 (concluding that

With respect to the term “plant varieties,” in the Plant Genetic Systems/Glutamine Synthetase Inhibitors case, the EPO Technical Appeal Board adopted a new definition of “plant variety” and refused a product claim to a transgenic plant.¹¹⁶ Plant Genetic System’s European Patent No. 242 236 was directed to transgenic plants containing in their cells a gene which conferred resistance to a particular herbicide.¹¹⁷ The patent contained a process claim to the methodology for transforming the plant and product claims to the vectors, plant cells, seeds, and the plant itself.¹¹⁸ The claims referred to plants in general, and were not limited to the particular species of plant. The Board applied a new definition of a “plant variety” borrowed from Article 1(vi) of the revised 1991 UPOV Convention¹¹⁹ and held that genetically modified plants were themselves varieties under EPC Article 53(b).¹²⁰ Furthermore, the Board held that the plant product claim could not be allowed under the “microbiological process” exception because the process of producing and propagating the transgenic plants, although involving a microbiological step, was not a

EPC Article 53 does not exclude a new and distinct animal engineered by biotechnology for cancer research).

116 Decision T356/93, Plant Genetic Systems/Glutamine Synthetase Inhibitors, *supra* note 97, at 374–75, 382.

117 *See id.* at 360–61.

118 *Id.*

119 *See* International Convention for the Protection of New Varieties of Plants of December 12, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, *available at* <http://www.upov.int/eng/convntns/1991/pdf/act.1991.PDF> (last visited Mar. 31, 2001) [hereinafter UPOV Convention].

“[V]ariety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder’s right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged

Id. art. 1(vi).

120 *See* Decision T356/93, Plant Genetic Systems/Glutamine Synthetase Inhibitors, *supra* note 97, at 375, 380.

microbiological process when considered as a whole.¹²¹ However, the Board upheld the plant cell claim, noting that plant cells are patentable because they are not considered a plant variety, but rather fall under the definition of a microbiological product.¹²² The Board's result is contrary to current EPC law because, under EPC Article 64(2), the protection conferred by a patent directed to a process of manufacture extends to the products directly obtained by such a process.¹²³ Although the process technology can still be patented,¹²⁴ the specific refusal of product claims to transgenic plants prevents the inventor from recouping research and development expenses and thus constitutes an enormous setback for the European plant biotechnology industry. In addition, it is hard to find an explanation for the fact that the EPO does not consider a transgenic mouse an animal variety,¹²⁵ but considers a transgenic plant a plant variety.¹²⁶

To conclude, while the EPC provides a cost-effective and time-efficient way of filing a single application, it has several weaknesses that present hurdles for biotechnology investors, and prevent the flow of investment capital into the biotechnology industry. The EPC does not provide for the most valuable element of a patent convention—the unification of property rights.¹²⁷ In addition, the grant of standing to citizens to challenge a patent in court and the lack of decision-making predictability on the EPO's part both contribute to the diminished interest in life science exploration in Europe.

B. Directive 98/44/EC of the European Parliament and the Council of the European Union on the Legal Protection of

121 See *id.* at 382.

122 See *id.* at 375, 380.

123 See European Patent Convention, *supra* note 13, art. 64(2).

124 See Decision T356/93, Plant Genetic Systems/Glutamine Synthetase Inhibitors, *supra* note 97, at 379–80.

125 See HARVARD/Onco-Mouse, *supra* note 72, at 526.

126 See Decision T356/93, Plant Genetic Systems/Glutamine Synthetase Inhibitors, *supra* note 97, at 380.

127 See European Patent Convention, *supra* note 13, art. 64 (stating that the European patent holder is granted in each of the Contracting States the same rights that would be conferred by a national patent in that state).

Biotechnological Inventions

The purpose of the Biotech Directive was to adapt European intellectual property rights to recent technological changes and to harmonize the domestic laws of the Member States with the goal of creating the legal certainty required to draw the biotech industry into the European Union, ending the competitive disadvantage that separated the European Union from the United States.¹²⁸

1. Procedure for Adoption of a Directive by the European Parliament

To supersede domestic laws, the European Union must adhere to lengthy multi-layered legislative procedures that require constant cooperation between the Commission, the Council of Ministers ("Council"), and the European Parliament ("Parliament"). Four different procedures (consultation, cooperation, co-decision, or assent) may be used depending on the Treaty of the European Community¹²⁹ (TEC) article that serves as the legal basis for the proposed legislation.¹³⁰ New legislation generally begins with a draft proposal from the Commission.¹³¹ In most cases, the Commission prepares a proposal on its own initiative, but it may do so on a suggestion from the Council or Parliament.¹³² The Commission publishes the proposal and submits it to the Council and Parliament.¹³³ What happens next varies according to the procedural route dictated by TEC.

The co-decision procedure¹³⁴ initiated by TEC Article 251 can

128 See Opinion of the Economic and Social Committee, *supra* note 9, paras. 1.1.1–1.3.2.

129 TREATY ESTABLISHING THE EUROPEAN COMMUNITY, Nov. 10, 1997, 1997 O.J. (C 240) 3.

130 See NUGENT, *supra* note 8, at 359.

131 See *id.* at 360.

132 See *id.* at 117, 360–61.

133 *Id.* at 363.

134 This is the procedural route for the adoption of the Biotech Directive. See Biotech Directive, *supra* note 14, at 13. TEC Art. 251 is the equivalent of EEC Art. 189B. *Id.* at 366–67.

be a one, two, or three-stage procedure.¹³⁵ If Parliament adopts the Commission's proposal (with or without amendments), and the Council adopts the text as approved by Parliament, the proposal is adopted.¹³⁶ The Council need not adopt the text as approved by Parliament.¹³⁷ It may introduce its own amendments to the proposal and then send the new version for a second consideration by Parliament.¹³⁸ This triggers the second stage of the co-decision procedure.¹³⁹ When presented with the proposal, as adopted by the Council, Parliament has the option of (1) taking no action; (2) approving by a simple majority; (3) rejecting the Ministers' position with an absolute majority; or (4) proposing yet additional amendments with an absolute majority.¹⁴⁰ In the first two cases, the proposal is adopted.¹⁴¹ In the third case, the proposal fails, and in the last case, the legislation is returned to the Commission.¹⁴² The Commission must then decide whether to adopt or reject Parliament's amendments. If the Commission rejects Parliament's amendments, the legislation must receive a unanimous vote from the Council to become law.¹⁴³ If the Commission adopts the amendments, then only a qualified majority vote in the Council is required.¹⁴⁴ If the Council does not approve Parliament's amendments, a Conciliation Committee is convened.¹⁴⁵ Its purpose is to attempt to prepare a joint text that could potentially be agreed on by both Parliament and the Council.¹⁴⁶ The Conciliation Committee's text can become law only if both the Council and Parliament accept it.¹⁴⁷

135 *Id.* at 367, 370–71.

136 *Id.* at 370.

137 *See id.*

138 *See id.*

139 *See id.*

140 *Id.* at 370–71.

141 *See id.* at 370.

142 *See id.* at 370–73.

143 *See id.* at 372–73.

144 *See id.*

145 *Id.* at 371.

146 *See id.*

147 *See id.*

2. *Acceptance of the Directive*

A proposal for a Directive on the Legal Protection of Biotechnological Inventions was first drafted in 1988¹⁴⁸ and amended in 1992.¹⁴⁹ In March 1995, however, Parliament rejected this first draft Directive.¹⁵⁰ Parliament failed to agree on the joint text prepared by the Conciliation Committee.¹⁵¹ The main reason for the failure of the Directive was the controversy about ethical issues, in particular, the patenting of materials derived from the human body.¹⁵²

Despite Parliament's rejection of the first draft Directive, the Commission maintained the opinion that this legislation was important in order to avoid discouraging research and to uphold the European Union's competitiveness with the rest of the world.¹⁵³ The Commission also presented a proposal in late 1995.¹⁵⁴ Following renewed opposition in Parliament and the adoption of sixty-six amendments, a modified version was proposed a year later and subsequently agreed to as the common position of the Council.¹⁵⁵ On May 12, 1998, Parliament formally gave its approval to the proposal, thus drawing a line after more than ten years of controversial discussion.¹⁵⁶

3. *The Biotech Directive*

The Biotech Directive consists of a fifty-six paragraph preamble and eighteen articles.¹⁵⁷ The preamble stresses the

148 See 1988 Commission Proposal, *supra* note 16.

149 See Amended Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, COM(92)589 final at 1.

150 1995 Commission Proposal, *supra* note 9, para. 10.

151 *Id.*

152 See *id.* para. 9; See also JEREMY RIFKIN, *THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD* 63–64 (1998).

153 See 1995 Commission Proposal, *supra* note 9, paras. 7, 10–11.

154 See *id.*

155 Amended Proposal for a European Parliament and Commission Directive on the Legal Protection of Biotechnological Matter, COM(97)446 final at 1; Biotech Directive, *supra* note 14, at 13.

156 Decision on the Common Position Adopted by the Council with a View to Adopting a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, 1998 O.J. (C 167) 26, 26–27.

157 See Biotech Directive, *supra* note 14.

importance of both biotechnology¹⁵⁸ and the legal protection of biotechnology inventions for the well being of the European Community.¹⁵⁹ The Biotech Directive recognizes the need for harmonization of patent laws among the member states¹⁶⁰ in order to secure research and development funds,¹⁶¹ to improve the functioning of the common market,¹⁶² and to clarify uncertainties in European patent law.¹⁶³ In addition, Parliament and the Council agree that there is no per se existing prohibition on the patentability of biological matter.¹⁶⁴ Nonetheless, Article 6(1) is very similar to EPC Article 53(a). It states that

[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.¹⁶⁵

Ordre public and morality correspond to ethical or moral principles recognized in a given Member State.¹⁶⁶ What is new in the Biotech Directive is the outright exclusion from patentability of human/animal chimeras,¹⁶⁷ human germ cells,¹⁶⁸ processes for modifying the germ line genetic identity of humans,¹⁶⁹ processes for human cloning,¹⁷⁰ and uses of human embryos for industrial and commercial purposes.¹⁷¹

Leaving aside the problem arising from the inclusion of the *ordre public* and morality provisions in the new Biotech Directive (which will be discussed in Part Five, *infra*), Article 6(2) might cause different problems in the future because it

158 *See id.* paras. 1, 3.

159 *See id.*

160 *See id.* para. 3.

161 *See id.* paras. 2–3.

162 *See id.* para. 5.

163 *See id.* paras. 4, 8–9.

164 *Id.* para. 15.

165 *Id.* art. 6, para. 1.

166 *Id.* para. 39.

167 *See id.* para. 38.

168 *See id.* para. 16.

169 *See id.* art. 6, para. 2(b).

170 *See id.* art. 6, para. 2(a).

171 *See id.* art. 6, para. 2(c).

precludes the acquisition of patent protection for methods of human germ line therapy regardless of future developments.¹⁷² Possibly, scientists will develop a method of germ line gene therapy that alleviates certain types of inherited conditions. This new method may remove the need for each generation with an inherited condition to be subjected to individual therapy. Removal of such a need for individual therapy may come to be regarded as more morally acceptable than it is at present. In fact, continuing to perform the treatment on each individual might be seen as a poor moral choice. In this sense, the absolute prohibition on such methods being patentable on moral grounds alone is difficult to support. If a new amendment, reflecting these scientific developments, takes as much time as it took to adopt this Biotech Directive, then there is a real possibility that the laws will prevent sick people from obtaining a potentially more humane treatment.

Products isolated from the human body through a technical process susceptible to industrial exploitation are patentable,¹⁷³ but patent law must be applied in a manner that safeguards the dignity and integrity of the person.¹⁷⁴ Transgenic plants, animals, and their progeny are also patentable according to the Biotech Directive.¹⁷⁵ Regarding animals, a balancing of the medical benefit versus the animal's suffering is required.¹⁷⁶ If the animal's suffering is incommensurate with the expected benefit, then a patent should not be granted.¹⁷⁷ Gene sequences are also patentable if the industrial application of the gene sequence is disclosed in the application.¹⁷⁸ These provisions are similar to the EPC, except that transgenic plants are patentable under the Biotech Directive, and unpatentable under the EPC in

172 *See id.* art. 6, para. 2(b). Parliament and the Council take the position that processes for modifying the germ line genetic identity of human beings should be excluded equivocally from patent protection. *Id.* para. 40.

173 *Id.* art. 5, para. 2.

174 *Id.* para. 16.

175 *See id.* art. 4, para. 2.

176 *See id.* art. 6, para. 2(d).

177 *See id.* The balancing test introduced by the Biotech Directive is similar to the test used by the EPO when determining the patentability of a transgenic animal. *See HARVARD/Onco-Mouse, supra* note 72, at 527.

178 *See id.* art. 5, paras. 2–3.

light of recent EPO decisions.

Article 11(1) deals with the so-called “farmer’s privilege” and represents a provision unique to the Biotech Directive.¹⁷⁹ It allows a farmer to retain material from one year to the next for his own use on his farm.¹⁸⁰ This provision would decrease the royalty income of seed companies for crops like wheat, rice, soybean, and cotton.¹⁸¹ The effect of this provision will be more products like Monsanto’s “Terminator” cottonseeds, which contain the gene for a ribosome inhibitor protein.¹⁸² This protein terminates protein production within the seed resulting in the death of all cells in the seed.¹⁸³ As a result of this genetic process, the farmer can grow cotton from the seeds he buys, but cannot retain the seeds for the next year because the plants are now infertile.¹⁸⁴

The sale of breeding stock to a farmer by the patentee, or with the patentee’s consent, implies authorization for the farmer to use the protected livestock for breeding purposes on his own farm in order to replenish their numbers.¹⁸⁵ This appears to indicate that the holder of a patent involving livestock would not be able to prevent the farmer from breeding that animal. However, any Member State that is a party to the Biotech Directive may limit the extent and conditions of the farmer’s right to use protected livestock for the farmer’s own purposes.¹⁸⁶ Apparently, this restriction does not apply to plant varieties because there is not a limitation in the corresponding plant section.¹⁸⁷

179 See *id.* art. 11, para. 1; *Biotechnology: Council Approves Directive on Protecting Inventions*, EUROPEAN REP., June 24, 1998, available at 1998 WL 19804781.

180 See Biotech Directive, *supra* note 14, art. 11, para. 1.

181 See Jim Webster, *Monsanto’s Terminator Leaves Seed Buyers No Hasta La Vista*, SCOTSMAN, Dec. 14, 1998, at 16. Farmers do not usually save the seed of hybrid crops because the seed from those crops is inferior due to the hybridization process. *Id.* Because wheat, rice, soybean, and cotton are not normally grown from hybrid seeds, farmers may save their seed, thus avoiding royalty fees. See *id.*

182 See *id.*

183 See *id.*

184 See *id.*

185 See Biotech Directive, *supra* note 14, art. 11, para. 2.

186 See *id.* art. 11, para. 3.

187 See *id.* art. 11, paras. 1, 3.

Article 12(1) states that when a breeder cannot acquire or exploit a plant variety without infringing a prior patent, he or she may apply for a compulsory non-exclusive license for a right to use the patented invention.¹⁸⁸ Similarly, Article 12(2) states that when the holder of a biotech patent cannot exploit it without infringing a prior plant variety right, then he or she may also apply for a compulsory license for the use of that plant variety.¹⁸⁹ With respect to both provisions, the right to claim a compulsory license is qualified because before such a license is granted, the person seeking the license must show that he or she has applied unsuccessfully to the rights holder for a license.¹⁹⁰ Additionally, he or she must show that the plant variety or the invention constitutes significant technical progress compared to the invention claimed in the patent or the protected plant variety.¹⁹¹

The Biotech Directive does not supersede the EPC because the two are separate bodies of law.¹⁹² The Biotech Directive is binding on the European Union Member States.¹⁹³ The Member States were required to update their laws for compliance with the Biotech Directive by July 30, 2000.¹⁹⁴

C. Patent Laws of the Various European Community Nations

As mentioned earlier, the EPC is exclusively a patent registration system.¹⁹⁵ The degree of protection afforded the inventor depends entirely upon the domestic patent laws of the individual nations. Though a discussion of the patent laws of the individual Member States is beyond the scope of this examination, it is sufficient to understand that these laws will afford a spectrum of protection. This lack of uniformity is the

188 *Id.* art. 12, para. 1.

189 *Id.* art. 12, para. 2.

190 *See id.* art. 12, para. 3.

191 *Id.* art. 12, para. 3(b).

192 *See id.* art. 1. In addition, some EPC members are not Member States of the European Union. Compare *supra* notes 8 and 86 and accompanying text.

193 *See* Biotech Directive, *supra* note 14, art. 18.

194 Seventeenth Annual Report on Monitoring the Application of Community Law (1999), COM(2000)92 final at 32.

195 *See supra* text accompanying notes 87–89.

weakness that patent opponents exploit in order to challenge an invention. The new Biotech Directive will bring some uniformity as to what living matter can be patented.

V. SHOULD THE EPO DEAL WITH MORALITY ISSUES?

Patent law is grounded in the assumption that new processes and products providing material benefits or enhancing the quality of human life are desirable and should be encouraged.¹⁹⁶ But other ideas should also be given weight if science and technology are not to lead to a sterile culture of consumerism. One of these ideas is the ethical dimension of biotechnology. European patent law is not silent on the question of morality.¹⁹⁷ EPC Article 53(a) has provided a convenient international forum for the Greens, animal rights activists, and others to object to the grant of specific biotechnology patents. While most of the arguments in a patent dispute are resolvable by factual inquiry and legal reasoning, moral arguments are more difficult to deal with because of competing policies and public views.¹⁹⁸

A. *The Morality of Patenting Inventions*

EPC Article 53(a) does not call for examination of the ultimate intentions of the patent holder, so the morality of the act of patenting does not come into question.¹⁹⁹ Leaving aside the patent publication aspect, it is the actual exploitation of the particular invention to which the moral test must be applied.²⁰⁰ The claim that it is wrong to patent certain substances, organisms, or processes calls for an ethical judgment that is

¹⁹⁶ See *supra* text accompanying notes 72–75.

¹⁹⁷ See European Patent Convention, *supra* note 13, art. 53(a) (disallowing the grant of a patent that is “contrary to morality”).

¹⁹⁸ See Christopher Joyce, *Patent on Mouse Breaks New Ground*, NEW SCIENTIST, Apr. 21, 1988, at 23 (noting that in the Harvard Mouse case moral arguments in the U.S. Patent and Trademark Office delayed Harvard scientists Leder and Stewart in obtaining a patent for their genetically altered mouse that was predisposed to breast cancer). It took the U.S. patent officials three times the normal eighteen months to study the Harvard mouse application. *Id.*

¹⁹⁹ See European Patent Convention, *supra* note 13, art. 53(a).

²⁰⁰ See *id.*

outside patent law, and a judgment which patent officials and judges are reluctant to make and should not be called upon to determine.²⁰¹

If one asserts that patenting biotechnology inventions is a morally questionable activity, the context in which it arises must be considered. First, there is productive research, which creates the subject matter to be patented. Next comes the patenting step, along with the publicity and commercial exploitation of the invention. Unless performing biotech research or commercially exploiting the fruits of such research is wrong, focusing on the ethical aspect of obtaining a patent is simply misplaced. Patenting itself is neither right nor wrong, and the refusal of a patent is a futile gesture that cannot stop the exploitation of an invention. On the other hand, if society were to judge that the practice of a particular invention deserved to be banned by law, then nobody would bother to patent it.

B. The "Patenting Life" Objection

The most fundamental objection to biotechnology patents is that they are patenting life, and therefore the patent holders own life.²⁰² Science cannot yet tell us precisely what life is but we

201 See HARVARD/Onco-Mouse, *supra* note 72, at 10–11 (concluding that the patent process is not the proper legislative tool for resolving issues that might arise regarding the patenting of higher organisms such as mice); see also Decision T356/93, Plant Genetic Systems/Glutamine Synthetase Inhibitors, *supra* note 97, at 361. ("[T]he assessment of risks and the consequent regulation of the exploitation of the invention were a matter [sic] for other bodies to consider."); Howard Florey/Relaxin, *supra* note 106, at 552 ("The imposition of a moratorium by the EPO on patenting human genes would . . . be inappropriate and moreover impossible because there is no legal mechanism in the EPC for doing so [T]he EPO is not the right institution to decide on fundamental ethical questions.").

202 See RIFKIN, *supra* note 152, at 37 (expressing the belief that "[g]enes are the 'green gold' of the biotech century" and explaining that biotech companies actively seek any organisms with rare genetic traits in order to isolate and modify the genes and obtain a patent). According to the author, this constitutes patenting life. See *id.* The author speculates that there is a real "possibility for the patenting of all of the separate parts, if not the whole, of a human being." See *id.* at 45; see also Howard Florey/Relaxin, *supra* note 108, at 549–50 (describing opposition to a patent relating to a human DNA fragment because the "patenting of human genes means that human life is being patented").

ordinarily use the word “life” as an abstraction from concrete living things. From the point of view of the patent laws, patenting life seems to be a meaningless notion because the law does not provide for patenting of abstractions. This unfortunately does not prevent the “patenting life” objection to be used as an effective slogan to mislead people into thinking that a sinister move is being made to monopolize the very essence of life.²⁰³

C. Patenting Microorganisms, Plants, and Animals

The objection to patenting microorganisms is usually merged into the general condemnation of patenting life.²⁰⁴ This claim is entirely nebulous. We cannot have bread, wine, antibiotics, and vaccines without the use of microorganisms. Efforts to produce such important products more effectively through improved and patentable strains of microorganisms are meritorious.

The morality argument is unpersuasive when applied to the patenting of plants. Usually the morality objection challenges the use of genetically manipulated plants on the grounds of public and environmental safety.²⁰⁵ Though the question of

203 See VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 3–5 (1997) (stating that the cultural knowledge and biological diversity of non-Western societies are being plundered by Western powers by means of obtaining patents on “life-forms” and by patenting their indigenous knowledge); see also RIFKIN, *supra* note 152, at 63 (stating that “[t]he idea of private companies laying claim to thousands of genes as their exclusive intellectual property has resulted in growing protests around the world”). Rifkin estimates that “within less than ten years, all one hundred thousand or so genes that comprise the genetic legacy of our species will be patented, making them the exclusive intellectual property of global pharmaceutical, chemical, agribusiness, and biotech companies.” *Id.* at 62–63.

204 See RIFKIN, *supra* note 152, at 41–43 (discussing the U.S. Supreme Court’s decision to allow Ananda Chakrabarty’s patent on a genetically engineered microorganism designed to consume oil spills in the oceans and noting that the “Supreme Court cleared the way for the commercial exploitation of life”).

205 See Decision T356/93, *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, *supra* note 97, at 363 (describing how Greenpeace, the opponent of the patent for a herbicide-resistant plant, insisted, as grounds for revocation, that the exploitation of the invention had resulted in “serious, irreversible environmental risks”); see also *Serving up the Future, Genetically Engineered Foods are Here—But the Best Are Yet to Come*, 2 LAB REPORTER 1, 44 (2000) (stating that critics of genetically modified foods claim that the use of gene markers that confer antibiotic resistance could spread those

safety is important, it is primarily a matter of complying with other laws and regulatory procedures, which have been established as matters of public policy. The mechanisms for proper use of genetically modified organisms²⁰⁶ and their deliberate release into the environment²⁰⁷ are set forth in detailed Directives of the Council of the European Union.²⁰⁸ It would clearly be immoral to act irresponsibly in matters affecting public health, but the legal control over genetically modified plants has nothing to do with granting patents on the plants themselves. To date, no positive evidence exists that genetically engineered plants are harmful to people, that there has been a spreading of herbicide-resistant genes to other plants, or that there has been a transformation of crops into weeds.²⁰⁹ It is normal to expect that some of the mistrust among Europeans regarding genetically modified crops is caused by their deadly experiences with mad cow disease. This public trust can be regained in part by establishing labeling laws and long-term monitoring systems that would allow early detection of potential problems.²¹⁰ Scientists should be more careful what they create as well.²¹¹ However, an outright refusal to grant

genes to pathogens in the consumer's body and diminish the disease-fighting ability of antibiotics) [hereinafter *Genetically Engineered Foods*].

206 Council Directive 90/219 on the Contained Use of Genetically Modified Micro-Organisms, art. 1, 1990 O.J. (L 117) 1.

207 Council Directive 90/220 on the Deliberate Release into the Environment of Genetically Modified Organisms, art. 1, para. 1, 1990 O.J. (L 117) 15.

208 See *supra* notes 206–07.

209 See Declan Butler et al., *Long-Term Effect of GM Crops Serves Up Food for Thought*, 398 NATURE 651 (1999) (stating that scientists believe that health risks caused by genetically modified foods are for the most part hypothetical); *Genetically Engineered Foods*, *supra* note 205, at 44 (discussing only potential risks and showing that risks are difficult to prove or disprove).

210 See Butler et al., *supra* note 209, at 651.

211 See, e.g., Barry A. Palevitz, *DNA Surprise: Monsanto Discovers Extra Sequences in its Roundup Ready Soybeans*, SCIENTIST, July 24, 2000, at 20. Monsanto's Roundup Ready soybeans contain two extra bacterial DNA sequences, one with seventy-two base pairs and the other with 250. *Id.* at 20–21. Monsanto is not certain how extra inserts got into their soybean genome. *Id.* at 21. U.S. and Canadian scientists believe that the extra DNA does not have any impact on the safety of the soybeans. See *id.* at 20. Both the U.S. Department of Agriculture and the Food and Drug Administration agree that there is no safety concern. *Id.* at 20. Nonetheless, the unexpected discovery has cast some doubts on the reliability of genetically modified foods in Europe. See *id.* at 22. Had

patents for genetically engineered plants will not be the best solution, especially for underdeveloped countries.²¹²

The morality argument appears more pertinent regarding the patenting of animals. Because we are dealing with sentient creatures, we must ask whether that has any moral implications. First, it is necessary to address the objection that animals are God's creatures, not the property of biotech companies, and should never be reduced to the status of invention, let alone a patentable one.²¹³ The term "invention" in patent law encompasses a wide variety of items that are presented as new and improved over what is already known and used.²¹⁴ Patent law is concerned with whether the difference from the prior art required inventiveness to accomplish or was obvious to the skilled person.²¹⁵ In the case of a transgenic organism, legal examination focuses upon the difference from the prior art. Because this difference does not occur naturally, it is reasonable to describe it as a work of human ingenuity. In the case of a transgenic organism, the inventor does not claim to have created the whole organism. The patent must cover the modified organism as a whole because the difference cannot be used in isolation.

It is true that animal experimentation is an important part of the development of human drugs and treatments for various diseases. It is also true that animals in research are often used as tools for human ends, in ways that may involve suffering. An animal's pain and suffering is distressing to many people. But such suffering, while a real moral issue for some, should have nothing to do with the question of patents for improved test animals. Rather than attacking research institutes and biotech

Monsanto's scientists sequenced the construct, they probably would have known about the additional DNA. *Id.* at 21. One may wonder whether the expense of sequencing the final construct would have been a rather small price to pay to prevent the public from turning against Monsanto's product.

212 See Palevitz, *supra* note 38, at 14 (asserting the benefits of high-tech foods for developing countries); see also Florence Wambugu, *Why Africa Needs Agricultural Biotech*, 400 NATURE 15, 15-16 (1999) (discussing the need for high-tech solutions to Africa's food needs).

213 See Rifkin, *supra* note 152, at 45-46.

214 See European Patent Convention, *supra* note 13, arts. 54(1), 56.

215 See *id.* art. 56.

companies for “patenting life,” the fundamental question that society must settle is when and how to utilize animal experimentation. The grant of patents is under attack because the European patent system presents an easy target and gives the opponents a platform for publicity.²¹⁶ But the truth is, patent officials decide the patentability of transgenic animals’ against a background in which the practice of breeding and using laboratory test animals is widely accepted, and even necessary if medical science is to advance.²¹⁷ If these practices are not immoral per se, then the opponents should have the burden of convincing patent officials that it becomes immoral by the introduction of genetic manipulation or some other technique of biotechnology in the breeding process.

D. Patenting Material Derived from Human Tissue

Patents have been granted on materials isolated from human tissues.²¹⁸ In the Howard Florey/Relaxin case, the Green Party challenged the validity of European Patent No. 112 149 granted to the Howard Florey Institute of Experimental Physiology and Medicine for the gene for human H2-relaxin, a hormone involved in reproduction.²¹⁹ The gene was isolated from ovarian tissue removed during gynecological procedures.²²⁰ Opponents’ argued that “it constitutes an offence against human dignity to make use of a particular female condition (pregnancy) for a technical process oriented towards profit.”²²¹ The opponents also claimed that patenting human genes amounts to patenting human life and “modern slavery since it involves the dismemberment of women and their piecemeal sale to

216 See *supra* notes 102–08 and accompanying text.

217 See HARVARD/Onco-Mouse, *supra* note 72, at 527–28 (noting that patent examiners balance the benefit that mankind will derive from the use of the transgenic animal against the cruelty that the animal and the environment will suffer as a result of the exploitation of the particular invention).

218 See Howard Florey/Relaxin, *supra* note 108, at 549, 553 (upholding a patent on material originally taken from human tissue).

219 *Id.* at 543–44, 546; Gerald Dworkin, *Should There Be Property Rights in Genes?*, 352 PHIL. TRANSACTIONS 1077, 1080 (1997).

220 Howard Florey/Relaxin, *supra* note 108, at 550.

221 *Id.* at 549.

commercial enterprises throughout the world”²²² despite the fact that the tissue was provided with consent.²²³ The Opposition Division rejected all objections and sustained the patent.²²⁴ The Opposition Division reasoned that many life-saving substances are isolated from the human body and that the practice is explicitly approved by Community regulations.²²⁵ The Opposition Division also stated that the allegations that human life is being patented were unfounded because DNA did not constitute life and a human being could not be reconstructed from the total of human genes.²²⁶ It is hard to conceive what harm or injury is caused to the tissue donor by patenting a gene or a derived cell line when the donor has expressly consented. What is disturbing in this case is that the Green Party members of Parliament turned to the EPO instead of attempting to change the law by the adoption of a legislative act.

E. Patenting Genes

Opponents argue that because genes exist in nature, they can be discovered but not invented.²²⁷ Consequently, because the law says that discoveries are not patentable, genes cannot be patented.²²⁸ Those who describe DNA sequences as a mere discovery could argue that gene cloning is a routine laboratory practice. This argument would be relevant only to the issue of inventiveness, i.e., the issue of how much ingenuity is required to isolate genes.²²⁹ The evaluation should be done on a case-by-case basis, and a broad general dismissal is not justified.

Another argument against patenting genes is the lack of novelty argument: because of their preexistence in nature, genes cannot fulfill the patent law test for novelty.²³⁰ But the novelty

²²² *Id.*

²²³ *See id.* at 550.

²²⁴ *Id.* at 553.

²²⁵ *See id.* at 550.

²²⁶ *See id.* at 551.

²²⁷ *See id.* at 548. *See also* Rifkin, *supra* note 152, at 45.

²²⁸ *See* Howard Florey/Relaxin, *supra* note 108, at 548.

²²⁹ *See* European Patent Convention, *supra* note 13, art. 56.

²³⁰ *See* Howard Florey/Relaxin, *supra* note 108, at 547–48; European Patent Convention, *supra* note 13, art. 54(1) (stating that an invention is novel “if it does not

test is framed in terms of availability to the public.²³¹ It focuses only upon what is already in the public domain through public disclosure or use prior to the filing of the patent application.²³² Genes do not easily fit into this scheme. To be considered novel, the gene must not have any known existence and must be isolated for the first time.²³³ The contribution to the art on which gene patents are based is the gene's availability in a form that can be utilized to produce an expression product or to transform an organism of another species giving rise to a new, transgenic organism. Genes are therefore a special case in the broad class of naturally occurring substances, which in appropriate circumstances can be patented.²³⁴ The mere pre-existence of the substance in nature is insufficient to overcome the objection to patentability.²³⁵

In conclusion, the crux of the matter is whether morality should play a part in the determination of an intellectual property right, or whether morality should be confined to the area of intellectual property law. For example, an intellectual property right, once granted, can be subjected to other restrictions by way of regulation, thereby controlling the exploitation of the protected material.

The UPOV Convention follows the latter model, stating the minimum requirements with which each Member State must comply, and is silent on the specific matter of morality.²³⁶ Article 17, however, could be read as providing the contracting parties with the option of including a morality clause if they think it is appropriate. Article 17(1) states that "[e]xcept where expressly provided in this Convention, no Contracting Party may restrict

form part of the state of the art").

231 See European Patent Convention, *supra* note 13, art. 54(2) (stating that the state of the art includes everything available to the public prior to the date of the filing of the patent application).

232 See *id.*

233 See Howard Florey/Relaxin, *supra* note 108, at 547–48.

234 See *id.* at 548 (explaining that, although a previously unknown substance may occur in nature, if that substance is isolated and a process for obtaining it is developed, the substance and the process may be patentable). An example of a naturally occurring patentable substance is blood clotting factors. *Id.* at 550.

235 See *id.* at 549.

236 See UPOV Convention, *supra* note 119, art. 6.

the free exercise of a breeder's right for reasons other than of public interest.²³⁷ As a result, Member States of the UPOV Convention must allow the breeder to fully exploit the rights he or she holds, unless such use would not be in the "public interest." What constitutes being in the public interest is left to the determination of each Contracting State.²³⁸

Although the UPOV Convention does not obligate its participating states to address the issue of public policy, that is not the case in the context of the Community plant variety rights.²³⁹ Council Regulation 2100/94 clearly shows that the Commission, for purposes of the Community plant variety rights, has chosen to interpret "public interest" as including a determination of morality. Article 13(8) of the Community Regulation states in part that

the exercise of the rights conferred by Community plant variety rights may not violate any provisions adopted on the grounds of public morality, public policy or public security, the protection of health and life to humans, animals or plants, the protection of the environment, the protection of industrial or commercial property, or the safeguarding of competition, of trade or of agricultural production.²⁴⁰

What is important regarding Article 13(8) is not that it incorporates issues relating to morality into the plant varieties law, but that it clearly indicates that a plant variety right, once granted, does not permit the rights holder to use that right for all purposes.²⁴¹ There is no morality determination with respect to the grant of a right.²⁴² Instead, there is a morality

237 *Id.* art. 17(1).

238 *See id.* If *ordre public* and morality are equated with matters relating to public policy, then the term "public interest" may encompass those same notions mentioned in the EPC. *See supra* text accompanying notes 97–101.

239 *See* UPOV Convention, *supra* note 119, art. 5; Council Regulation 2100/94 of 27 July 1994 on Community Plant Variety Rights, art. 13, para. 8, 1994 O.J. (L 227) 1, 6 [hereinafter Council Regulation 2100/94], *amended by* Council Regulation 2506/94 on Community Plant Variety Rights, 1995 O.J. (L 258) 3.

240 *See* Council Regulation 2100/94, *supra* note 239, art. 13, para. 8.

241 *See id.*

242 *See id.* art. 6.

determination in regard to the exercise of the granted right.²⁴³ This shift has the effect of moving the question of morality away from the intellectual property right itself, and placing it within the more appropriate context of regulation of the use of the protected right, which should be regulated to be consistent with factors outside the plant variety rights system.

In conclusion, it is undeniable that biological research presents profound moral questions, especially in the field of human reproductive technology. But the relevant debates should begin with the research and its potential uses, and not with the wholly subordinate issue of patents. The patent issue is not a shortcut to the resolution of more difficult questions, and until those are properly addressed, patenting should not be singled out for attack. Article 17(1) of the UPOV Convention and Article 13(8) of Community Regulation 2100/94 provide an excellent example of an alternative means by which issues relating to morality can be, or are removed, from the framework of the intellectual property rights system.

VI. CONCLUSION

The European Union recognizes the importance of biotechnology as one of the most promising technologies of the future. The Member States have spent a considerable amount of time and effort to come to an agreeable position regarding what biotechnology developments they would embrace for the future and what biotechnology techniques they would ban on various moral and ethical grounds. The Commission, the Council of Ministers, and the European Parliament have finally been able to adopt a law that reflects the Member States' predominant views on the subject of patentability of biotech inventions. The newly adopted Directive represents an improvement in the development of patent law for most of the Member States. The Directive harmonizes European patent laws to some extent, in an attempt to provide sufficient legal protection for biotech inventions with the hope of strengthening the European biotech industry through increased levels of research and development investment in European life science companies. Nonetheless,

²⁴³ See *id.* art. 13, para. 8.

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there are major hurdles on the way to the desired success. The morality and *ordre public* provisions in the new Directive, while somewhat less constraining on inventors than EPC Article 53, are an obstacle for the development of the European biotechnology industry. In light of the prolonged ethical debates in the European Parliament during the adoption of the Directive, removal of these provisions from European patent law does not seem plausible in the foreseeable future. It is unfortunate that the legislators have put those provisions in such an inappropriate place. Still, patent examiners must interpret the EPC Article 53 exceptions narrowly in order to minimize their use for disruptive purposes. This is the most that the current European patent laws can provide to boost capital investment in life sciences.

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* This Comment received the Chong Choe Writing Award.