THE EUROPEAN UNION'S SELF-DEFEATING POLICY: PATENT HARMONIZATION AND THE BAN ON HUMAN CLONING

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1. INTRODUCTION

The European Parliament's\(^1\) approval of a directive,\(^2\) ten years in the making, represents a huge step towards improving the cli-

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\(^1\) The European Parliament, located in Strasbourg, is a governmental body of the European Community ("EC") created by the founding Treaty on European Union. See TREATY ESTABLISHING THE EUROPEAN COMMUNITY, Feb. 7, 1992, O.J. (C 224) 1 (1992), [1992] 1 C.M.L.R. 573 (1992) [hereinafter Maastricht Treaty]. It is composed of representatives of the member nations ("MEP"s) who are elected to five-year terms. Although it has recently taken on a greater legislative role, the European Parliament is primarily a consultative and supervisory body. It has the power to refuse assent to agreements and protocols, which is, in effect, a veto power. The European Commission is accountable to the Parliament who can censure and require Commissioners' resignations. The Parliament also monitors the activities of other European Union ("EU") institutions through committees of inquiry and is empowered to conduct inquiries into complaints or petitions and bring proceedings before the Court of Justice. The Treaty Establishing the European Community defined the Parliament as a consultative body whose views should be taken into consideration regarding issues of common foreign and security policy in addition to activities generally concerning Justice and Home Affairs. See PAUL CRAIG & GRAINNE DE BURCA, EU LAW: TEXT, CASES, AND MATERIALS 57-65 (1995). For a discussion of the power of the Parliament in EU decision making, see infra Section 3.2, noting that Parliamentary amendments can only be overruled by a unanimous vote of the European Council.

\(^2\) A directive is a type of EC legislation that can be aimed at one or more specific member states and is "binding as to the end to be achieved while leaving choice of form and method open to the Member States." CRAIG & DE BURCA, supra note 1, at 99. It is distinguishable from a regulation which is
mate for the biotechnology industry in Europe. The Directive on the Legal Protections of Biotechnologies ("the Directive")\(^3\) rewrites European patent law in an effort to attract and retain the profitable business of biotechnological innovation.\(^4\) However, moral concern about the innovation at the edge of this field, including human and animal cloning\(^5\) and transgenic experimentation,\(^6\) threatens to undermine the effort to be at the forefront of a new field. The Directive, reflecting these ethical reservations, contains strict limitations on patentable subject matter and an explicit prohibition against human cloning. The inclusion of such

binding on all member nations and provides specific means to the stated end. In this way, directives are more flexible and more accommodating to national law, making them a "particularly useful device when the aim is to harmonize the laws within a certain area, rather than produce strict uniformity." Id. at 100.


\(^4\) See id. art. 1 (stating its goal to "maintain and encourage investment in the field of biotechnology").

\(^5\) A whole animal was cloned from an adult donor cell for the first time in February 1997 when Dr. Ian Wilmut revealed his cloned sheep. Scientists have known for some time that, theoretically, cloning could be achieved by placing the nucleus of a cell from the animal to be copied in an egg whose nucleus has been removed. See What Do You Get If You Cross . . . ?, ECONOMIST, Aug. 15, 1987, at 67-68. Wilmut solved a long-standing problem with this theory by recognizing that the donor cell must be in the same phase of the cell cycle as the egg. By starving the donor cell, Wilmut stopped cell division and assured that the donor cell and egg were in the same phase and could be fused. After fusion, he placed this "zygote" in a surrogate mother to mature. See Estelle J. Tsevdos et al., Law and Nature Collide, NAT'L L.J., June 16, 1997, at Cl. For a more thorough and scientific discussion of the cloning process, see I. Wilmut et al., Viable Offspring Derived From Fetal and Adult Mammalian Cells, 385 NATRE 810 (1997).

\(^6\) Transgenesis is defined as the introduction of foreign genetic material into embryos at early stages of development. This process has been very useful in agriculture to improve livestock and create "tastier steak" and "softer sweater[s]." What Do You Get If You Cross . . . ?, supra note 5, at 67. It has also been used to introduce the genes from one species to another to create chimeras, or animals composed of a mosaic of cells. Geeps, created in Cambridge, England in 1983, have the horns of a goat and the coat of a sheep and mating can yield either a sheep, a goat, or a hybrid. Transgenesis was also used to inject rat-growth hormone into fertilized mouse eggs to create "mighty mice." The process has enormous potential for medical research as well. Researchers have injected mice embryos with cancer causing human oncogenes to study the disease. The technique was used to inject human blood-clotting chemicals into sheep which then produced milk containing this chemical that was purified and sold to hemophiliacs. See id. at 67-69.
limitations directly contradicts the stated purpose of the Directive to attract biotechnology innovation.\(^7\)

The impetus for this revision of the European Union ("EU") patent laws was the perceived benefits that the biotechnology industry could bring to Europe's medical, veterinary, stockbreeding, and agro-food industries.\(^8\) Biotechnological innovation not only promised huge strides in the understanding of illness and fighting disease, but also offered the prospect of job creation.\(^9\) In addition, the EU saw that it had fallen far behind the United States in the competition for biotechnology dollars and had to act to create a friendly environment for biotechnological research.\(^10\)

With this goal in mind, the EU aggressively pursued a harmonization of patent policy that would give Europe a competitive advantage in biotechnology innovation. However, while the EU was willing to reform its economics, it was not willing to sacrifice its morals to attract the industry's attention.\(^11\) The result was a basic contradiction between an economic policy designed to encourage innovation and a social policy that feared it. This Comment will explore the evolution in patent law and ethical

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\(^7\) See Biotech Directive, supra note 3, at ¶ 1-3, 10.


\(^9\) See id. § 1.3.1.

\(^10\) See id. §§ 1.3.1-1.3.2. The Economic and Social Committee specifically mentioned that competition with the United States is a motivating factor in patent reform, attributing a "brain drain" to the United States, which had issued 65% of the world's patents for biotechnological research in pharmaceuticals and had 1,300 biotechnology firms. See id. §§ 1.2.2-1.3.2. When compared with the European Community's 15% share and 485 firms, it became clear that the EU had to take steps to remain competitive. See id.; see also Peter Ford, Wary Europe Enters Biotech Age, CHRISTIAN SCI. MONITOR, June 10, 1998, at 1 (comparing 1996 figures). Ford reports that Europe's 584 biotechnology firms generated $2.2 billion in sales, whereas in the United States, 1300 firms generated $7.7 billion in sales. See id.

\(^11\) Europe's hesitancy is well noted. Biotechnology critic Jeremy Rifkin of the Foundation for Economic Trends has commented that "the European Community has a much greater sensibility to these issues." Good Morning America: Human Animal Mixing (ABC television broadcast, Apr. 3, 1998), available in LEXIS, News Library, ABCnews File; see also Ford, supra note 10, at 1 (comparing "different mindsets: hard charging American optimism and enthusiasm for the fruits of science against a more conservative and skeptical Europe," and suggesting that Europeans are "more worried about the ethical implications and the environmental effects of genetically engineered organisms than their American counterparts").
thought that has brought the EU to this state of contradiction. Section two will provide background on the economics of patent law in an effort to explain why Europe relied on patent reform to stimulate biotechnological investment. Section three will examine the flaws of earlier patent laws and the motivation to improve upon them. It will discuss the importance of harmonization for the stimulation of investment and employment and how the Directive was debated with these ends in mind. Section four will address the substantive law on human and animal cloning and other biotechnology that was included in the Directive. It will trace the social attitude toward this type of innovation in the EU and how this moral debate is reflected in the ultimate Directive. These discussions will include a comparison of the Directive with U.S. patent law and policy on biotechnological innovation in order to assess how the EU has positioned itself to compete in the international market. Finally, this Comment concludes that the EU’s contradictory policies may undermine the progress it had hoped the Directive would bring.

2. THE ECONOMICS OF PATENTS

In the words of economist Adam Smith, patents are a way in which the “state can recompense [innovators] for hazarding a dangerous and expensive experiment, of which the public is afterwards to reap the benefit.”12 While Smith did not invent the idea,13 he recognized the importance of the patent to safeguarding intellectual property and the profits that flow from such inquiries. It was precisely this role that the EU hoped patents could play in attracting biotechnological innovation.


13 The first patent is believed to have been awarded in 1474 when the Council of Venice enacted the first patent statute which offered a 10-year privilege to the inventor of a machine or process that improved or expedited silk-making. See id. at 996. Black’s Law Dictionary defines a patent as a “grant of some privilege, property, or authority, made by the government or sovereign of a country to one or more individuals,” and more specifically, as a “grant of right to exclude others from making, using or selling one’s invention and includes right to license others to make, use or sell it.” BLACK’S LAW DICTIONARY 1125 (6th ed. 1990).
Patent law corrects a market failure by allowing ownership of technological information which, in turn, creates the correct incentives for the production and consumption of information. The result is an efficient market for intangible technological information. Without patent law, the market for technology is burdened by externalities. Patents allow innovators to internalize the benefits of their investment by excluding benefit to others. Therefore, "the incentive to invent . . . is fostered by states


See SCHLICHER, supra note 14, at 1-16. Externalities are either external benefits enjoyed by people who do not pay for them or harms borne by people who are not compensated. See id. In either case, these benefits and harms distort the costs and benefits to producers and lead them to make inefficient decisions. "[T]he economic goal of patents is to induce investment and risk-taking in producing technological information about new products and processes that, in the absence of patents, the market would be unlikely to produce or produce as quickly due to an anticipated externality problem." Id. at 2-61.

Schlicher discusses the theory that, even without patent regulation, people would reach efficient bargains whereby consumers would agree to pay producers to develop desirable products. See id., at 1-16. The idea that absent the constraints of legal regulation, people would find the efficient amount of technological information is known as the Coase Theorem. See 1 THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 270 (Peter Newman ed., 1998). Schlicher notes that information, because of its intangible nature, is difficult to allocate in the bargaining process. See SCHLICHER, supra note 14, at 1-16. First, there is no way to limit its dissemination to the bargaining parties only, making it likely that some will refrain from the bargaining process in the hopes of getting a "free ride." Second, the Coase Theorem is contingent upon the assumption that there are zero transaction costs hindering the bargaining process; however, allocation of technological information has extremely high transaction costs. Unaware of what technology is necessary, people will overpay for the production of every type of innovation. For example, a person would have to enter into a bargain for an innovation to cure cancer long before that person knew whether he or she would need this technology personally. It is too costly for all potential beneficiaries to strike a bargain with all potential suppliers. For these reasons, pre-production agreements are impractical, and producers are forced to rely on legal structures to ensure a return on their investment. See id. at 2-5 to 2-7.

"One characteristic of technology is that it is difficult for the innovator to prevent others from using his innovation without his consent." SCHLICHER, supra note 14, at 2-5 (quoting W.F. Baxter, Issues in Science and
that grant innovators of new and useful products or processes the right to exclude others from using the new technologies. Because patents secure a return on investment, they encourage technological innovation. In turn, they stimulate the economy and are extremely important to the economic welfare of a nation.

Patents stimulate technological investment by creating security, the key to instilling incentive to innovate. An efficient, predictable patent system attracts businesses in search of guarantees that they will benefit from their research and development investments. Full commercial value can only be realized when inventions are not only patentable, but when the patents are enforceable with predictable reliability. Such predictable

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Technology, in _ANTITRUST LAW AND TECHNOLOGICAL INFORMATION_ 83 (National Academy of Sciences 1985). Patents prevent others from using the invention and assure that all the profits from innovation flow to the investor. For this right of exclusion, one must apply to the relevant regulatory body and comply with specified requirements that usually include documentation of an inventive step and industrial application. _See id._ at 1-45 to 1-46. A written description of the invention and often a physical sample must also be included with the application. Once approved, an applicant has a monopoly on the use and licensing of the invention for a statutorily determined length of time. For this period of time, the inventor reaps all the financial benefits of his discovery and collects licensing fees when he grants permission for the use of his work. The written and physical submissions then become public information, allowing others to expand upon the initial invention. _See_ Scalise & Nugent, _International Intellectual, supra_ note 14, at 86-88.

17 Scalise & Nugent, _International Intellectual, supra_ note 14, at 86.

18 The importance of technology to industrial growth has been empirically supported. One such empirical analysis found that technology alone accounted for 50% of the growth in industrial output in the United States from 1948 to 1985. _See_ Michael J. Boskin & Lawrence J. Lau, _Capital, Technology, and Economic Growth, in TECHNOLOGY AND THE WEALTH OF NATIONS_ 17 (Rosenberg et al. eds., 1992) (measuring the effect of technical progress and capital growth on industrial output).

19 _See_ The Harm of Patents, _ECONOMIST_, Aug. 22, 1992, at 17 (discussing the American patent system, but recognizing that "[c]onfusion, and the litigation that inevitably accompanies it, are threatening to suffocate innovation"). Unclear regulations and unpredictable judicial decision-making undermines the certainty required to encourage research and development expenditure.

20 _See_ Tsevdos, _supra_ note 5, at C1. For instance, scientific methodology is patentable; however, a claim for method infringement is difficult to enforce. It may be difficult for the regulator, and even the inventor himself, to detect an infringement on a method patent by inspecting the final product. In addition, enforceability depends upon the care with which the patent itself is drafted. _See id._ (noting that any patent on Dolly, the cloned sheep, should be carefully worded to include her offspring in order to protect the fruits of the inventor’s labors. If so drafted, a simple DNA test could prove infringement allowing the patent to be readily enforceable); _see also_ Ford, _supra_ note 10, at 1 (quoting
protection creates incentive for experimentation and spurs the advancement of science. It encourages rapid innovation through a winner-take-all mentality that handsomely rewards the first innovator and denies all benefits to the second-place finisher. In addition, the disclosure of information prevents the duplication of research and thus frees resources for new endeavors. 21 Disclosure also allows newcomers to build on the knowledge of their predecessors.

The protection of a predictable patent system is of particular importance to the biotechnology industry where success requires massive investment. "[T]he development costs are high with long lead times before significant commercial returns are achieved." 22 "It is estimated that 90 percent of biotech companies will have drugs that fail or are delayed," incurring research costs for projects that may never produce a profit. 23 Without the opportunity to recoup the sizable research and development costs, many would be deterred from biotechnological experimentation. 24 Therefore, life science firms find that "patent protection is essen-

Brian Yorke, head of corporate intellectual property for the Swiss pharmaceutical giant Novartis, describing the need for patent legislation to protect biotech inventions as "essential to give the stability and assurance we need to develop our biotech business").

22 Liz McRobb, Patents Row Over Genetics Breakthrough, SCOTSMAN, Mar. 12, 1997, at 26; see also Scalise & Nugent, Patenting Living Matter, supra note 12, at 997; The Harm of Patents, supra note 19, at 17 ("[H]ard as they may try, patent offices cannot be certain of what is truly new and 'non-obvious'—particularly in fast-moving fields like electronics and biotechnology."). The article recognizes biotechnology patents as an area where uncertainty can raise legal costs and confusion and ultimately create a disincentive to innovation. See also 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 (recognizing that it takes a quarter of a billion dollars and four to seven years to bring a biotechnology-based pharmaceutical product to market).
23 Lisa Buckingham, Shock for Shares as Treatments Fail to Yield Hoped-For Dividends, GUARDIAN (London), Apr. 28, 1998, at 3.
24 See, e.g., Biotechnological Patent Protection Act of 1991: Hearings on H.R. 1417 Before the Subcomm. on Intellectual Property and Judicial Admin. of the House Comm. on the Judiciary, 102d Cong., 1st Sess. 13 (1991) [hereinafter House Hearings] (justifying increased patent protection with the fact that biotechnology firms spend almost half their revenues on research and development); Greens v. Genes, ECONOMIST, July 19, 1997, at 18 ("[W]ithout proper patent protection, biotech firms are unlikely to spend the huge sums needed . . . as European firms have shown.").
tial if they are to risk financial resources and years of research and development bringing new and useful products to market.”

3. **THE EVOLUTION OF PATENT PROTECTION: EUROPE’S SEARCH FOR THE OPTIMAL REGIME**

The efficiencies of harmonized patent law have been internationally recognized for over a century. Europe, while involved in international harmonization efforts, saw the advantage of a uniform system for the European Community and harmonized the patent application process. This Section will examine the uniformity that the European Patent Commission (“EPC”) created. More importantly, it will examine the weaknesses of this system that spurred the drafting of the Directive. The harmonization achieved by the Directive’s revision of patent law and its implications for the biotechnology industry will also be examined.

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26 For a discussion of the benefits of harmonization, see infra Section 3.3.

27 See Scalise & Nugent, *Patenting Living Matter*, supra note 12, at 996-98. Efforts to harmonize world patent treatment date back to The Paris Convention for the Protection of Industrial Property in 1883. See Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583 [hereinafter Industrial Property Convention]. This Convention required nations to afford foreigners the same protections that it granted its own citizens. However, it did not require nations to provide any protections for its own citizens at all. The Convention also lacked any provision for settling disputes. See Laurinda L. Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U. J. INT’L L. & POL’Y 769, 778-79 (discussing early international cooperation in intellectual property protection). Industrial Property Convention, supra. The World Intellectual Property Organization, a specialized agency of the United Nations, was responsible for administering the Patent Cooperation Treaty and the Paris Convention among other intellectual property agreements. See Hicks & Holbein, supra, at 781. In 1993, when the World Trade Organization (“WTO”) replaced the General Agreement on Tariffs and Trade (“GATT”), The Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”) was created and it is regarded as “the most significant advance in the international protection of intellectual property since . . . the late 19th century.” *Id.* at 783. Unlike its predecessors, TRIPS provided for a Dispute Settlement Body that can protect and enforce with teeth. See *id*. However, while TRIPS does provide “detailed minimum standards of intellectual property protection,” the signatory nations preserved significant autonomy over their own patent systems to allow for the considerable regional disharmony that motivated the EU to draft the Directive. *Id.* at 784. For instance, TRIPS allows, but does not require, member nations to limit patentability to “protect public order or morality, serious prejudice to the environment, and human, animal, or plant life.” *Id.* at 787. Despite efforts to strengthen international regulation of intellectual property rights, significant differences between national laws persist.
3.1. The European Patent Commission: Imperfect Protection

The European Community’s effort to create uniform patent policy commenced in 1973 when eleven nations adopted the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention and the International Convention for the Protection of New Varieties of Plants.\textsuperscript{28} The resulting EPC\textsuperscript{29} had, as its founding principle, a provision allowing applicants to be awarded patent rights in more than one country with a centralized registration system.\textsuperscript{30} One application resulted in a granting of a bundle of national patents. It was designed to be cost-effective and time-efficient.\textsuperscript{31}

3.1.1. Uniform Patent Application and Review Process

The EPC contained a uniform application process for granting patents in the member states. An application had to be filed in one of the European Patent Offices ("EPO") in Munich, Berlin, or the Hague, in English, French, or German.\textsuperscript{32} All applications included a request for a patent, a description of the invention, one or more claims, any drawings referred to in the description or claims, and an abstract.\textsuperscript{33}

\begin{footnotes}
\item[29] This was signed into existence in Munich as the Convention on the Grant of European Patents on October 5, 1973, with the intention of "strengthen[ing] co-operation between the States of Europe in respect of the protection of inventions." Convention on the Grant of European Patents, Oct. 5, 1973, 1 B.D.I.E.L. 985, preamble [hereinafter EPC]. Current members of the EPC include nations that are not EU members. Member nations are Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. See generally GERALD PATERSON, A CONCISE GUIDE TO EUROPEAN PATENTS: LAW AND PRACTICE (1995).
\item[30] The preamble of the EPC declares as its purpose the establishment of a single procedure for the grant of patents. See EPC, supra note 29, preamble. Under this common procedure, a "European Patent" is granted by the European Patent Office under the supervision of the Administrative Council. See id. arts. 2 & 4.
\item[31] See Scalise & Nugent, Patenting Living Matter, supra note 12, at 1013.
\item[32] See EPC, supra note 29, arts. 14(2) & 75(1)(b).
\item[33] See id. art. 78(1).
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All complete applications underwent an extensive and uniform review process after which the EPO rendered a decision on patentability. The Receiving Section of the EPO accepted applications and examined both filing and application requirements. Article 96 and Rule 51 of the EPC governed the substantive analysis of the patentability of the invention carried out by the Examination Division. The Legal Division was then responsible for entering the decision into the Register of European Patents from which the applicant was guaranteed an appeal as of right. The Boards of Appeal acted as courts, interpreting the EPC on a case by case basis. While they usually followed precedent, they were not bound to do so. After a written examination and an optional oral proceeding, the Boards issued decisions that were final.

Under EPC law, the contents of an application became public within eighteen months of the filing. Often, a final decision was not reached within this time frame, and thus the applicant ran the risk of publication before patent protection was approved. If the patent request was denied after publication, the inventor's work was left unprotected and open to public scrutiny. This possibility was not the only potential pitfall for an applicant as others could file in opposition to the patent within nine months of a grant. The Opposition Division heard opposition claims on the basis that: (a) the subject matter of the European patent was not patentable within the terms of EPO Articles 52 to 57; (b) the

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34 See PATERSON, supra note 29, at 3.
35 See id. at 12; see also EPC, supra note 29, art. 96 & rule 51.
36 See PATERSON, supra note 29, at 3.
37 See id. at 4.
38 See id. at 4-5 (discussing the organization and powers of the Boards of Appeal); see also EPC, supra note 29, art. 106 (granting appeal as of right).
40 See PATERSON, supra note 29, at 4.
41 See EPC, supra note 29, art. 93. This will apply unless the applicant requests earlier publication. See id.
42 See PATERSON, supra note 29, at 2-3.
43 See id.
44 See id. at 3.
European patent did not disclose the invention in a manner sufficiently clear and complete for it to be executed by a person skilled in the art; or (c) the subject-matter of the European patent extended beyond the content of the application as filed. If not revoked on opposition review, the right to the granted patent lawfully and exclusively belonged to the inventor or the successor in title for twenty years.

The centralized EPC not only followed a uniform procedure but applied a uniform standard when evaluating a patent application. They would grant patent protection to "any invention which is susceptible of industrial application, which are [sic] new and which involve [sic] an inventive step." The EPC allowed for two exceptions for those inventions that were "contrary to 'ordre public'" and were "plant or animal varieties or . . . biological processes for the production of plants or animals."

3.1.2. EPC Weaknesses: The Coexistence of Inconsistent Laws

The weakness of this centralized registration system was that it coexisted with national patent law. The EPC granted a patent that was theoretically valid in all member nations; however, the interpretation and enforcement of the patents were reserved for the laws of the individual member nations. The members were not bound by the EPC or the decisions of the Boards of Appeal and reserved the power to reject patents that were contrary to national law. When discussing patent law reformation, the Economic and Social Committee of the EU specifically cited the diverging national intellectual property laws as an obstacle to internal market development. In their words, the EU was

45 See EPC, supra note 29, art. 100 (citing grounds for opposition).
46 See PATTERSON, supra note 29, at 3, 21.
47 Scalise & Nugent, Patenting Living Matter, supra note 12, at 1013.
48 EPC, supra note 29, art. 53.
49 See PATTERSON, supra note 29, at 1; see also EPC, supra note 29, art. 74 (requiring that the European patent application be subject to the laws applicable in each state regarding national patent applications).
50 See PATTERSON, supra note 29, at 6-7.
51 See Opinion of the Economic and Social Committee, supra note 8, at § 1.1.1.
"over-compartmentalized," resulting in legal uncertainty and, consequentially, additional costs for businesses.\(^{52}\)

Considerable difficulties arose as a result of the often conflicting sources of patent law. One illustration was the granting of the EPC patent for the “Harvard Mouse” in April 1992.\(^{53}\) The “Harvard Mouse” was a mouse genetically engineered to be susceptible to cancer for research purposes. Under pressure from animal rights activists, the European Parliament revoked the patent in February 1993 and banned further animal patenting until a formal policy could be researched and enunciated.\(^{54}\) In deference to national law, this revocation was non-binding, resulting in diverging laws.\(^{55}\) Some member nations passed regulations specifically allowing the patenting of living matter,\(^ {56}\) thus confirming the ineffectiveness of the EPC’s harmonization attempt.

Without a consistent EU policy on the protection of innovations involving living matter, the result has been uncertainty and increased costs that undermine the value of patent law. Innovators remain unsure, not only of the patentability of their findings

\(^{52}\) Id. §§ 1.1.2., 1.3.2. The Economic and Social Committee’s concern about the lack of harmony in patent law is well recognized. See generally House Hearings, supra note 24 (discussing the history of international cooperation in intellectual property rights dating back to the Paris Convention for the Protection of Industrial Property in 1883). The importance of harmonization on a regional level has been recognized as well. “The effective and harmonious protection of intellectual property rights by member nations is a fundamental element for the implementation of a common market.” Hicks & Holbein, supra note 27, at 805. For example, the four member nations of Mercosur—Argentina, Brazil, Paraguay, and Uruguay—have expressed concern over radical differences that separate their respective intellectual property regimes. They are struggling with the “tension between the territorial nature of intellectual property norms and the implementation of the free circulation of goods and services within the region.” Id. at 802. This is the same tension the European Union was facing when considering harmonization. Similarly, the signatories of NAFTA confronted regional harmonization. “The NAFTA’s entire chapter on intellectual property rights raised the level of international protection of intellectual property, and thus serves as a model for the harmonization of intellectual property norms within a regional framework.” Id. at 803.

\(^{53}\) See Tsevdos, supra note 5, at C27.

\(^{54}\) See id.

\(^{55}\) See id. at C1.

\(^{56}\) Specifically, Germany and the U.K. are particularly progressive in the area of life patents and have both approved them since the mid-70’s. Thus, the revocation of the Harvard Mouse patent had no impact on its enforceability in these jurisdictions. See American Cyanamid v. Berk Pharm., 1976 R.P.C. 231 (1976) (approving of life patents in the United Kingdom); Baker’s Yeast Decision, 1975 GRUR 430 (BGH 1975) (allowing life patents in Germany).
but of the enforceability of a patent in the member nations. In addition, different interpretations of the patent and divergent national patent laws have led to differences in what constitutes an infringement. Patentees have been forced to defend their patents from infringement under differing national regimes. They have been forced to litigate in multiple jurisdictions to establish the scope of their patent, each time restructuring their tactics to conform with national law. The result has been preclusively expensive litigation that erodes or even wipes out the benefits of monopoly profits.

This inconsistency has also inhibited efficiency. In this era of technology and economic integration, goods and services must cross national borders freely to realize the efficiencies of a common market. However, when each nation has its own individual patent law, the privileges of patent ownership are territorial.

When protection is jurisdictionally limited, as was the case under the EPC, so are the benefits of free trade. The return to innovation, and thus the incentive to innovate, would be boosted by intellectual property rights that are "global commodities" with rights to exclude that are respected throughout the European Common Market.

Conceptually, the EPC was designed to lure the biotechnology industry by allowing innovators, with one application, to receive a patent in all the member states. However, a lack of enforcement power that did not allow the EPC to supersede the national patent law, was fatal to this goal. Uncertainty about the protection a given nation would afford innovation and the cost of defending the patent in numerous national courts obliterated the advantage that the EU hoped to achieve through a standardized registration system. As individuals, the members of the EU could

58 See Hicks & Holbein, supra note 27, at 771 (noting an inherent contradiction between the free circulation of goods in a common market and the exclusive right of patent, which offers protection within national borders only); see also Carroll, supra note 22, at 2441 ("Patent rights are independently defined and granted by individual nations, thereby making protection of these rights territorial.")).
59 See Hicks & Holbein, supra note 27, at 770-71.
not compete for biotechnology dollars with the likes of the United States and Japan.\textsuperscript{60}

3.2. \textit{The Directive: Improving Safeguards for Investment}

The lessons derived from the EPC were that patent law could only lure industry and stir innovation when uniformity allowed economies of scale and certainty of protection created inventor incentives. For the EU, it took ten years to construct a system of patent laws that could achieve these ends.\textsuperscript{61} Members of the EU debated issues of national sovereignty, economic position, and ethics. The end result, with its critics and supporters, was a giant step toward harmonization that created the legal certainty required to draw the biotechnological industry to the EU and end the competitive disadvantage that separated the EU from the United States and Japan.

To supersede national law, the EU must adhere to a multi-layered procedure that guarantees input from all sources but greatly slows change in the EU. Generally, legislation begins as a proposal in the Commission that is next submitted to the Council of Ministers.\textsuperscript{62} Once the Ministers have adopted a common position, they consult the European Parliament.\textsuperscript{63} The Parliament is free to: (a) take no action; (b) approve by a simple majority; (c) reject the common position; or (d) propose amendments and return the legislation to the Commission.\textsuperscript{64} The Commission must then decide whether to adopt the Parliament’s amendments or reject them.\textsuperscript{65} If it chooses the latter course, the legislation must receive a unanimous vote in the

\textsuperscript{60} For a statistical analysis of the relative productivity of the U.S., Japanese, and European biotechnology industries, see COOPERS & LYBRAND, EC COMMENTARIES: INTELLECTUAL PROPERTY 85, 15.2 (1992).


\textsuperscript{63} See \textit{id} at 1022-23.

\textsuperscript{64} See \textit{id}. (discussing the ratification of the Directive entitled “Patentability of Living Matter” by the EU).

\textsuperscript{65} See \textit{id}.
Council, which is nearly impossible to achieve. If the amendments are adopted, only a qualified majority vote in the Council is required. Finally, the legislation returns to the Parliament for a second reading and final approval.

3.3. Acceptance of the Directive

On October 20, 1988, the European Commissioners proposed the Directive on the Legal Protections of Biotechnological Inventions to supersede the EPC and harmonize European patent law to protect the biotechnology industry. The proposal mandated the amendment of member states’ national laws to conform with the universal system established in the Directive. In 1995, the European Parliament rejected the proposal, sending the Commissioners back to the drawing board for twenty more months.


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66 See id.
67 See id. at 1023.
71 See id.
73 See id.
74 See Biotechnology: Inventions Proposal, supra note 68.
75 See Emma Tucker, EU States Agree Genetic Patenting Law, FIN. TIMES (London), Nov. 28, 1997, at 2. The Netherlands voted against the Directive (Belgium and Italy both abstained from voting), but the law was able to achieve the qualified majority required. See Biotechnology: Human Life Forms, supra note 72.
tive became effective with its publication on July 30, 1998, and it ordered Member States to comply with its mandate by July 30, 2000.\textsuperscript{77}

This new Directive is a radical departure, not only because it requires members to adapt their domestic patent law, but because, for the first time, the EU has coercive powers to assure that harmonization becomes a reality.\textsuperscript{78} Under Article 1 of the Directive, the Commission is granted the power to sanction members that do not appropriately alter their national law.\textsuperscript{79} All members are required to enforce patent protection for “novelty, inventive activity and industrial application.”\textsuperscript{80}

"Supporters of the [D]irective argued that big investors in genetic engineering would take their huge research budgets out of Europe to the United States if the EU failed to harmonize patent law.”\textsuperscript{81} The result is a solid plan for harmonization and many opinions that the Directive adds legal certainty to patent law and thus creates the potential to achieve its goal of luring the biotechnology industry to the EU. Commissioner Mario Monti praised the Directive for avoiding non-uniform policy and encouraging long-term investment in the biotechnology industry.\textsuperscript{82} The Forum for Coordination of European Biotechnological Industries likewise commended the Directive for: (a) aiming for harmonization; (b) encouraging invention of new medicines; (c) promoting research and development investment and employment; (d) addressing ethical concerns by broadening the role for the EU’s advisors on biotechnological ethics and banning human cloning; and (e) allowing Europe to catch up with Japan and the United States.\textsuperscript{83} Clearly, the EU recognized the importance of harmoni-

\textsuperscript{77} See Biotech Directive, supra note 3, art. 15, 17, at 20, 21.
\textsuperscript{78} See id. art. 1, at 18.
\textsuperscript{79} See id.
\textsuperscript{80} Biotechnology: Human Life Forms, supra note 72; see also Biotech Directive, supra note 3, art. 3(1), at 18.
\textsuperscript{81} Tucker, supra note 75, at 2.
\textsuperscript{82} See generally Biotechnology: Human Life Forms, supra note 72 (noting that there have been various reactions to the ministerial agreement).
\textsuperscript{83} See Biotechnology: Varied Reactions to Agreement on Protection of Inventions, EUR. REP., Dec. 6, 1997, available in LEXIS, News Library, Eurrupt File. The Forum is a body representing various European industry groups and is comprised of the CIAA (food and drink), CEFIC (chemicals), Europabio (biotechnology), BCPA (plant health), EFPIA (pharmaceuticals), and FEDESA (animal health). See id.

https://scholarship.law.upenn.edu/jil/vol20/iss2/3
zation to the enunciated goal of encouraging biotechnological investment and, with the Directive, the EU attempted to create an environment which would foster such innovation.

In addition to providing strict guidelines for the enforceability of patents, the Directive sets out uniform laws to govern the substance of biotechnological experimentation in the EU. The Directive explicitly bans certain types of innovation, such as human cloning, and limits the patentability of others. While the purpose of the strict harmonization is to create economies of scale that will attract the lucrative biotechnology industry, the substantive limitations that actually may counteract this effort will be the subject of the next part of this comment.

4. COUNTERACTING PROGRESS: THE EU’S ETHICAL RESERVATIONS ABOUT BIOTECHNOLOGICAL INNOVATION HANDICAPS HARMONIZATION

Within the last several years, the biotechnology industry has made huge innovative strides. An application for a patent for the world’s first successful cloning of a mammal was filed. Cross-species genetic engineering continued to advance at a rapid pace with the Japanese creation of mice from adult chromosomes. Genetically engineered food is flooding into the European Market. Biopiracy, an exploitation in which developing countries’ resources are appropriated, patented, and sold back to the locals with a high mark-up, is a growing phenomenon.

With this rapid change comes an understandable fear of science that has gotten ahead of policy controls. This section will

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84 See, e.g., Biotech Directive, supra note 3, art. 6, at 18 (denying patents whose commercial exploitation would be contrary to public order or morality).
85 See id. art. 6(2)(a), at 18; see also id. art. 10, at 19 (limiting the scope of protection conferred by a patent).
88 See European Parliament, supra note 86.
89 See id. (providing recent examples of “biopiracy”); see also Carroll, supra note 22, at 2465 (noting developing countries reject stringent patent laws because “the patents granted within these countries are granted predominantly to foreigners”); Brian Tokar, Corporate Pirates: Mining Humanity (visited Jan. 23, 1999) <http://gen.free.de:80/gentech/1999/Jan-Feb/msg00061.html>.
explore the EU’s history of reticence towards biotechnological experimentation from the EPC through the approval of the new Directive. It will explore the ethical debates that delayed the new Directive and how compromise was reached. Finally, it will conclude by asserting that, despite a concerted effort to harmonize patent law and improve the business environment for the biotechnological industry, ethical reservations will force the EU to continue to lag behind the United States in this field. Conservative apprehensions about genetic experimentation expressed as bans and limitations in the Directive might be sufficient to drive the gains of harmonization away. At the very least, these limitations are counter to the realization enunciated in the preface of the Directive that “biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions can be considered of fundamental importance for the Community’s industrial development.”

4.1. The Manifestations of Historical Ethical Conservatism in the EPC

The EPC allowed patents for any inventions that were susceptible to industrial application, that were new, and that involved an inventive step. The agreement carved out sizable exceptions denying patents for “[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.” Inventions contrary to the “ordre public” or morality were named as exceptions to patentability. Plant and animal varieties, and processes that were “es-

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90 Draft Directive, supra note 61, preamble. This section remained unchanged in subsequent revisions of the initial proposal. See Biotech Directive, supra note 3, preamble 1.
91 See EPC, supra note 29, art. 52(1).
92 Id. art. 52(4) (denying patents for medical treatments despite commercial application in order to keep inexpensive medical procedures generally available).
93 Id. art. 53(a). “Ordre public,” undefined in the EPC, was interpreted individually in each member state, leading to a great deal of disparity, especially in the area of life patents. This concept was revisited during the debate over the Draft Directive in an attempt to unify the interpretation of this doctrine. See generally Draft Directive, supra note 61. This doctrine is important in EU patent law as there is no comparable standard in the United States. It is discussed more thoroughly infra Section 5.2., in connection with EU/U.S. competition.
sentially biological," were also precluded from patent protection.94 Although these categorizations appear to offer bright-line distinctions, the EPC respected national sovereignty by allowing diverging national interpretations that often made patentability murky.95

4.1.1. Plant and Animal Varieties

The people and politicians of Europe experienced serious reservations and contested the patentability of plant and animal varieties. Historically, the EU had denied patents in this area for two reasons. First, it was thought that these varieties were mere biological phenomenon and that the "inventive step" criteria were not met.96 Second, pro-farmer social and economic policy rejected patents on inventions that would allow global food corporations to lock up technology, charge farmers handsomely to use the latest techniques, and essentially turn Europe's farmers into contract laborers.97 Strong pro-farmer involvement and popular interest in the debate surrounding biotechnology in the EU assured that this history was incorporated in the EPC.98

4.1.2. Human Material

Restrictions on patents for human materials were significantly less inventor-friendly. Because biotechnological experimentation with human material is an ethically sensitive area, the EPO hesitated to impose a common code of morals on its members. The EPC did not mention patents on human material specifically. However, it appears that the relevant test was the "ordre public" standard enunciated in Article 53(a).99 This provision gave the EPO the discretion to deny applications for patents on "inventions the publication or exploitation of which would be contrary to . . . morality."100 Notably, it empowered the member states to

94 EPC, supra note 29, art. 53(b).
95 See McRobb, supra note 22, at 26 (describing the English interpretation of "industrial application" that excludes all methods of medical treatment from patentability).
96 See Scalise & Nugent, Patenting Living Matter, supra note 12, at 1014 (excluding existing varieties under EPC's Article 53 exception to patentability).
97 See European Parliament, supra note 86.
99 See EPC, supra note 29, art. 53(a).
100 Id.
refuse to enforce patents that conflicted with their national sense of morality. This resulted in situations like the Harvard Mouse patent, discussed previously in Section 3.1.2., where its revocation as contrary to public policy was not recognized uniformly throughout the EU. In this way, the EPC's lack of harmony in patent procedural law affected the substantive law governing biotechnological experimentation as well. It also resulted in confusion, uncertainty of the patentability of innovation, and high litigation costs.\footnote{See supra note 52 and accompanying text.}

4.2. Historical Reservations in the Debates and Compromises of the Draft Directive

The Biotech Directive has clarified some policies, liberalized others, and, in some instances, become more restrictive in its substantive biotechnological law.\footnote{See Biotechnology: Human Life Forms, supra note 72. The specific areas labeled unpatentable by the Directive are: (1) plant varieties and animal species; (2) biological procedures for the production of plants or animals; (3) the human body or the discovery of its elements including the sequence of a gene; and (4) inventions contrary to public policy or morality. This list formed the basis for the discussion that follows, which traces the history of each restriction. See id.} However, the issues debated during the several drafts of the Directive are not far removed from the concerns raised traditionally and those raised within the confines of the EPC.

4.2.1. Narrow Exception Allowed in Plant Patentability

The Directive reflects the hesitancy over plant varieties by clarifying the EPC and adopting a compromise with vocal interest groups. It expressly excludes plant varieties from patentability, but allows innovators to patent all non-biological processes by which the variety was produced.\footnote{See Biotech Directive, supra note 3, arts. 3-4, at 18.} The non-biological requirement assures that such inventions pass the innovative step test. This allows farmers to use the product without a licensing fee,\footnote{There is a question whether the farmers gain anything from the unpatentability of animal and plant varieties when the process is patentable. Companies are still granted monopolies for their production process which allows them to charge inflated prices even without the licensing fee. This is the complaint of an internet posting from Genetic Resources Action International that

https://scholarship.law.upenn.edu/jil/vol20/iss2/3
4.2.2. Continuing Social Conscience

The agrarian interests that shaped the EPC were replaced by concern for other social issues. The Greens, a vocal environmental interest group, objected to proposals of the Directive because they did not address the issue of the high failure rate on animal cloning and the repercussions for animal welfare.105 The proposals also failed to address the problem of loss of global biodiversity.106 Finally, activists objected to the dismissal of the problems of animal cloning with a mere reference to medical, agricultural, and economic benefits.107

Biopiracy, the harvesting of developing areas for inexpensive genetic materials, induced a fear of the debating parties and played an important role in the ethical discussions.108 Developing areas often have no patent law in place, enabling foreign nations to harvest genetic material cheaply and then patent it in their home nations. Consequently, industrial nations reap tremendous profit with no reward to the developing nations.109 Another concern is that international patent-harmonization movements will force the developing nations to afford the same patent rights to foreign and domestic innovators. This will force the developing nation to award patent protection to the foreigner,110 even if the domestic


106 See EU/EP/Bioethics, supra note 105.

107 See id.


109 “Fraud, deception and bribery are being used to take samples from indigenous populations around the world.” Tokar, supra note 89 (quoting Debra Harry, founder of the Indigenous Peoples’ Coalition of Biopiracy). Indigenous people are never informed about the use made of their genetic material and are never made a party to the multi-million dollar deals. See id.

110 See Carroll, supra note 22, at 2465 (discussing the effect of developed patent systems on nations with weak or non-existent patent laws).
industry has the capability to exploit the technology, affording a clear advantage to developed nations.\textsuperscript{111}

Several recent incidents validate the concern over biopiracy. In July of 1998, hundreds of Thai farmers gathered at the U.S. Embassy in Bangkok to protest the granting of U.S. patents on "Jasmati" and "Basmati" rice to RiceTech, Inc.\textsuperscript{112} These varieties of rice are genetically modified strains that have been grown in Thailand and India for thousands of years.\textsuperscript{113} The farmers alleged biopiracy and urged revocation of the patent.\textsuperscript{114} In another example, India alleged that the patent application submitted by the Roslin Institute of Great Britain for the gene construct of a milk protein was the gene construct of a rare Indian Vechur cow.\textsuperscript{115} This cow’s milk is desirable because its fat content is much higher than Europe’s variety, making replication of this milk extremely profitable.\textsuperscript{116} As these examples indicate, less-developed areas can lose the profits they gain from their indigenous resources to biopiracy. These incidents, among others, fueled the movement against the Directive, with a member of Greenpeace denouncing it as an “open invitation to biopiracy in third-world countries.”\textsuperscript{117}

\subsection*{4.2.3. Conservatism Remains Strong in Human Patentability}

The effort to define a clear policy in the Directive has led to a narrowing of the acceptable patentable material. To create a uniform definition for "ordre public," the EU enunciated absolute prohibitions on patents that may clarify what constitutes pro-
tected innovation but that severely limit the scope of biotechnological experimentation.

The European Parliament was particularly offended by patents involving the human body and made this a priority during early drafting of the Directive. An amended draft, submitted by the European Commission on October 20, 1992, included a ban on patenting "the human body or parts of the human body per se . . . [and] processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man." This would have the effect not only of preventing protection for human genetic engineering and human cloning, it would also outlaw patents on animals cloned with useful human products. This was a contentious issue between the medical community and the animal rights activists for the duration of debate on the Directive.

4.3. The Culmination of Conservative Trends: The Ban on Human Cloning

Consistent with the distaste for patents on human material, Directive drafters and interested spectators were quick to react to the announcement of the successful cloning of a sheep by Scottish biotechnology company PPL Therapeutics Plc. In its resolution of March 12, 1997, the European Parliament spoke out against human cloning and on May 5, 1997, the Group of Christian Democrats ("EEP") at the European Parliament submitted an amendment to the Directive. The amendment called for a le-

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120 Cloning has been suggested as a method for creating human "spare parts." See Genetic Resources Action International, supra note 104 (noting that "[r]esearchers have already inserted human chromosomes into mice, and human genes into fish, sheep and other animals; kidneys for human use can be produced in pigs, and human proteins by sheep."). One successfully altered, an animal with a human part could be cloned to efficiently create human parts that could be easily and profitably harvested on demand. See id.


gally binding ban on human cloning and a prohibition against patents for human cloning in all member states which would supersede national law.\textsuperscript{123}

The ensuing debate was an attempt to balance moral condemnation with an uneasiness about losing all potential medical benefits and profits associated with this new technique. The EU’s Group of Advisors on the Ethical Implications of Biotechnology rejected human cloning as ethically unacceptable.\textsuperscript{124} They did not, however, condemn the technique for animals which could have “medical, agricultural and economic benefits.”\textsuperscript{125} The more liberal European Parliament Legal Affairs and Citizen Rights Committee voted on June 18, 1997 to allow patents on living organisms including human parts, plants, and animals, although it expressly disallowed “whole” human clones.\textsuperscript{126} They were anxious to promote commercially motivated research.\textsuperscript{127}

4.3.1. Codification and Implementation of the Ban

The text of the Directive approved by the European Parliament on May 12, 1998 expressly bans patents on human cloning.\textsuperscript{128} Altering the germinal genetic identity of human beings and techniques involving the use of human embryos are also not

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\textsuperscript{123} See id.


\textsuperscript{125} Id.

\textsuperscript{126} See European Parliament, supra note 86.

\textsuperscript{127} See id.

The Directive further limits the biotechnological industry by precluding patents for the "discovery" of substances present in nature. Isolation of a human gene constitutes human intervention and allows for patentability, however, only if this invention has an industrial application. This requirement of an industrial application limits the value of this concession because the company that invests in the research and development to isolate a gene may not be the first to discover an adequate application and may lose out to another that is able to monopolize the gene and all of the innovations stemming from it.

Finally, indicative of its concern for the ethical complexity of the lines drawn in creating a universal system of patentability, the Commission agreed to establish an ethical committee headed by French expert Noelle Lenoir prior to implementing the Directive. The committee is charged with the continuing evaluation of ethical aspects of biotechnological inventions. Daniel Tarshys, Secretary General of the Council of Europe, stressed the need for examination of ethical issues when he commented, "at a time when voices are being raised to affirm the acceptability of the cloning of human beings and even to speed up its achievement, it is important for Europe to express its solemn determination to defend human dignity from the excesses of certain scientific applications."

4.4. The Resulting Interaction of Ethics and Economics Reflects a Surviving Conservatism

Despite the fact that the Maastricht Treaty does not empower the Union with competency in ethics, the ethical debate and Europe's tradition of conservatism in biotechnology triumphed over economic concerns in two important ways. First, the Directive erodes the ability of the biotechnological industry to profit from research that is now cutting edge, in what the EU's
Advisory Group on Ethics in Biotechnology has characterized as an overreaction. The Harvard scientists that created an onco-mouse were motivated by potential profit when they undertook the experiment to understand the genes responsible for cancer. Likewise, Alzheimer’s and Downs Syndrome may be better understood by experimentation with and isolation of genetic material. The rewards for these efforts must be certain and large in order to entice biotechnology’s research and development dollars. Cloning, genetic engineering, and the use of human embryos are the new frontiers in biotechnology, and profits are potentially enormous both for the inventor and the nation that can offer protection for investment return.

The second area in which ethical issues have superseded economic concerns is the preservation of the “ordre public” doctrine in the final draft of the Directive. The doctrine has been harmonized by a balancing test and is no longer an area of individual member state discretion. An invention that has a benefit to man or animal that outweighs the suffering or handicap is deemed non-offensive to public policy. This calls for a case-by-case analysis that allows a close examination of the ethical considerations of a specific patent application but creates uncertainty that may deter innovation. The specific enumeration of prohibited inventions, cloning, manipulations of human genes, and the genes themselves, may limit biotechnology investment; however, it provides clear information on which companies may base their investment decisions. The catch-all “ordre public” clause erodes the bright-line rule and forces risk-minimizing companies to take their innovations elsewhere.

137 See id. (concluding after hearings that there are no grounds for assuming the accomplishment of animal cloning will be transposed to humans and that this fear does not justify the drastic limitation of human genetic research).

138 The Harvard Mouse case is an example of the doctrine incorporating a balancing test.

139 See McRobb, supra note 22, at 26 (discussing the use of the balance test in providing patents for biotechnological inventions); see also Perry, supra note 124 (discussing the acceptance of animal cloning when aims and methods are ethically justified and animal suffering is avoided or minimized); European Parliament, supra note 86 (criticizing this doctrine for allowing animal suffering if there is “substantial medical benefit”).
5. Consequences of Ethical Choices: Biotechnology Forced to Other Markets

5.1. Liberal Life Patents in the United States

It is likely that biotech companies will take their innovations to the United States which, historically, has had a more liberal approach to life patents. U.S. policy has evolved to allow patents on "anything under the sun that is made by man." This standard has been approved by the Patent and Trademark Office ("PTO") and upheld in the courts. Innovators invest with the reassurance of a broad standard that will guarantee protection for their investment return.

The United States Code defines the requirements for patentability as "novelty, utility and non-obviousness." "Scientific principles, laws of nature, physical phenomena, abstract ideas and products of nature [are expressly labeled non-patentable]." Prior to 1980, living matter was not protected because it was considered a product of nature and therefore unpatentable. This changed with the decision in Diamond v. Chakrabarty, in which the Court held that genetically altered living matter could be patented. The patent was granted for a bacteria that degraded oil because that function was not a naturally-occurring characteristic of the bacteria. The Court relied on legislative history that interpreted "any" novel, useful, non-obvious invention to mean "anything under the sun that is made by man." This decision allowed for great expansion of the biotechnological and genetic engineering industries in the United States.

This expansion was delayed by the PTO's slow acceptance of the Chakrabarty decision. It was not until April 7, 1987 that the

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141 Scalise & Nugent, Patenting Living Matter, supra note 12, at 999; see also 35 U.S.C.A. § 101 (West 1998) (listing as the two main requirements for U.S. patents that they be "new" and "useful").
142 Scalise & Nugent, Patenting Living Matter, supra note 12, at 999.
143 See id. at 1003.
144 See Diamond, 447 U.S. at 310 ("His discovery is not nature's handiwork, but his own; accordingly it is a patentable subject.").
145 See id. at 309.
146 Id.
147 See Scalise & Nugent, Patenting Living Matter, supra note 12, at 1006.
PTO issued a formal statement expressing its intent to fully comply with Chakrabarty. The notice stated unequivocally that "[t]he PTO now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter."

Case law confirms the integration of Chakrabarty into U.S. patent law. In Ex parte Allen, decided in 1987, the patent was denied for obviousness, but the "anything under the sun" test from Chakrabarty was applied, making this case significant for its dicta. Similarly, Animal Legal Defense Fund v. Quigg, although dismissed on procedural grounds, confirmed that the test for patentability would be "whether that subject matter is made by man." Following the precedent of Chakrabarty, the first patent on a multi-cellular living organism was granted for the Harvard Mouse, a mouse genetically engineered to be susceptible to cancer, in April of 1988. This sent the reassuring message that the PTO did intend to be bound by the decision of the Court in Chakrabarty and would provide protection for innovations involving multi-cellular living organisms. With this confirmation, the U.S. biotechnology industry became an international leader in biotechnological innovation.

148 See id.
149 1077 OFF. GA2. PAT. OFFICE 24, Apr. 21, 1987.
The liberal approach to the patenting of multi-cellular, living organisms has been applied to the patenting of genes. In a 1990 case, a patent was confirmed for a cell line developed from the spleen of a leukemia patient, thus suggesting that genes harvested from a special individual and isolated for commercial use would be patentable. Likewise, a project known as the Human Genome Project has sought two patents in the United States for their efforts to isolate the genes of indigenous populations around the world. It is a well-accepted principle in the United States that the isolation of a gene is patentable; the inventor has created something that does not exist in that form in nature. Additionally, placing foreign genes in organisms where they do not naturally occur is patentable.

5.2. Patentability of Cloning in the United States and the EU

While Congress has banned federal funding of cloning and the National Bioethics Advisory Panel has examined the legal and

155 See Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990) (holding humans lose ownership interest in their cells when they are removed so that this extracted material may be patentable when potential commercial use is shown); see also Ned Hettinger, Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics, 22 B.C. ENVTL. AFF. L. REV. 267, 270-71 (1995) (discussing the controversial patent given for cell line developed from the spleen).

156 See Hettinger, supra note 155, at 287 n.109. In connection with this project, the National Institute of Health ("NIH") filed patent applications for hundreds of human gene fragments isolated in an effort to discover and document all the genetic material of a human being. The applications were denied, not for ethical reasons, but because the applications failed to specify an application for their innovation. See id. at 271. The "utility" prong of the U.S. patentability test was not met. Since withdrawal of NIH's application, more than a dozen companies have come forward with possible applications seeking to commercialize the sequences. See Amy E. Carroll, Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law, 44 AM. U. L. REV. 2433, 2436, 2437 & n.23 (1995). While this issue is not yet solved, the rejection of NIH's application on utility grounds, rather than ethical grounds, has left open the suggestion that such a patent would be acceptable under U.S. law.

157 See Hettinger, supra note 155, at 288; see also Rifkin, supra note 25, at 4 (noting that in the United States "the isolation and classification of a gene's properties and purposes is sufficient to claim it as an invention").

158 See Hettinger, supra note 155, at 289.

159 In response to a unanimous recommendation from the National Bioethics Advisory Commission, President Clinton proposed a ban on human cloning. See Steve Sternberg, Human Cloning: Seed Sees A World With Disease-Free Children, USA TODAY, Jan. 8, 1998, at 1A. Chicago scientist Dr. Richard Seed's announcement that he would attempt to clone a human being is ex-
ethical ramifications of cloning and recommended a congressional ban. U.S. patent law seems to allow for the patentability of cloning.\textsuperscript{160} As the Harvard Mouse patent and subsequent patents on other transgenic mice, asthmatic guinea pigs, and schizophrenic mice indicate, higher animals can be patented under U.S. law.\textsuperscript{161} A patent for the cloned animal itself may be prohibited under the "product of nature" doctrine, as the clone would exactly resemble an animal that exists in nature. However, if the inventor added an extra gene that is not naturally occurring during the cloning process, this would assure patentability.\textsuperscript{162}

A U.S. patent for the cloning methodology is more certain than one for the actual cloned product itself. For instance, Ian Wilmut's method of transferring a nucleus from a donor cell to a recipient, called somatic cell nuclear transfer technology, meets the requisite criteria of utility, novelty, and non-obviousness.\textsuperscript{163} Because cloning cannot take place without this process, infringement of this claim would be proven by the existence of another clone.\textsuperscript{164}

\begin{quote}
\textsuperscript{160} See Suzanne Perry, EU Joins World Debate on Animal Cloning, \textsc{Reuter Eur. Community Rep.}, Feb. 27, 1997, available in LEXIS, Europe Library, Reuec File (discussing Clinton's request that the National Bioethics Panel offer a recommendation on cloning after a 90-day examination period).
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\textsuperscript{161} See, e.g., Tsevdos, \textit{supra} note 5, at C1.
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\textsuperscript{162} See \textit{id.}
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\textsuperscript{163} See \textit{id.}
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\textsuperscript{164} See \textit{id.; see also Jeffrey Kahn, Gene Research Is Straining the Limits and Spirit of the Legal System, \textsc{Star Trib.} (Minneapolis), July 22, 1998, at 20A (criticizing efforts to patent cloned animals and determining that protection of the technique itself should be sufficient). This "patent technique" argument is also being used by the creators of Dolly, Ian Wilmut, and Keith Campbell, who argue for its application against a team of scientists from the University of Massachusetts and from Advanced Cell Technology who claim to have cloned cows using a technique not covered by Wilmut and Campbell's patent. Dolly was created using quiescent cells, which are cells in genetic slumber that do not divide. The cow cloners claim that they used actively dividing cells. Wilmut and Campbell assert that the production of cow clones indicates that quiescent cells must have been present and further assert that the existence of the cows
\end{quote}
In contrast, the EU’s broad “ordre public” doctrine makes the patentability of Ian Wilmut’s method and Dolly, the cloned sheep, questionable. The Scottish biotechnology company PPL Therapeutics has filed for a patent in Britain. The application remains confidential for eighteen months so it is unknown whether the company was seeking a method or product patent or both. Nonetheless, one overwhelming likelihood is that PPL Therapeutics will take their technology elsewhere if denied EU patent protection.

6. CONCLUSION

The ethical restrictions enumerated in the patent-harmonization Directive make it clear that the EU intends to be true to a history of conservatism toward biotechnological innovation. This stubborn adherence assures that the EU will not achieve a competitive advantage in biotechnological research and threatens the stated goals of the Directive. The EU has put in place the mechanisms to entice innovation by harmonizing patent law, thereby creating the simplification and certainty required for large biotechnological investments. However, the unequivocal ban on human cloning and other exclusionary regulations will counteract progress and deter biotechnological investment.

Commissioner Mario Monti “stressed that a balance had been struck between the absolute need to take account of ethical factors designed to protect the human body and the economic imperatives linked to the goal of completing the Single Market.” The World Intellectual Property Organization preserves PPL Therapeutics’ right to file for this patent in the United States first. See id.; see also Sternberg, supra note 159 (remarking on Dr. Richard Seed’s comment that he will take his cloning research to Tijuana if the U.S. government interferes, indicating a willingness to innovate in the most experimentation-friendly regions).

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logical market share. Until there are world standards, those nations with more ethically relaxed standards will gain a competitive advantage in the industry and reap the benefits of successful innovation. This paper does not mean to suggest that the EU should encourage unethical, unexamined science for the sake of profit. Instead, it must accept that the price of the moral high ground is in biotechnology dollars that find other markets.