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BOUND FUTURES: PATENT LAW AND MODERN BIOTECHNOLOGY

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I. INTRODUCTION

Since the 1970s much attention has been paid to the patentability of biotechnology. Most of that attention has focused on genetically modified organisms, whole and partial deoxyribonucleic acid (DNA) sequences, and other products derived from living systems using recombinant DNA and associated techniques ("modern biotechnology"[1]).[2] In recent years it has been

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[1] The distinction between "modern biotechnology" and "traditional biotechnology" corresponds to the revolution in molecular biology precipitated by the Watson–Crick discovery of the double-helix structure of DNA in the early 1950s. *See* J. D. Watson & F. H. C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953). *Cf.* André

accepted that patent law can and does protect these subject matter, prompting assertions that the legal issues surrounding the patenting of modern biotechnology ("biotech patenting") have been largely resolved.[3] It is in the context of such assertions that some commentators have begun to shift their attention away from the question of whether and how modern biotechnology can be patented to whether and how approaches to biotech patenting can be harmonized.[4]

It is increasingly clear, however, that the problems created for patent law by modern biotechnology are far from resolved, and that the need for harmonization reflects in part their continued existence. In addition, the nature of those problems is such that formal attempts at harmonizing patent law can only make them worse. The reason is that they arise largely from the effects of biotech patenting in having politicised and otherwise destabilised contemporary patent law, which effects can only be exacerbated by future harmonization initiatives. The aim of the present Article is to consider this impact of modern biotechnology with reference to the patent systems of Europe,[5] Australia,[6] and the United States. In so doing it will be argued that an expedient approach to biotech patenting has made the substantive

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Heitz, *Intellectual Property in New Plant Varieties and Biotechnological Inventions*, 10 EUR. INTELL. PROP. REV. 297, 297–98 (1988) (describing the present state of the art in biotechnology as the result of evolution over many years rather than a revolution). In patent law contexts the term "traditional biotechnology" generally refers to the methods and products of selective breeding, the patentability of which is discussed below in Section II.

[2] Recombinant DNA and associated techniques [hereinafter recombinant technologies] include the array of techniques used to isolate, cultivate, purify, replicate and convert DNA sequences and other biological products such as lower and higher life forms, cell lines and plasmids. Succinct explanations of these techniques and their various products [hereinafter recombinant products] intended for the layperson abound in science and patent law literature. *See*, *e.g.*, *In re* O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988); JOHN E. SMITH, BIOTECHNOLOGY (3d ed. 1996); Brian C. Cannon, Note, *Toward a Clear Standard of Obviousness for Biotechnology Patents*, 79 CORNELL L. REV. 735, 737-40 (1994); Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 784-86 (1992). *See also* MATT RIDLEY, GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN 23 CHAPTERS (1999) (a popular account of the human genome around which much modern biotechnological research revolves).

[3] *See*, *e.g.*, Anthony McInerney, *Biotechnology:* Biogen v. Medeva *in the House of Lords*, 1 EUR. INTELL. PROP. REV. 14, 14-15 (1998).

[4] *Id*. at 15.

[5] Unless the context otherwise indicates, "Europe" refers throughout this Article to the Contracting States of the Convention on the Grant of European Patents, *opened for signature* Oct. 5, 1973, 13 I.L.M. 268. The European Patent Convention [hereinafter EPC] entered into force October 7, 1977.

[6] Unless the context otherwise indicates, "Australia" refers throughout this Article to Australia, and the United Kingdom prior to its adoption of the EPC in 1977 (*see* Patents Act, 1977, ch. 37 (Eng.)).

harmonization of contemporary patent law both imperative for its future viability and unlikely to be achieved.

II. THE EARLY RESPONSE TO MODERN BIOTECHNOLOGY: ESTABLISHING A COMMITMENT TO BIOTECH PATENTING

Use of the patent system to protect modern biotechnology has been supported by most patent law commentators and decision makers since the issue first arose in the 1970s.[7] Initially such use was justified as involving an uncontroversial extension of the patent system to cover a developing branch of an (old and) historically patentable technology.[8] This justification reflected the way in which the question of biotech patenting was originally approached. In theory that question was whether and how traditional principles of patentability could be applied to such a new and different form of technology. In practice it was resolved by considering the comparability of modern biotechnology with other forms of patentable technology, and asking whether it was sufficiently

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[7] *See*, *e.g.*, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (genetically engineered bacterium capable of breaking down crude oil); Amgen, Inc. v. Chugai Pharm. Co., 13 U.S.P.Q.2d (BNA) 1737 (D. Mass. 1989) (purified and isolated DNA sequence encoding human erythropoietin), *aff'd*, 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991); Kirin-Amgen, Inc. v. Bd. of Regents of Univ. of Wash. (1995) 33 I.P.R. 557 (Dep. Comm'r Patents Austl.) (isolated DNA sequence encoding human erythropoietin), *aff'd sub nom*. Genetics Institute, Inc. v. Kirin-Amgen, Inc. [No. 3] (1998) 41 I.P.R. 325 (Fed. Ct. Austl.); *Re* Ranks Hovis McDougall Ltd. (1976) 1976 A.O.J.P. 3915 (Assistant Comm'r Patents Austl.) (genetically engineered micro-organisms capable of producing edible protein); Genentech/t-PA, T923/92, 1996 E.P.O.R. 275 (Technical Bd. App. 1995) (isolated DNA sequence encoding human tissue plasminogen activator (t-PA)); Plant Genetic Systems/Glutamine Synthetase Inhibitors, T356/93, 1995 E.P.O.R. 357 (Technical Bd. App. 1995) (genetically engineered plants and seeds resistant to certain herbicides); Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541 (Opposition Div. 1994) (isolated DNA sequence encoding human H2-relaxin); Harvard/Onco-Mouse, T19/90, 1990 E.P.O.R. 501 (Technical Bd. App. 1990) (genetically engineered oncogenic test mouse); Biogen/Recombinant DNA, T301/87, 1990 E.P.O.R. 190 (Technical Bd. App. 1989) (isolated DNA sequence encoding human IFN-alpha type proteins); Lubrizol/Hybrid Plants, T320/87, 1990 E.P.O.R. 173 (Technical Bd. App. 1988) (genetically engineered phenotypically uniform hybrid plants). *Cf.* Genentech, Inc. v. Wellcome Found., 1989 R.P.C. 147 (Eng. C.A. 1988) (deciding that an isolated DNA sequence encoding human t-PA could not support a patent). *But see* Biogen, Inc. v. Medeva, Plc., 36 I.P.R. 438 (H.L. 1996) (deciding that an isolated DNA sequence encoding the hepatitis B virus could support a patent). The early academic literature in support of biotech patenting is vast, but includes Bradford C. Auerbach, Note, *Biotechnology Patent Law Developments in Great Britain and the United States: Analysis of a Hypothetical Patent Claim for a Synthesized Virus*, 6 B.C. INT'L & COMP. L. REV. 563 (1983); Harold C. Wegner, Comment, *The Chakrabarty Decision: Patenting Products of Genetic Engineering*, 2 EUR. INTELL. PROP. REV. 304 (1980). *Cf.* Dean Ellinson, *The Patent System — Time to Reflect*, 1988 LAW INST. J. 292, 293 (1988) (supporting sui generis protection for modern biotechnology on public policy grounds).

[8] *See* discussion *infra*.

similar to those forms of technology to be regarded a proper subject matter for patent protection.

In answering this question decision makers took as their frame of reference a spectrum of patentability defined by classical chemical and mechanical inventions at one end and plants and animals at the other.[9] In so doing they were inevitably influenced by the debate that had occurred several decades earlier regarding the patentability of plant varieties.[10] The main issue in that debate concerned the ability of living things and natural substances to be regarded as new inventions amenable to individual ownership.[11] Opposition to the idea of patents for such subject matter was strong,[12] and was the reason for

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[9] *Id*.

[10] On the patenting of plant varieties see Heitz, *supra* note 1; Timothy Millett, *The Community System of Plant Variety Rights*, 24 EUR. INTELL. PROP. REV. 231 (1999); Robin Nott, *Patent Protection for Plants and Animals*, 14 EUR. INTELL. PROP. REV. 79 (1992); Tim Roberts, *Patenting Plants Around the World*, 18 EUR. INTELL. PROP. REV. 531 (1996); Geertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 IDEA 143 (1999); Gerd Winter, *Patent Law Policy in Biotechnology*, 4 J. ENVTL. L. 167 (1992).

[11] *See* Van Overwalle, *supra* note 10, at 149–52; Winter, *supra* note 10, at 169.

[12] On the patentability of natural phenomena see Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293 (1995); Jasper Utermann, *Reflections on Patent Protection of Products of Nature Part One*, 9 INT'L REV. INDUS. PROP. & COPYRIGHT L. 409 (1978); Jasper Utermann, *Reflections on Patent Protection of Products of Nature Part Two*, 9 INT'L REV. INDUS. PROP. & COPYRIGHT L. 523 (1978). On the patentability of living phenomena see Paul Blunt, *Selective Breeding and the Patenting of Living Organisms*, 48 SYRACUSE L. REV. 1365 (1998); Rainer Moufang, *Patentability of Genetic Inventions in Animals*, 20 INT'L REV. INDUS. PROP. & COPYRIGHT L. 823 (1989). Exclusions of living phenomena from patentability have historically been justified by reference to the unpatentability of natural phenomena. *See*, *e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (bacterium); *Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123 (Comm'r Patents 1889) (plant fibers); *Ex parte* Allen, Patent Application Serial No. 647,963 (1984) (oysters), *rev'd in part*, 2 U.S.P.Q.2d (BNA) 1425 (B.P.A.I. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988); *Ex parte* Bergy, 197 U.S.P.Q. (BNA) 78 (PTO Bd. App. 1976) (micro-organism), *rev'd*, 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub nom*. Parker v. Bergy, 438 U.S. 902 (1978), *on remand*, *In re* Bergy, 596 F.2d 952 (C.C.P.A. 1979), *cert. granted sub nom*. Parker v. Bergy, 444 U.S. 924 (1979), *vacated and remanded with instructions to dismiss as moot sub nom*. Diamond v. Chakrabarty, 444 U.S. 1028 (1980)); *In re* Merat , 186 U.S.P.Q. (BNA) 471 (PTO Bd. App. 1975) (selectively-bred chicken), *aff'd on other grounds*, 519 F.2d 1390 (C.C.P.A. 1975); *In re* Chakrabarty, Patent Appeal No. 3,923,601 (1975) (bacterium), *rev'd*, 447 U.S. 303 (1980); . The exclusion of natural phenomena derives from the historical distinction between (patentable) technical objects and (unpatentable) abstract principles that was first articulated in eighteenth century English case law. *See*, *e.g.*, Boulton v. Bull, 126 E.R. 651 (H.L. 1795) (distinguishing between (patentable) manufactures and (unpatentable) abstract notions or elementary truths of the arts and sciences); Le Roy v. Tatham, 55 U.S. 156, 157 (1852) (citing *Boulton*, *supra* to support a finding that "a principle is not patentable" because it is "a fundamental truth; an original cause; a motive" in respect of which "no one can claim . . . an exclusive right");

the decision in most jurisdictions to introduce exclusive sui generis protection for plant varieties[13] — the view being that plants, as "manifestations of nature", should be "free to all men and reserved exclusively to none."[14] This view helped shape an early perception that biotech patenting depended, fundamentally, on whether modern biotechnology could be distinguished from

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EPC, Oct. 7, 1977, art. 52(2) (excluding discoveries, scientific theories and mathematical methods from patent protection). More recent rationalisations of the natural phenomena exclusion have focused on the inability of such phenomena: (i) to be proprietised by an individual (being already owned collectively by the public); (ii) to be regarded as "new" (being already in existence); (iii) to be regarded as "novel" (being previously available to the public); (iv) to be regarded as the product of human and/or technical action (being the product of natural conditions); and/or (v) to offer anything of use to the public that does not already exist. *See* cases cited *supra*, especially *Funk Bros. Seed*, 333 U.S. at 130; *Genentech*, 1989 R.P.C. at 147 (deciding that an isolated DNA sequence was unpatentable because the properties and functional characteristics of the protein for which it encoded had long been known, preventing it from being regarded as a new substance); *Biogen*, 36 I.P.R. at 449 (accepting the statement of Mustill L.J in *Genentech*, *supra*, at 264, that water cannot be considered an invention because it is not new). Separation of the living and natural phenomena exclusions coincided with the recognition of the patentability of microbiological processes and their products, discussed below.

[13] Sui generis protection for plant varieties was first introduced in the United States in 1930 and in Australia in 1964. *See* Townsend-Purnell Plant Patent Act, ch. 312, § 1, 46 Stat. 376 (1930) (current version at 35 U.S.C. § 161 (2000)) [hereinafter PPA]); Plant Varieties and Seeds Act, 1964, ch. 14 (Eng.) (amended 1997). *See also* Plant Variety Rights Act, 1987, ch. 2 (Aust.) (repealed 1994). On the availability of sui generis protection for plant varieties in Europe prior to 1977 see Heitz, *supra* note 1, at 297; Van Overwalle, *supra* note 10, at 161-63. An international varieties regime, with a rule against double (sui generis and patent) protection, was created in 1961 (International Convention for the Protection of New Varieties of Plants, *opened for signature* Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 90 [hereinafter UPOV]) and adopted soon after in most jurisdictions — in the case of some countries (for example, the United States), even before becoming signatories. In the United Kingdom, see Plant Varieties and Seeds Act, 1964, ch. 14 (Eng.) (amended 1997). In the United States, see Plant Variety Protection Act of 1970, 7 U.S.C. §§ 2321-2583 (2000). The rule against double protection was abolished in 1991. *See infra* note 22. In the United States, the connection between the exclusion of living and natural phenomena from patent protection and the PPA has been expressly recognised by the Supreme Court. *See* J. E. M. Ag Supply. Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 134-35 (2001); *Chakrabarty*, 447 U.S. at 310-11. In Australia, the same connection is implicit in the historical view of plants and seeds as unpatentable on the basis of the inability of selective breeding methods to be regarded as methods of manufacture. *See*, *e.g.*, *Re* National Research Development Corp., 102 C.L.R. 252, 278 (Austl. 1959) (fruit and other growing crops); *Re* N.V. Philips' Gloeilampenfabrieken, 71 R.P.C. 192, 194 (Pat. App. Trib. 1954) (new and improved form of Poinsetta); *Re* R.H.F., 61 R.P.C. 49, 50 (Pat. App. Trib. 1944) (dictum) (fruit and other growing crops); *Re* Rau G.m.b.H., 52 R.P.C. 362, 364 (Pat. App. Trib. 1935) (selectively cultivated seeds). On the patentability of plant and animal varieties in Europe prior to 1977, see Heitz, *supra* note 1, at 297; Van Overwalle, *supra* note 10, at 161-63.

[14] *Funk Bros. Seed*, 333 U.S. at 130.

the plants and other living and natural phenomena for which patents had historically been denied.

In resolving this issue decision makers were inevitably guided by their particular understanding of modern biotechnology, which reflected the first types of genetically engineered products for which protection was sought.[15] Such products consisted of DNA sequences and micro-organisms that had been derived in a laboratory using recombinant techniques, and that had a proven utility not possessed by the sequence or micro-organism in its natural state.[16] In considering how best to categorize these subject matters, decision makers were also influenced by an emergent jurisprudential ease with the idea of patenting "life" and "nature", as a result of the (then-) growing number of patent applications for methods involving the use of micro-organisms.[17] Indeed, by the mid-twentieth century a distinction existed in Anglo and European jurisdictions between such methods on one hand, and the selective breeding techniques at issue in the plant varieties debate on the other, on the basis of the level and type of human intervention that each involved. According to that distinction, whilst processes of treating and breeding plants and animals typically involved the mere modification of natural conditions, methods of using lower life forms involved the harnessing of those conditions in a biochemical process conducted in the artificial environment of a

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[15] *See* Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 784 (2000).

[16] *See*, *e.g.*, cases cited *supra* note 7.

[17] An inevitable consequence of the contemporary patent system in which the grant of a patent is no indication of its legal validity is that questions of patent eligibility are generally determined after a patent office practice of allowing or refusing patents for the subject matter in question has been established. Confirmation of the patentability of modern biotechnology has generally followed — and been supported by reference to — a practice amongst patent examiners of granting biotech patents. *See*, *e.g.*, *J. E. M. Ag Supply*, 534 U.S. at 131 (citing the "unbroken practice" of the United States Patent and Trademark Office [hereinafter U.S. PTO] of granting patents for plants to support the patentability of a plant); *Chakrabarty*, 447 U.S. at 314 n.9 (citing the history of patent grants for lower life forms to support the patentability of a micro-organism); *Howard Florey/Relaxin*, 1995 E.P.O.R. at 548 (citing "the long-standing practice of the European Patent Office concerning the patentability of natural substances" to support the patentability of a protein and its encoding DNA sequence). *See also Ex parte* Swift & Co., 2 R.P.C. 37, 43 (Q.B. 1962) (citing a change in the established practice of Australian and New Zealand patent examiners following *Re National Research Development*, 102 C.L.R. 252, to support the patentability of methods of using plants and animals contrary to national patent office practice); American Cyanamid Company (Dann's) Patent, 1971 R.P.C. 425 (H.L. 1970) (Diplock, L.J., dissenting) (citing the availability of patents for new antibiotics in foreign countries to support the patentability of an antibiotic contrary to national patent office practice). On the relationship between patent offices and courts and its significance for the development of substantive principles of biotech patenting see, for example, Arti Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL'Y 199 (2000) (relationship between the U.S. PTO and Court of Appeals for the Federal Circuit [hereinafter U.S. Federal Circuit]).

laboratory.[18] Thus conceived, microbiological methods were viewed as identical in all material respects to chemical processes and as suitable for patent protection on that basis.[19] Recognition of the patentability of the

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[18] *See*, *e.g.*, City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 583 (7th Cir. 1934) (deciding that a method of using aerobic bacteria in the treatment of waste was patentable because it involved "physical methods and apparatus for handling, treating, and controlling the sewage and the bacterial flocculi in such a way as to promote the development and activity of the bacteria and to bring the bacterial matter into play in a new and different way" and was not a process of nature per se); Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 F. 453, 462-63 (2d Cir. 1908) (deciding that a method of using anaerobic bacteria in the treatment of waste was patentable because it was a method of using "the agencies of nature for a practical purpose" and not a process of nature per se) (quoting Risdon Iron & Locomotive Works v. Medart, 158 U.S. 77 (1895)); Guaranty Trust Co., v. Union Solvents Corp., 54 F.2d 400, 403, 410 (D. Del. 1931) (deciding that a method of producing alcohol by bacterial fermentation (as in *Commercial Solvents v. Synthetic Products*, *infra*) was patentable because it "called for the exercise of inventive genius" and was not merely "the life process of a living organism"), *aff'd* 61 F.2d 1041 (3d Cir. 1932); *Ex parte* Prescott, 19 U.S.P.Q. (BNA) 178, 179 (PTO Bd. App. 1932) (deciding that a method of producing alcohol by bacterial fermentation was a method for the use of the bacteria's inherent functions to achieve a new and useful result, and did not consist merely of those functions per se); *Re National Research Development*, 102 C.L.R. at 278-79 (dictum) (confirming that fruit and other growing crops are not patentable because "[h]owever advantageously man may alter the conditions of growth, the fruit is still not produced by his action", and distinguishing methods of using micro-organisms on the ground that unlike methods of selective breeding, they are "analogous to a chemical process in that, given the micro-organisms and the appropriate conditions, the desired result inevitably follows from the working of the process"); Commercial Solvents Corp. v. Synthetic Prods. Co., 43 R.P.C. 185, 225 (Ch. 1926) (deciding that a method of producing alcohol by bacterial fermentation was a chemical or biochemical process that called for the exercise of inventive genius, and was patentable on that basis); *Re N.V. Philips' Gloeilampenfabrieken*, 71 R.P.C. at 194 (deciding that a method of producing a new and improved form of Poinsetta was not patentable because the modification of natural conditions could not be regarded as a manner of manufacture); *Re R.H.F.,* 61 R.P.C. at 50 (deciding that fruit and other growing crops were not patentable because they did not result from a manner of manufacture); *Re Rau G.m.b.H.,* 52 R.P.C. at 364 (deciding that selectively cultivated seeds were not patentable because selective breeding processes could not be regarded as methods of manufacture); *Re* A.D. Goldhaft, 1957 R.P.C. 276, 277 (Superintending Exam'r 1957) (deciding that a method of treating an avian egg to effect the sex of the chicken hatched therefrom resulted in the production of an agricultural or horticultural product and was therefore distinguishable from the method in *Re Joseph Szuecs*, *infra*, so as to be unpatentable); *Re* Joseph Szuecs, 1956 R.P.C. 25, 26 (Superintending Exam'r 1955) (deciding that a method of producing edible mushroom tissue was patentable because it did not produce a plant or animal and was carried out in a laboratory).

[19] *Id*. *Cf. Funk Bros. Seed*, 333 U.S. at 127 (refusing a patent for bacterial strains on the ground of "want of invention"). *But see* IVER P. COOPER, BIOTECHNOLOGY AND THE LAW § 2.02 at 2-5 (rev. vol. 1999) (noting the argument that the decision in *Funk Bros. Seed*, *supra*, assumed initial classification of the bacterium as statutory subject matter).

products of such processes was a short and natural advance on this view.[20] After the explosion of modern biotechnology in the 1970s, such products were inevitably understood to include genetically engineered micro-organisms and DNA sequences[21] and, later, plants and animals per se.[22]

Thus the nature of early recombinant products and the circumstances of their derivation supported a view of modern biotechnological subject matter as analogous if not identical to chemical compounds.[23] In particular, they

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[20] *See*, *e.g.*, Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958) (vitamin B(12)); Parke-Davis & Co. v. H.K. Mulford & Co., 189 F. 95, 103 (S.D.N.Y. 1911) (adrenalin), *aff'd*, 196 F. 496 (2d Cir. 1912); *In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1977) (micro-organism); *In re* Bergstrom, 427 F.2d 1394 (C.C.P.A. 1970) (prostaglandins). *Cf.* American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11-12 (1931) (deciding that an orange rendered decay-resistant by injection with borax was not patentable because such injection did not produce "an article for use which possesses a new or distinctive form, quality, or property," with the result that the orange remained an orange which was a product of nature and thus unpatentable).

[21] *See*, *e.g.*, cases cited *supra* note 7.

[22] *See*, *e.g.*, *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1427 (B.P.A.I. 1987) (deciding that selectively cultivated oysters were non-naturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. § 101 on the authority of *Chakrabarty*, 447 U.S. 303); *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (B.P.A.I. 1985) (deciding that selectively cultivated plants were patentable subject matter on the authority of *Chakrabarty*, *supra*, discussed *infra* note 26); Australian Patent Office, Patent Applications Concerned with Living Organisms 50 A.O.J.P. 1162 (1980) (confirming the patentability of life forms as manners of new manufacture within the meaning of Patents Act, 1990, ch. 83, § 18(1) (Austl.) on the authority of *Re National Research Development*, 102 C.L.R. 252, discussed *infra* note 26, as construed in *Re* Ranks Hovis McDougall Ltd. (1976) 1976 A.O.J.P. 3915 (Assistant Comm'r Patents Austl.); *Ex parte* Schreiner (Red Dove/"*Rote Taube*"), BGHZ 52 (F.R.G. 1969), *translated and abridged in* 1 INT'L REV. INDUS. PROP. & COPYRIGHT L. 136, 139 (1970) [hereinafter Red Dove] (deciding that animals and other living phenomena "consist of a substance constructed of basic elements present on the earth, just as in the case of other material phenomena", and are governed by forces that "may be classified within the general principles of physics and chemistry" so as to be patentable on the same principles as inanimate matter); Harvard/Onco-Mouse, T19/90, 1990 E.P.O.R. 501, 510–11 (Technical Bd. App. 1990) (deciding that animals are not excluded from patentability under European law unless they fall within EPC art. 53(b)); Lubrizol/Hybrid Plants, T320/87, 1990 E.P.O.R. 173, 179–80 (Technical Bd. App. 1988) (deciding that plants are not excluded from patentability under European law unless they fall within EPC art. 53(b)). Since the abolition of the UPOV rule against double protection (UPOV art. 2) in 1991, the United States Supreme Court and European Patent Office [hereinafter EPO] have each confirmed the prima facie suitability of varieties of plants and animals for patent protection. *See J. E. M. Ag Supply*, 534 U.S. at 134-35 (confirming the patentability of plant and animal varieties on the authority of *Chakrabarty*, *supra*); Novartis/Transgenic Plant, G01/98, 2000 E.P.O.R. 303, 315-18 (Enlarged Bd. App. 1999) (confirming the patentability of individual plant and animal varieties for which sui generis protection is not available).

[23] *See* Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J., 721, 728-29 (1990); Rai, *supra* note 17, at 203-05; Ulrich Schatz, *Patentability of Genetic Engineering Inventions in European Patent Office Practice*, 29 INT'L REV. INDUS. PROP. & COPYRIGHT L.

supported a view of life forms and natural substances as structurally distinct physical objects that, with technical means, could be presented in non-natural forms and thereby imbued with different and improved utilities.[24] In this way early conceptions of modern biotechnology helped blur the already indistinct line between nature and artifice, and challenge the intuitive appeal of a threshold exclusion from patentability covering all living and natural phenomena.[25] It is thus no surprise that when the first wave of patent applications for recombinant products forced the principle of that exclusion before the courts and patent offices of Europe, the United States and Australia the response was unanimous: as a general proposition it had no merit, there being nothing inherent in life nor nature to prevent it from constituting or forming the basis of an invention.[26] The result was to confirm what was

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2, 5 (1998); Joseph Straus, *Patenting Human Genes in Europe — Past Developments and Prospects for the Future*, 26 INT'L REV. INDUS. PROP. & COPYRIGHT L. 920, 925-26 (1995).

[24] *See*, *e.g.*, *Chakrabarty*, 447 U.S. at 310 ("[T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own: accordingly it is patentable subject matter under § 101."); *Re Ranks Hovis McDougall*, 1976 A.O.J.P. at 3918 (distinguishing between naturally occurring micro-organisms derived by altering their conditions of growth (unpatentable), and new micro-organisms derived by means of a human controlled microbiological process and having a new or improved use (patentable)). *See also* Kirin-Amgen, Inc. v. Bd. of Regents of Univ. of Washington (1995) 33 I.P.R. 557, 569 (Dep. Comm'r Patents Austl.) ("By being directed to a purified and isolated DNA sequence [the patentee] claim[s] 'an artificially created state of affairs'" and not "a mere chemical curiosity"). *Cf.* Genentech, Inc. v. Wellcome Found., 1989 R.P.C. 147 (Eng. C.A. 1988) (deciding that an isolated protein and its encoding DNA sequence were unpatentable because the protein's properties and functional characteristics had long been known, preventing it from being regarded as a new substance). The view of life forms and natural substances herein described was consistent with the view previously taken of non-recombinant natural phenomena. *See*, *e.g.*, *Merck*, 253 F.2d at 164 (deciding that an isolated and purified form of vitamin B(12) was a new thing of improved utility and patentable on that basis); *Parke-Davis*, 189 F. at 103 (deciding that adrenalin in isolated form was patentable because the act of removing it from its natural environment rendered it "for every practical purpose a new thing commercially and therapeutically"); *Bergy*, 563 F.2d at 1038 (deciding that a biologically pure micro-organism created by a patentable fermentation process was "more akin to inanimate chemical composition such as reactants, reagents and catalysts than they are to horses and honeybees or raspberries and roses" and was patentable on that basis); *In re Bergstrom*, 427 F.2d at 1402 (deciding that isolated purified prostaglandins were patentable as new chemical compounds).

[25] *See* David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 90 (1995) (describing the natural phenomena objection as "derived from the inherent truth that something cannot be new if it already exists in nature"). *Cf.* Eisenberg, *supra* note 15, at 786 (describing the treatment of DNA sequences as akin to new and useful chemical products as "not simply a lawyer's trick, but a persuasive response to the intuition that patents should only issue for human inventions").

[26] In the United States and Australia the demise of the living and natural phenomena

already accepted amongst most patent professionals; namely, that modern biotechnology was inherently suitable for patent protection, and that biotech patenting was no more than a new stage in the long and developing history of patent law's involvement with the biochemical sciences.[27]

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objections was the result of the decisions in *Chakrabarty*, 447 U.S. 303 and *Re National Research Development*, 102 C.L.R. 252, respectively. *See* sources cited *supra* note 22. In *Chakrabarty*, the Supreme Court held that patents may be granted for "anything under the sun that is made by man" (*id*. at 309) (quoting S. REP. NO. 1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 1923, at 6 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399), whether living or not (*id.* at 313), and excluding only such products of nature as "a new mineral discovered in the earth . . . a new plant found in the wild" or Einstein's "celebrated law that $E=mc^{2}$" (*id*. at 309). In *Re National Research Development,* the High Court held that patents may be granted for any "artificially created state of affairs [of economic significance]" (*id*. at 277) whether or not involving living or natural phenomena (*id*. at 263–04). In Europe, the patentability of living and natural phenomena has been presumed since introduction of the EPC (*see* Straus, *supra* note 23, at 925) and supported since then by a view of EPC arts. 52(2) & 53(b) as exclusions of restrictive operation. *See*, *e.g.*, Leland Stanford/Modified Animal, Application No. 88312222.8, 2002 E.P.O.R. 16, ¶ 42 (Opposition Div. 2001) (accepting that "the gist of [*Novartis/Transgenic Plant*, *supra*], namely that claims which have a broader scope than merely consisting of a 'variety' are patentable, should also be valid for animal cases"); *Novartis/Transgenic Plant*, 2000 E.P.O.R. at 312-13 (construing EPC art. 53(b) narrowly in the context of plants to cover claims directed to specific plant varieties as distinct from more generally worded claims that include plant varieties within their scope); Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541, 548-49 (Opposition Div. 1994) (construing EPC art. 52(2)(a) narrowly in the context of natural phenomena to cover only such naturally occurring substances as are found); Harvard/Onco-Mouse, Application No. 85 304 490.7, 1991 E.P.O.R. 525, 527 (Examining Div. 1991) (construing EPC art. 53(b) narrowly in the context of animals to cover only "sub-unit[s] of a species" and not species and other higher taxonomic classifications of animals per se); *Lubrizol/Hybrid Plants*, 1990 E.P.O.R. at 179–80 (construing EPC art. 53(b) narrowly in the context of plants to cover only such "multiplicit[ies] of plants which are largely the same in their characteristics (that is, 'homogene[ous]') and remain the same within specific tolerances after ever propagation or every propagation cycle (that is, 'stab[le]')"). *See also* Ciba-Geigy/Propagating Material, T49/83, 1979-85 E.P.O.R. Vol. C 758, ¶ 2 (Technical Bd. App.) ("[N]o general exclusion of inventions in the sphere of animate nature can be inferred from the EPC."), cited with approval in *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, T356/93, 1995 E.P.O.R. 357, 367 (Technical Bd. App. 1995). The European approach to living and natural phenomena has a strong foundation in Continental law by reason of its consistency with the widely respected approach of the Bundesgerichtshot (German Federal Supreme Court). *See especially* Baker's Yeast ("Backerhefe"), 1975 GRUR 430 (BGH 1975), *translated and abridged in* 6 INT'L REV. INDUS. PROP. & COPYRIGHT L. 207 (1975) (confirming that micro-organisms were patentable on the same principles as chemical products); Red Dove, 1 INT'L REV. INDUS. PROP. & COPYRIGHT L. 136, 137 (1970) (deciding that patents could properly be granted for any methodological utilization of natural biological forces and phenomena).

[27] *See* discussion *supra* note 17. Many academic discussions on biotech patenting open by emphasising that neither modern biotechnology nor biotech patenting is new. *See*, *e.g.*,

There remained, however, a practical impediment to the realisation of this conclusion, arising from the insufficiency of written forms of description to ensure a third party's ability to repeat an invention involving biological material.[28] It followed from the requirements of enablement and disclosure[29] that if biotech patenting were to be allowed, traditional conceptions of reproducibility would need to be revised or an alternative means of description introduced. The latter solution was chosen and implemented by the 1977 Budapest Treaty,[30] which recognized the sufficiency for descriptive purposes of a physical deposit of lower life forms in any recognized depositing agency. At the time even those arguing the case for sui generis protection of modern biotechnology viewed this development as having removed the last real obstacle to biotech patenting.[31]

Thus, the legitimacy of biotech patenting was overwhelmingly confirmed as involving a natural extension of the patent system to cover a developing branch of an old and historically patentable technology. To the extent that specific changes to that system were required by such extension, they were viewed as readily identifiable and easily made. To the extent that ongoing challenges would be presented in the system's application, they were presumed capable of being resolved analogously by reference to existing technologies in the same manner that the challenges inevitably presented by all new subject matter for

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Robert A. Armitage, *The Emerging US Patent Law for the Protection of Biotechnology Research Results*, 1989 EUR. INTELL. PROP. REV. 47, 49 (1989) ("Any debate on the patentability of living subject-matter should begin . . . with a recognition that man has long had and practised the art of creating 'new' plants and animals. . ."); Tade Matthias Spranger, *Ethical Aspects of Patenting Human Genotypes According to EC Biotechnology Directive*, 31 INT'L REV. INDUST. PROP. & COPYRIGHT L. 373, 376–77 (2000) ("[T]he general point first needs to be made that protection for living organisms was already being granted under patent law in the century before last — for the first time on July 24, 1843. The problem is therefore by no means new." (citations omitted)).

[28] *See* Paul Anthony Power, *Interaction Between Biotechnology and the Patent System*, 3 AUSTL. INTELL. PROP. J. 214, 220-23 (1992). The requirement for written description was a problem for all subject matter involving biological material and not just modern biotechnology, and was resolved in some jurisdictions before explicit confirmation of the patentability of modern biotechnology per se. *See*, *e.g.*, *In re* Argoudelis, 168 U.S.P.Q. (BNA) 99 (C.C.P.A. 1970) (recognizing the sufficiency of the deposit of a micro-organism for disclosure purposes under U.S. patent law).

[29] *See* 35 U.S.C. § 112 ¶ 1 (2000); EPC arts. 83 & 84; Patents Act, 1990, ch. 83, § 40 (Austl.).

[30] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241, 1861 U.N.T.S. 361 [hereinafter Budapest Treaty].

[31] *See*, *e.g.*, Ellinson, *supra* note 7, at 293. *Cf.* R. S. Crespi. *Biotechnology and Patents: Outstanding Issues*, 8 EUR. INTELL. PROP. REV. 201, 204 (1983) (noting the additional problems that introduction of the Budapest Treaty created within Europe as a result of the failure of some nations to accept the deposit of a micro-organism as fully meeting their description requirements).

which patent protection is sought are resolved. These views underlined the confidence of early assertions that modern biotechnology raised no new issues for patent law such as to require its prima facie exclusion from the patent system. As has been noted, also underlining that confidence was a conception of modern biotechnology as involving the technological manipulation of living and/or natural phenomena to produce structurally distinct (chemical) objects of new or improved utility.

Since the early years of the biotech patenting debate, however, this conception of modern biotechnology and the approach to biotech patenting it supports have been gradually eroded.[32] That erosion has coincided with a struggle by patent law decision makers and commentators to apply traditional principles of patentability to existing and emerging forms of modern biotechnological products.[33] In the course of this struggle it has become increasingly apparent that whatever traits modern biotechnology can be said to share with classical technologies, when forced within the patent system it repeatedly reveals its differences to, and the patent system's discomfort beyond, those technologies.[34] In addition, the source of those differences has been revealed as running deeper than the concern of modern biotechnology with living and natural phenomena.[35] For example, it is now apparent that the commercial value and scientific teaching of modern biotechnology lies as much in the information it conveys as the functions it supports, such that many modern biotechnological products are more accurately described as "carriers of information"[36] than physical objects of practical use per se.[37] The immediate

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[32] *See* discussion *infra* Section III.

[33] *Id*.

[34] *See* discussion *infra* notes 50-53 and accompanying text.

[35] *Id*.

[36] Rai, *supra* note 17, at 204.

[37] *See* discussion *infra* note 51 and accompanying text. On the informational nature of modern biotechnology see generally The British Group of AIPPI, *Report Q 150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes*, 22 EUR. INTELL. PROP. REV. 39, 41 (2000); Eisenberg, *supra* note 10, at 785, 786-90; Clarisa Long, *Patent Law and Policy Symposium: Re-Engineering Patent Law: The Challenge of New Technologies: Part II: Judicial Issues: Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL'Y 229, 233 (2000); Straus, *supra* note 23, at 922; Winter, *supra* note 10, at 180. *See also* Genetics Institute, Inc. v. Kirin-Amgen, Inc. [No. 3] (1998) 41 I.P.R. 325, 343 (Fed. Ct. Austl.) (accepting "cDNA" as capable of bearing "several secondary meanings, including not only DNA molecules but also information."); Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541, 551 (Opposition Div. 1994) ("DNA is . . . a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be medically useful."). Recognition of the informational nature of modern biotechnology is increasingly unavoidable as biotech patentees become increasingly explicit in their concern to patent information by seeking protection for research results stored and managed in electronic form. On the patenting of such "bioinformatics" see generally Eisenberg, *supra* note 15; Charles Vorndran and Robert L. Florence,

significance of this for biotech patenting lies in its creation of the following quandary. Accommodating modern biotechnology within the patent system on the basis of its equivalence to new chemical compounds is problematic because, at a fundamental level, no such equivalence exists.[38] However, accommodating modern biotechnology within the patent system as information is also problematic because information, according to traditional patent jurisprudence, is not a subject matter that patent law protects.[39]

Bioinformatics: Patenting the Bridge Between Information Technology and the Life Sciences, 42 IDEA 93 (2002). The emerging phenomenon of bioinformatic patents confirms the significance of biotech patenting generally as part of the wider phenomenon involving use of the patent system to promote emerging and existing information industries, and suggests that the future of biotech patenting will depend less on the principles developed around biochemical subject matter than on principles relating to computer and other information technologies. *See* Eisenberg, *supra* note 15, at 792.

[38] The failure of the biotechnology–chemical compound analogy results not from the physical structure of modern biotechnological products, but rather from the relationship between those products' structure and function. *See* discussion *infra* note 51 and accompanying text. As a consequence, recognition of the informational nature of modern biotechnology involves neither a denial of the chemical composition of modern biotechnology, nor an abandonment of the formal description of DNA sequences and other forms of modern biotechnology as "chemical compounds" per se. *See*, *e.g.*, cases at *supra* note 37.

[39] The historical view of information as unpatentable derives from the same distinction between abstract principles and technical objects as the exclusion of natural phenomena. Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."). *See also* Int'l Bus. Machines Corp. v. Comm'r of Patents (1990) 22 I.P.R. 417, 419-20; IBM/Document Abstracting and Retrieving, T 22/85, 1990 E.P.O.R. 98, 103–04 (Technical Bd. App. 1988). For most of the twentieth century the distinction between principles and objects has supported the exclusion from patentability of arrangements of information and other subject matter considered to be of purely abstract value including, most contentiously, mathematical algorithms and business methods. *E.g.*, *Gottschalk*, *supra* (mathematical algorithms); Hotel Security Checking Co. v. Lorraine Co., 160 F. 467 (2d Cir. 1908) (systems of business); *In re* Sterling, 70 F.2d 910 (C.C.P.A. 1934) (methods of banking); *Re* Cooper, 19 R.P.C. 53, 54 (Att'y Gen. 1901) (arrangement of newspaper text, and in dictum, business methods and political schemes); *Re* Johnson, 19 R.P.C. 56, 56 (Sol. Gen. 1901) (system of business correspondence); Stahl & Larsson's Application, 1965 R.P.C. 596 (App. Trib. 1965) (method of recording travel information); *Re* Badger Co. Incorporated's Application, 1970 R.P.C. 36 (App. Trib. 1968) (method of preparing, tabulating and codifying information for computation); *Int'l Bus. Machines Corp.*, 1990 I.P.R. at 419 (mathematical algorithms). In the EPO the distinction between abstract principles and technical objects continues to inform applications of article 52(2). *Infra* note 44. *See*, *e.g.*, PBS Partnership/Controlling Pension Benefits Systems, T931/95, 2002 E.P.O.R. 522 (Technical Bd. App. 2000) (method of controlling a pension benefits program (business method)); IBM/Card Reader, T854/90, 1994 E.P.O.R. 89 (Technical Bd. App. 1992) (method of operating a self-service machine (business method)); *IBM/Document Abstracting and Retrieving*, 1990 E.P.O.R. 98 (method of abstracting and storing a document electronically (computer program and abstract

Of central interest in this context is the response of the patent law community to the situation thus created, and to the ongoing issue of modern biotechnology's suitability for patent protection generally. That response has, loosely speaking, followed one of two lines. The first, supported principally by the U.S. Court of Appeals for the Federal Circuit, has been to ignore the ongoing challenges to the suitability of modern biotechnology for patent protection by persisting with a conception of modern biotechnological products as equivalent to chemical compounds and as patentable on that basis.[40] And the second, supported by the majority of other (European, Australian, and United States) decision makers and commentators, has been to concede the deficiencies in that conception by acknowledging that traditional principles of patentability are less accommodating of modern biotechnology than originally thought, but to treat this as reflecting upon those principles and not upon biotech patenting per se.[41] Central to this approach has been a shift in the terms in which the biotech patenting question has been framed, with its initial focus on the comparability of modern biotechnology to other forms of patentable technology giving way to a new focus on the capacity of the patent system adequately to deal with modern biotechnology and other new technologies as a test of that system's strength and legitimacy. The result, however, has been the same; namely, a path of reform aimed in theory at adapting the patent system to accommodate modern biotechnology, and resulting in practice in the dismantling of all theoretical and doctrinal obstacles to the recognition of modern biotechnology's suitability for patent protection.[42]

Faced with this result it is difficult to avoid the impression that biotech patenting has, from the outset, been less about patenting than about biotechnology, and that the success of patent law's accommodation of modern biotechnology ultimately reflects the success of legal expediency over legal reasoning. Certainly this impression has been felt by many public observers of the biotech patenting phenomenon, and accounts for much of the disillusionment that exists amongst such observers regarding patent law today. That disillusionment has in turn played a critical role in the further evolution of the biotech patenting debate. In particular, by fuelling the politicisation of patent law, public disillusionment in relation to biotech patenting and the way it has been achieved is strengthening, albeit in a negative direction, the link already established by the patent law community between the future of patent law and its response to modern biotechnology.

The purpose of the remainder of the present Article is to explain this link and, in so doing, to show how it is that ongoing responses to modern

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scheme)). On the current state of the information exclusion *see* discussion *infra* note 61.

[40] *See* discussion *infra* Section III, *especially* note 57 and accompanying text.

[41] *See* discussion *infra* Section III, *especially* note 58 and accompanying text.

[42] *See* discussion *infra* Section III. The dismantling of all obstacles to biotech patentability has been widely commented upon, *see*, *e.g.*, sources cited *infra* note 78, and has been described by one commentator as part of a "[p]atent [g]old [r]ush." Rai, *supra* note 17, at 199.

biotechnology have exacerbated rather than resolved the problems endemic to biotech patenting. Such explanation is undertaken in four parts. The first (Section III) describes in greater detail the issues canvassed above regarding modern biotechnology's impact on patent doctrine and the expediency of decision makers' responses thereto. The second (Section IV) and third (Section V) consider the theoretical and jurisprudential underpinnings of those responses, and the politicisation of patent law they have fuelled. And the fourth (Section VI) discusses the future viability of patent law in the light of such politicisation and of biotech patenting generally. As will be seen, an unstated theme of Sections III to V is that of patent law's harmonization. Hence the argument in Section VI, that biotech patenting and the controversy it has precipitated, make the substantive harmonization of patent law both necessary and yet unlikely to be achieved.

III. THE IMPACT OF MODERN BIOTECHNOLOGY ON PATENT DOCTRINE

The problem of biotech patenting was initially resolved as a problem of patent eligibility.[43] The principle of patent eligibility derives from the requirement, in all jurisdictions, that a subject matter for which a patent is sought be inherently suitable for patent protection in the sense of falling within the scope of subject matter that patent law prima facie exists to protect.[44] The

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[43] *See* discussion *supra* Section II.

[44] The principle of patent eligibility is explicated differently in different jurisdictions. In the United States, eligibility is defined in positive terms to mean "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101 (2002). In Australia, eligibility is defined as "any manner of new manufacture the subject of letters patent and grant of privilege within Section 6 of the Statute of Monopolies [21 Jam. 1, ch. 3 (1623)], and includ[ing] an alleged invention." Patents Act, 1990, ch. 83, § 18(1) (Austl.). In Europe, in contrast, eligibility is defined in negative terms to exclude: discoveries, scientific theories and mathematical methods; literary, dramatic, musical and artistic works, and any other aesthetic creations whatsoever; schemes, rules and methods for performing a mental act, playing a game or doing business, and programs for a computer; and presentations of information. EPC art. 52(2). Also excluded are animal and plant varieties and essentially biological processes for the production of animals and plants, not being a microbiological process or the product of such a process. EPC art. 53(b). Despite their prescriptive and proscriptive nature, EPC arts. 52(2) and 53(b) have been consistently interpreted purposively by the EPO to denote a positive requirement for technical character. *See*, *e.g.*, IBM/Computer Programs, T1173/97, 2000 E.P.O.R. 219 (Technical Bd. App. 1998); Vicom/Computer-Related Invention, T208/84, 1987 E.P.O.R. 74 (Technical Bd. App. 1986). In relation to EPC art. 53(b) see also Novartis/Transgenic Plant, G01/98, 2000 E.P.O.R. 303 (Enlarged Bd. App. 1999). This interpretation of EPC arts. 52(2) and 53(b) is consistent with pre-1977 Continental understandings of eligibility and patent jurisprudence generally. *See* Mobil/Friction Reducing Additive, G02/88, 1990 E.P.O.R. 73, 78-79 (Enlarged Bd. App. 1989) (describing the difference between the semantic and non-semantic patent philosophies of pre-EPC U.K. and European law and its reflection of a concern respectively with tangible inventions and technical contributions to the art (*cf.* discussion *infra* note 77 (questioning the extent of such

line between eligible and ineligible subject matter has traditionally been denoted by the terms "invention" and "discovery," with patent law thus being seen to rest on a fundamental distinction between (protectable) inventions on one hand and (unprotectable) discoveries on the other.[45]

The requirement of eligibility is a threshold requirement of patentability because of its role in identifying and determining the subject matter to which a patent will attach; which subject matter is therefore also the subject matter for which the other, substantive principles of patentability must be satisfied.[46] It

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difference))). The EPC definition of eligibility has recently been explicated in the specific context of modern biotechnology by Council Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, 1998 OFFICIAL J. EUR. CMTYS. (L 213) 13-21 [hereinafter EU Directive], the main provisions of which have been incorporated into the Implementing Regulations to the EPC. By express provision the EU Directive requires Contracting States to provide national patent protection for "biotechnological inventions" (art. 1(1)), including products "consisting of or containing biological material" (art. 3(1)), and further states that: (i) naturally occurring biological material must be "isolated from its natural environment or produced by means of a technical process" to support a patent (art. 3(2)); (ii) "plant and animal varieties," and "essentially biological processes for the production of plants [and] animals," are not patentable (art. 4(1)); and (iii) elements of the human body, including whole and partial DNA sequences, must be "isolated from the human body or otherwise produced by means of a technical process" (art. 5(2)) and shown in the patent application to have an "industrial application" (5(3)). Internationally, eligibility is also dealt with in the Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS]. Section 5 of TRIPS requires Member States to provide patent protection "for any inventions, whether products or processes, in all fields of technology . . ." (TRIPS art. 27(1)), with provision for exclusions of form similar to EPC art. 53(a), *infra*, and EPC art. 53(b), *supra* (TRIPS arts. 27(2), 27(3)(b)). Finally, note that not all exclusions from patentability are eligibility-related in the sense of reflecting a view of the (excluded) subject matter as of a type inherently unsuited to patent protection. An example of a non-eligibility related exclusion is EPC art. 53(a) (excluding from patentability inventions the publication or exploitation of which would be contrary to public ordre or morality). S*ee also* EU Directive art. 6; TRIPS art. 27(2). In addition to applying expressly to "inventions" (*i.e.*, eligible subject matter), this exclusion has been construed by the EPO as importing a factual inquiry and as not supporting the threshold exclusion of entire classes of subject matter per se. *See* discussion *infra* note 137.

[45] The extent to which patent legislation itself suggests usage of the terms "invention" and "discovery" to denote eligible and ineligible subject matter respectively varies between jurisdictions. In Europe and Australia it does, but in the United States it does not. *See* EPC art. 52 ("European patents shall be granted for any inventions. . ."); Patents Act, 1990, ch. 83, s. 18(1) (Austl.) ("[A] patentable invention is an invention . . . ."); 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process. . . ."). *See also* TRIPS art. 27(1) ("[P]atents shall be available for any inventions, whether products or processes, in all fields of technology. . . .").

[46] The so-called substantive principles of patentability are those principles that inform the requirements that must be satisfied for an inherently patentable subject matter (*i.e.*, an

thus precedes as a matter of logic the determination of those principles and constitutes the linchpin of the patent system generally.[47] It is also this threshold nature of the eligibility requirement that makes that requirement the inevitable point of initial intersection between new technologies and the patent system. Thus it is no surprise that the fate of biotech patenting was initially conceived as depending on the eligibility of modern biotechnology for patent protection or, and equivalently, on the capacity of modern biotechnological products to be regarded as inventions.[48]

As has been seen,[49] the eligibility of modern biotechnology for patent protection was initially resolved by reference to an analogy between biotechnological products and chemical compounds. In more recent years, however, there has been an increased awareness of the failure of that analogy when consistently applied to ensure clear and adequate protection for modern biotechnology.[50] Consideration of the reasons for this has produced a range of

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invention) to be granted a valid patent. Principally they are the requirements of novelty, inventiveness (nonobviousness), utility (industrial applicability) and sufficient description. The first three of these requirements [hereinafter non-threshold requirements] set the basic standards of patentability by ensuring that individual inventions: (i) were not previously available to the public; (ii) are sufficiently different from what was previously available to the public; and (iii) are actually (in the United States and Australia) or potentially (in Europe, except for DNA sequences, *see* EU Directive art. 5(3), *supra* note 44) capable of use.

[47] *See* Biogen, Inc. v. Medeva, Plc., 36 I.P.R. 438, 449 (H.L. 1996) (conceding the logical necessity to identify an invention under European law before considering the non-threshold requirements, but deciding nonetheless that patentability should in virtually every case be determined by reference exclusively to those requirements); *In re* Bergy, 596 F.2d 952, 960 (C.C.P.A. 1979) (describing the identification of an inventor and invention as the first door that must be passed through when determining patentability).

[48] *Cf.* Brad Sherman, Comment, *Patent Law in a Time of Change: Non-Obviousness and Biotechnology*, 10 OXFORD J. LEG. STUD. 278, 279 (1990) (attributing the early preoccupation of commentators with the eligibility of modern biotechnology to the nature of eligibility as a linguistic rather than a factual inquiry).

[49] *See supra* note 23 and accompanying text.

[50] *See*, *e.g.*, Armitage, *supra* note 27, at 55-57; Peter F. Corless, *Recombinant DNA Inventions After* Fiers, 16 HOUS. J. INT'L L. 509, 512–15 (1994); Tatsuya Izukawa, *Research and Study on Protection of Results of Genome* Research, 9 INST. OF INTELL. PROP. BULL. 20, 27-29 (2000); Ko, *supra* note 2, at 791; Charles Lawson, *Patenting Genetic Materials: Old Rules May Be Restricting the Exploitation of a New Technology,* 6 J.L. & MED. 373, 380-86 (1999); Eli A. Loots, *Intellectual Property: Patent: Validity: Written Description: The 2001 USPTO Written Description Guidelines and Gene Claims*, 17 BERKELEY TECH. L.J. 117, 120-24 (2002); Rai, *supra* note 17, at 203–06; Sherman, *supra* note 48, at 280–82. In particular, it has become apparent that anchoring biotech patenting to the jurisprudence developed around chemical inventions leaves modern biotechnology with too little protection too late. The reason is that it forces prospective patentees to wait until they have a structurally distinct object before obtaining a patent, and then restricts the protection thus obtained to that object. The effect of this approach is to make biotech patents easy to obtain but of little value to the patentee once obtained. *See* Loots, *supra*, at 121; Arti K. Rai,

insights regarding the differences between modern biotechnology and chemical inventions including, in particular, the complexities of the relationship between structure and function in the former when compared with the latter.[51] In addition, the manner and circumstances in which modern biotechnology and chemical inventions are created have been shown to differ markedly. Thus, according to classical paradigms at least,[52] the hypothetical chemical inventor is a person who works in an isolated environment expending creative intellectual effort in order to derive a physical object of practical use and value in a standard commercial industry. The biotechnological inventor, in contrast,

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Intellectual Property Rights in Biotechnology: Addressing New Technology, 34 WAKE FOREST L. REV. 827, 834-35 (1999). *See also* Julia Alpert Gladstone, *Why Patenting Information Technology and Business Methods is Not Sound Policy: Lessons from History and Prophecies for the Future*, 25 HAMLINE L. REV. 217 (2002) (describing a similar situation in respect of Internet business methods); David E. Huizenga, Comment, *Protein Variants: A Study on the Differing Standards for Biotechnology Patents in the United States and Europe*, 13 EMORY INT'L L. REV. 629 (1999) (demonstrating the impact of structural conceptions of modern biotechnology on the patenting of protein variants); discussion *infra* note 51 and accompanying text (regarding the scientific reasons for the failure of the biotechnology-chemical compound analogy to ensure adequate protection for modern biotechnology).

[51] *See*, *e.g.*, Corless, *supra* note 50, at 514–16; Loots, *supra* note 50, at 121–22; Rai, *supra* note 17, at 204-05. These commentators demonstrate the complexities of the relationship between structure and function in modern biotechnological products by reference to recombinant proteins. In contrast to chemical compounds, proteins can be created recombinantly without knowing the structural identity of the protein's encoding DNA sequence (or a structurally similar sequence) on the basis only of their partial or complete amino acid sequence. Corless, *supra* note 50, at 514–16; Rai, *supra* note 17, at 204-05. As a consequence, the focus of a researcher seeking to create a recombinant protein is generally on identifying specific cloning procedures that will result in expression of the protein and not on determining the structural identity of the encoding DNA sequence itself — a determination that will usually represent an advanced stage of the production process. Corless, *supra* note 50, at 514–16. In addition, the mutability of DNA and amino acid sequences is such that once a protein's defining sequence is known, a relevantly skilled person will be able to use the information represented by that sequence to produce a functionally equivalent protein of different structure in a range of species. Loots, *supra* note 50, at 121–22. It is for this reason that the value of much modern biotechnology is said to lie in the information it conveys. *See supra* note 37 and accompanying text. It is also for this reason that granting a patent for the specific (DNA or amino acid) sequence defining a protein is said to offer little or no protective value for the patentee. *See id*.

[52] This paradigmatic view of the chemical inventor has long ceased to be representative even in the chemical field. For a discussion of the evolving reality of creative production generally and how intellectual property law deals with it see Rochelle Cooper Dreyfuss, *Collaborative Research: Conflicts on Authorship, Ownership, and Accountability*, 53 VAND. L. REV. 1161 (2000). For another example of the chemical industry's outgrowth of the patent jurisprudence developed around it see William D. Marsillo, *How Chemical Nomenclature Confused the Courts*, 6 U. BALT. INTELL. PROP. L.J. 29 (1997) (discussing the changing approach of U.S. decision makers to chemical patents having a genus-species relationship).

is a team of people that interacts and competes with other teams of people to expend the time and resources necessary to generate information of use and value in an industry built exclusively around such information.[53]

The precise implications of these insights for the theoretical and doctrinal boundaries of patent law are still being unravelled. What is increasingly clear, however, is that the paradigmatic shift they reflect is sufficiently deep to have cast into doubt all of the fundamental concepts on which the patent system rests, from notions of technology and industry to the very concept of private property per se.[54] At a practical and normative level the issues thus raised converge at the site of eligibility, by asking whether modern biotechnology, however conceived, is a suitable subject matter for patent protection, or whether it is truly beyond the normative and doctrinal capacities of the patent system as that system currently exists.

Despite this, in recent years there has been very little direct acknowledgement of that convergence, nor of the ongoing importance of the eligibility enquiry generally in the context of biotech patenting.[55] On the contrary, since the early declaration of modern biotechnology's eligibility for patent protection the focus of decision makers has overwhelmingly been on the other substantive requirements when considering issues of biotech patenting. As a result, the criterion of eligibility has effectively been written out of the biotech patenting equation.[56]

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[53] *See* Julian David Forman, Comment, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 680 (2002) ("Much of the work product of the biotechnology industry is not commercially viable in the conventional sense, but may nevertheless be deserving of patent protection because it has great practical utility within the market boundaries of the industry itself."); Long, *supra* note 37, at 233 ("An entire industry has sprung up surrounding the creation of genomic information." (Citation omitted.)); Sherman, *supra* note 48, at 283 ("[I]f the role of management in contemporary research continues to increase it will not be long before the concept of inventiveness and the stereotyped picture of the scientist that underpins it are questioned."). *See also* Biogen/Hepatitis B, T296/93, 1995 E.P.O.R. 1, 20 (Technical Bd. App. 1994) (deciding that the number of teams working concurrently on a problem the solution of which represents the subject matter of a patent is irrelevant when determining that subject matter's inventiveness); Biogen/Alpha-Interferon II, T500/91, 1995 E.P.O.R. 69, 76 (Technical Bd. App. 1992) ("[I]n accordance with the established jurisprudence of the Boards of Appeal, the notional skilled person who may be represented by a team of appropriate specialists . . ., is oriented towards practicalities, . . . and the development of the art normally expected by him does not include solving technical problems by performing scientific research in areas not yet explored." (citations omitted.)).

[54] *See* Long, *supra* note 37, at 233.

[55] *Cf. infra* note 100 and accompanying text.

[56] As will be shown, in all jurisdictions the treatment of eligibility as a non-issue for modern biotechnology has been the combined effect of: (i) an expansive interpretation of patent eligibility and (complementarily) restrictive interpretation of specific eligibility exclusions, *see* discussion *supra* note 26 and *infra* note 61); and either (ii) a view of modern biotechnology's eligibility for protection as established and as thus not in issue; or (iii) a

At an immediate level, the result of this whitewashing of eligibility has been to facilitate the two contradictory approaches to biotech patenting outlined above. Thus, in the United States, it has enabled the Federal Circuit to persist with a structural conception of modern biotechnology even as deficiencies in that conception have emerged, resulting in a continued reliance on chemical patenting jurisprudence when resolving issues of biotech patenting.[57] In Europe and Australia, in contrast, treating eligibility as a non-issue for modern biotechnology has permitted an abandonment of the biotechnology–chemical compound analogy and dissociation of biotech patenting generally from chemical patenting and its attendant jurisprudence.[58] Thus the emphasis on modern biotechnology's identity with chemical compounds has given way to an emphasis on its difference from such compounds and, indeed, on its difference from classical inventions of all forms. A critical aspect of this development has been a further shift in focus from the specific place of modern biotechnology in the tradition of biochemical sciences on one hand to its generic place amidst the range of "new" twentieth century technologies on the other. However, rather than prompting an explicit re-conception of modern biotechnology and renewed undertaking of the eligibility enquiry by reference thereto, recognition of modern biotechnology's newness has been used precisely to support the avoidance of such tasks. As a result, the claim made is

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view of the whole question of modern biotechnology's eligibility for protection as ill-conceived.

[57] The substantive requirements most affected by the specific terms in which individual subject matter are conceived are those of inventiveness and enablement/disclosure which have, accordingly, been the principal sites in which the U.S. Federal Circuit's structural conception of modern biotechnology has been reflected. *See*, *e.g.*, Enzo Biochem, Inc., v. Gen-Probe Inc., 296 F.3d 1316, 1328-29 (Fed. Cir. 2002); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997); *In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993); Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied sub. nom.* Genetics Inst., Inc. v. Amgen, Inc., 502 U.S. 856 (1991). Some U.S. commentators have contrasted the approach of the U.S. Federal Circuit in these cases (and to the requirements of inventiveness and enablement/disclosure generally) with that of the U.S. PTO, describing the latter in terms that reflect a conception of modern biotechnology more in keeping with that of European and Australian decision makers. *See* discussion *infra* note 58 and accompanying text. *See*, *e.g.*, Loots, *supra* note 50, at 129-30; Rai, *supra* note 17, at 204–06. Compare also the approach of U.S. decision makers to the requirement of utility. *See* discussion *infra* notes 68, 78.

[58] Consistent with the discussion immediately above (note 57), the dissociation of biotech patenting from chemical patenting has been reflected most strongly in the contexts of inventiveness and disclosure/enablement. *See*, *e.g.*, Genetics Institute, Inc. v. Kirin-Amgen, Inc. [No. 3] (1998) 41 I.P.R. 325 (Fed. Ct. Austl.); Biogen, Inc. v. Medeva, Plc., 36 I.P.R. 438 (H.L. 1996); Genentech/t-PA, T923/92, 1996 E.P.O.R. 275 (Technical Bd. App. 1995); Biogen/Recombinant DNA, T301/87, 1990 E.P.O.R. 190 (Technical Bd. App. 1989); Genentech I/Polypeptide Expression, T292/85, 1989 E.P.O.R. 1 (Technical Bd. App. 1988). *Cf.* Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541 (Opposition Div. 1994). *See* discussion *infra* note 67.

not that modern biotechnology (as reconceived) remains eligible for patent protection, but rather that it confirms the redundancy and/or inappropriateness of the notion of eligibility itself. Thus the very question of modern biotechnology's inherent patentability has come to be viewed as ill-founded.

Paradoxically this view, and the approach to biotech patenting it supports, derives from the very decisions in which modern biotechnology's eligibility for patent protection (by reference to its analogousness to chemical compounds) was first confirmed.[59] Indeed, this explains the dissonance that currently exists in the United States as a result of the Federal Circuit's persistence with a structural conception of biotechnological products which, whilst consistent with the doctrinal foundations of biotech patenting,[60] is nonetheless contrary to the basic trend of higher court authority and patent jurisprudence generally.

At the centre of that trend lies the attack on eligibility described above, which has been expressed through three central claims.[61] The first is that

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[59] *See especially* discussion *infra* notes 61, 63 & 65, and accompanying text.

[60] *See* discussion *supra* Section II.

[61] A fourth central way in which the eligibility criterion has been undermined in all jurisdictions is by attacking each of the individual exclusions that it supports so as to deprive those exclusions (and thus the criterion) of meaningful practical application. Over the last half-century this approach has been used to complement the expansive, positive definitions of eligibility discussed above (see *supra* note 26), and has reduced the traditional exclusions of information and natural phenomena to de minimis status. On the current state of the natural phenomena exclusion see discussion *supra* Part II, especially note 26. On the current state of the information exclusion see generally Eisenberg, *supra* note 15; Gladstone, *supra* note 50; Sam S. Han, *Analyzing the Patentability of "Intangible" Yet "Physical" Subject Matter*, 3 COLUM. SCI. & TECH. L. REV. 2 (2002); Rai, *supra* note 17; John R. Thomas, *The Post-Industrial Patent System*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 3 (1999). The patenting of informational products has also been permitted in Europe, despite the express exclusions of EPC art. 52(2) (*supra* note 44). *See*, *e.g.*, Philips/Record Carrier, T1194/97, 2001 E.P.O.R. 193 (Technical Bd. App. 2000) (construing EPC art. 52(2)(d) narrowly to permit the patenting of a picture retrieval system); IBM/Computer Programs, T1173/97, 2000 E.P.O.R. 219 (Technical Bd. App. 1998) (construing EPC art. 52(2)(c) narrowly to permit the patenting of computer programs claimed as computer programs); Vicom/Computer-Related Invention, 1987 E.P.O.R. 74 (Technical Bd. App. 1986) (construing EPC art. 52(2)(c) narrowly to permit the patenting of a method of digitally processing images). In addition, to the extent that *PBS Partnership/Controlling Pension Benefits Systems*, T931/95, 2002 E.P.O.R. 522 (Technical Bd. App. 2000), suggests an exception to this trend by affirming the ineligibility for protection of a method of doing business, it is undermined by the Board's decision that a separate claim directed to a computer apparatus programmed to implement the same method was eligible. *See PBS Partnership/Controlling Pension Benefits Systems*, 2002 E.P.O.R. ¶¶ 3, 5. The decision in *Philips/Record Carrier*, *supra*, reflects the contemporary approach by which traditional jurisprudential emphases on the ineligibility of *presentations* of information are construed as indicating an intention not to deny patents for information per se; albeit in the context of the EPC with additional reliance on the 'as such' restriction of article 52(3). This reasoning has been explicitly adopted to support the patenting of modern biotechnology, consistent with

eligibility restrictions discriminate between "old" (*i.e.*, classical chemical and mechanical) inventions and "new" (*e.g.*, biotechnology) inventions — and, more emotively, between old and new inventors[62] — thereby offending the very purpose of the patent system in promoting new fields of technological endeavour.[63] The second is that eligibility has been made conceptually and/or technologically redundant by such new technologies, and that it therefore does not apply to those (and on some arguments to any) technologies.[64] And the

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the growing view of modern biotechnological products as information rather than chemical compounds or even living and natural phenomena per se. *See*, *e.g.*, The British Group of AIPPI, *supra* note 37, at 41. *See also* Eisenberg, *supra* note 15, at 787 (noting the argument).

[62] *See*, *e.g.*, Stephen Crespi, *Biotechnology Patenting: The Wicked Animal Must Defend Itself*, 1995 EUR. INTELL. PROP. REV. 431, 437; Moufang, *supra* note 12, at 831; Scalise & Nugent, *supra* note 25, at 95-96.

[63] The argument that eligibility discriminates between old and new technologies is reflected in the reliance on patent law's purpose to undermine specific eligibility restrictions to patentability. *See*, *e.g.*, J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 135 (2001) ("Denying patent protection under § 101 simply because such coverage was thought technologically infeasible in 1930 . . . would be inconsistent with the forward-looking perspective of the utility patent statute."); Diamond v. Chakrabarty, 447 U.S. 303, 316 (1980) (citing the tendency for "inventions most benefiting mankind" to be those that are "unforeseeable" and "that 'push back the frontiers of chemistry, physics, and the like'" to support the rejection of the living phenomena exclusion (quoting Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 154 (1950)); Red Dove, 1 INT'L REV. INDUS. PROP. & COPYRIGHT L. 136, 137 (1970) (citing the purpose of patent law in protecting the results of cutting-edge research to support the rejection of the living phenomena exclusion); *Re* National Research Development Corp., 102 C.L.R. 252, 269-70 (Austl. 1959) (referring to "a widening conception of the notion [of 'manufacture']" as a characteristic of the growth of patent law to support the rejection of the living phenomena exclusion). *See also* Biogen, Inc. v. Medeva, Plc., 36 I.P.R. 438, 449 (H.L. 1996) (citing the concern of the drafters of the EPC to ensure a definition of patentability "in conformity with developments in science and technology" to support an expansive view of patent eligibility in the context of modern biotechnology). The same use of purposive reasoning to override eligibility restrictions is reflected in the context of informational products. *See*, *e.g.*, AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352, 1356 (Fed. Cir. 1999) (citing the need for the patent system to be "responsive to the needs of the modern world" to support an expansive view of 35 U.S.C. § 101 as permitting patents for mathematical algorithms, contrary to the historical principles discussed above (*see supra* note 41)).

[64] The argument of technological redundancy has been made primarily in the context of plant and animal varieties and biological processes. *See*, *e.g.*, *J. E. M. Ag Supply*, 534 U.S. at 135 (confirming the eligibility of plant varieties for patent protection despite their historical treatment as unpatentable, on the basis that such treatment reflects "the reality of plant breeding in 1930" and is attributable to a belief at that time that "coverage [of sexually reproduced plants] was . . . technologically infeasible," which has since been undermined). *See also* Lubrizol/Hybrid Plants, T320/87, 1990 E.P.O.R. 173, 179–80 (Technical Bd. App. 1988) (construing EPC art. 53(b) narrowly to exclude recombinant plants; *see supra* note 26); Harvard/Onco-Mouse, Application No. 85 304 490.7, 1991 E.P.O.R. 525, 527 (Examining Div. 1991) (construing EPC art. 53(b) narrowly to exclude recombinant

third is that eligibility introduces an arbitrariness into patent law as a result of the inherent uncertainty, from a linguistic point of view, of the specific concepts by which it is defined and explicated.[65] In combination these arguments assert that the threshold requirement of invention must be removed in order to rid the patent system of its inherent prejudice and uncertainty, and thereby ensure the future capacity of that system to fulfil its purpose of promoting innovation within a changing technological landscape.[66] The reliance on modern biotechnology's newness to support this reasoning reflects the wider approach to biotech patenting that has followed (and been facilitated

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animals; *see supra* note 26). The argument of technological redundancy is also reflected widely in the academic literature. *See*, *e.g.*, Robin Nott, *The Novartis Case in the EPO*, 1990 EUR. INTELL. PROP. REV. 33, 35-36; Schatz, *supra* note 23, at 7-8, 10.

[65] *See*, *e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 134-35 (1948) (Frankfurter, J., dissenting) ("It only confuses the issue [of patentability] to introduce such terms as 'the work of nature' and the 'laws of nature.' For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent."); *Re National Research Development Corp.*, 102 C.L.R. at 263-64, 269 ("The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. . . . The inquiry which the definition [of 'invention'] demands is an inquiry into the scope of the permissible subject matter of letters patent and grants of privilege protected by the section. It is an inquiry not into the meaning of a word so much as into the breadth of the concept which the law has developed by its consideration of the text and purpose of the *Statue of Monopolies*."). Again, the argument of prejudice and uncertainty is also reflected widely in the academic literature. *See*, *e.g.*, N. J. Byrne, *Patents on Life*, 1979 EUR. INTELL. PROP. REV. 297, 299; Crespi, *supra* note 62, at 432; Michael Kern, *Patentability of Biotechnological Inventions in the United Kingdom: The House of Lords Charts the Course*, 29 INT'L REV. INDUS. PROP. & COPYRIGHT L. 247, 253-54 (1998); Moufang, *supra* note 12, at 837; Michael Spence, Note, *Patents and Biotechnology*, 113 LAW Q. REV. 368, 370–71 (1997); Hans Christian Thomsen, *The Exception to Patentability Under Article 53(b) EPC and Corresponding Laws of the EPC Contracting States*, 28 INT'L REV. INDUS. PROP. & COPYRIGHT L. 850, 856 (1997); Utermann, *supra* note 12. Indeed, some commentators appear to have viewed language itself as insufficiently certain of meaning to support threshold exclusions of any nature. *See*, *e.g.*, Byrne, *supra*, at 299; Margaret Llewelyn, *The Patentability of Biological Material: Continuing Contradiction and Confusion*, 2000 EUR. INTELL. PROP. REV. 191, 194.

[66] In addition to being criticised for undermining patent law's capacity to fulfil its purpose of encouraging innovation in all fields of technology, eligibility has been portrayed as adding nothing of substance to the non-threshold requirements and as thus being of purely academic interest. This portrayal, which is essentially self-fulfilling (*see* discussion *supra* note 61), has been maintained even in the face of the EPC art. 52(2) exclusions, and has been the result of literal as well as purposive constructions of patent legislation. *See*, *e.g.*, Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 162 (4th Cir. 1958) (literal reading of 35 U.S.C. § 101); *Biogen*, 36 I.P.R. at 449 (purposive reading of EPC art. 52); Vicom/Computer-Related Invention, 1987 E.P.O.R. at 80–81 (purposive reading of EPC art. 52).

by) the shifting conception of modern biotechnology. Pursuant to that approach, those aspects of traditional patent doctrine that look to obstruct biotech patenting are distinguished as inappropriate or inapplicable in the realm of recombinant technologies and thereby removed of their restrictive effect.[67] This approach has been a principal means by which biotech patenting in all jurisdictions has been cut free from the strictures of chemical patenting jurisprudence.[68]

However, and as the development of biotech patenting itself reveals, this approach is misconceived for two related reasons. First, because of its assumption that the historical prejudice and uncertainty of traditional patent law can be resolved by avoiding the requirement (and the site) through which they have historically been expressed. And second, because of its failure to concede the importance of the role performed by the eligibility criterion in explicitly defining, as a matter of law, what it is that makes a subject matter suitable (or unsuitable) for patent protection.

The assumption that the problems of traditional patent law can be resolved by removing the eligibility criterion is problematic because of the fundamental interrelatedness of the threshold and non-threshold requirements of patentability, such that the latter are predicated on the same conception of (inherent) patentability denoted by the former and are meaningless when applied to subject matter not fitting that conception. What this means is that whitewashing the formal criterion of eligibility in order to secure the patenting of potentially ineligible (and thus otherwise unpatentable) subject matter of

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[67] For examples of the approach herein described see discussion *infra* note 78. The expediency of this approach is underlined by the fact that where traditional patent doctrine facilitates biotech patenting it has been retained. Thus, just as the rejection of a structural conception of modern biotechnology has not involved a denial of the chemical composition of DNA sequences and other biotechnological products per se (*see* discussion *supra* note 38), the dissociation of biotech patenting from chemical patenting jurisprudence generally has not prevented European decision makers from relying on the latter explicitly to support findings of patentability. An example is *Howard Florey/Relaxin*, No. 83 307 553.4, 1995 E.P.O.R. 541 (Opposition Div. 1994), where the EPO's Technical Board of Appeal [hereinafter Board] relied on the chemical nature of DNA sequences: (i) to support a finding of inventiveness in respect of a recombinant protein on the basis of the protein's structural novelty (*see* discussion *infra* note 78, at point (ii); cases cited *supra* note 57); and (ii) to reject a claim of unpatentability under EPC art. 53(a) (*see* discussion *infra* note 108). In relation to the expediency governing approaches to biotech patenting generally see, for example, Sherman, *supra* note 48, at 285 (describing the approach of U.K. decision makers to questions of inventiveness in the context of modern biotechnology as reflecting an "openness of interpretation" that "involves choosing and selecting attributes of that knowledge which are appropriate to the new sciences"). *See also* discussion *infra* note 68.

[68] Even in the United States there has been a dissociation of biotech patenting from chemical patenting in contexts where such dissociation has not required a direct rejection of the structural conception of modern biotechnology per se; an example being the dilution of the *Brenner v. Manson*, 383 U.S. 519 (1966), principles of utility established in the context of chemical compounds. *See* discussion *infra* note 78.

itself cannot work, for the non-threshold requirements will continue to give effect to that criterion — either by obstructing patentability, or by reflecting generally their incomprehension of the subject matter in question.

This interrelatedness of the eligibility criterion with the non-threshold requirements has always existed, but has been particularly apparent in the context of biotech patenting. That it has always existed is clear from both the nature of such criterion and from the history of patentability generally. In relation to the former there is the very fact of the necessity to identify and thereby define the subject matter for which protection is sought, and for which the non-threshold requirements must therefore be satisfied.[69] In the opposite direction, it has always been a requirement of eligibility that a subject matter not be inherently incapable of satisfying one or more of those requirements.[70] Similarly, the history of the eligibility criterion shows the separate articulation of the threshold and non-threshold requirements to have been a twentieth century phenomenon attributable more to developments within general legal philosophy than to developments within patent jurisprudence per se.[71] Thus separation of those requirements coincided with the emergence within western jurisprudence of legal formalism, which gave rise to a highly prescriptive and rule-based approach to patent law in Anglo and European jurisdictions.[72] The

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[69] *See supra* text accompanying notes 46–47.

[70] See, for example, the historical rationalisations for the ineligibility of natural phenomena discussed above, *supra* note 12, including in particular the view of such phenomena as inherently lacking in novelty (because of their prior existence) and/or inventiveness (because of their derivation from natural conditions). One question not clearly settled in Australian and U.S. law is whether new and inventive in this threshold sense mean more than novel and nonobvious per se — *i.e.*, whether the threshold requirements of newness and inventiveness operate, for example, to exclude subject matter that previously existed in nature, even if not in a readily available form, and/or subject matter manifesting inventive merit but not of a particular (for example, technical) type. In the United States this question was considered in part by the U.S. Federal Circuit in *In re* Bergstrom, 427 F.2d 1394, 1401 (C.C.P.A. 1970), where the Court construed the threshold requirement of newness in 35 U.S.C. § 101 as having the same meaning as novelty under 35 U.S.C. § 112. The recent trend of Australian cases supports the same general position, undermining early High Court authority in the opposite direction (*see*, *e.g.*, Griffin v. Isaacs, 12 A.L.J. 169 (Austl. 1938)). Deprived of wider significance the effect of a threshold requirement of newness and/or inventiveness is to permit a finding of invalidity or unpatentability in respect of subject matter revealed on the face of the specification to be lacking in novelty/inventiveness without the need to resort to analysis of the prior art. *See* N.V. Philips Gloeilampenfabrieken v. Mirabella Int'l Pty. Ltd., 183 C.L.R. 655 (Austl. 1995) (establishing this principle for Australian law).

[71] On the history of legislative and judicial explications of patentability see Justine Pila, *Methods of Medical Treatment Within Australian and United Kingdom Patents Law*, 24 UNIV. NEW SOUTH WALES L.J. 421, 429-30 (2001) (Australia); Thomas, *supra* note 61, at 8–10 (U.S.); Geertrui Van Overwalle, *The Legal Protection of Biological Material in Belgium*, 31 INT'L REV. INDUS. PROP. & COPYRIGHT L. 259, 283-84 (2000) (Belgium).

[72] Whilst formalism in patent law probably reached its high point with the introduction of the EPC, it is also reflected in the increasingly prescriptive examination guidelines and other

attraction of formalism in bringing order and clarity to the otherwise complicated concept of patentability, however, has come at the cost of having forgotten (or denied) the original complexity itself.[73] This accounts for its effect in having encouraged a view of the substantive requirements of patentability as mutually exclusive and therefore capable of independent application and, if necessary, of independent abolition.

The fallacy of this view is revealed by the impact that the two approaches to eligibility described above have had on biotech patenting. Thus, in the United States, the Federal Circuit's continued adherence to a structural conception of modern biotechnology has left it wedded to a body of principle that depends for its efficacy upon scientific justifications that do not apply to most biotechnological products.[74] As a result, many of the patents tested pursuant to those principles are easily sustained but in a form that makes them of little ultimate value in the marketplace.[75] Indeed, it is for this reason that the European approach to biotech patenting has attracted so much support, for rather than ignoring the scientific realities of modern biotechnology in order not to disrupt its claim to eligibility, such approach takes as its starting point precisely the need to understand those realities and to adapt the patentability criteria in a way that accommodates them.[76] As has been seen, a principal

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documents that continue to issue from all jurisdictions in an effort to explicate traditional patent principles in the context of existing and emerging forms of modern biotechnology. *See*, *e.g.*, discussion *infra* note 79 (regarding the EU Directive and (revised) U.S. PTO Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001)).

[73] Another example of the effect of formalism in trivialising the patentability inquiry concerns the question, raised in all jurisdictions over the last century, of whether the inventive merit of an invention can derive exclusively from part of the invention that would in isolation be ineligible for patent protection. By separating the invention from the inventive act that gives rise to it, formalism encourages a linear conception of the inventive process itself (as involving the practical implementation of a discovery or idea), which has at times encouraged the view that a subject matter's inventiveness must derive in part from the act of such implementation. That view, which is particularly unsympathetic to the modern biotechnology research paradigm described above (*supra* text accompanying note 53; *see also* Long, *supra* note 37, at 233), has been consistently rejected. *See*, *e.g.*, *Re National Research Development Corp.*, 102 C.L.R. 252, 263 (Austl. 1959) ("It is not decisive — it is not even helpful — to point out . . . that beyond discovery of a scientific fact nothing has been added except the suggestion that nature, in its newly ascertained aspect, be allowed to work in its own way. Arguments of this kind may be answered as Justice Frankfurter answered them in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*" (Citation omitted.)); Vicom/Computer-Related Invention, 1987 E.P.O.R. 74, 80-81 (Technical Bd. App. 1986) ("Decisive is what technical contribution the invention as defined in the claim when considered as a whole makes to the known art.").

[74] *See* discussion *supra* notes 50-51 and accompanying text. *See especially* Rai, *supra* note 17, at 203-06.

[75] *Id.*

[76] *See*, *e.g.*, cases cited *supra* note 58 (reflecting the approach herein described); Huizenga, *supra* note 50 (criticising the approach of the Federal Circuit to patents for protein variants in contrast to that of the EPO by reference in part to the understanding of

aspect of such adaptation has involved removing eligibility from the patent law equation altogether.

However, even this approach is problematic, and has been revealed as such by its impact on biotech patenting. On its face, removing eligibility from the doctrinal landscape of patentability involves divorcing patentability from notions of tangible and technological manifestation, and marrying it with notions pertaining exclusively to the investment expended by a (prospective) patentee in producing a subject matter, and the value of the subject matter to society once produced. Put differently, it involves recasting patent law's object in terms of inventive results of practical utility (*i.e.*, useful inventiveness) and not, as the need to establish eligibility has historically assumed, particular tangible or technological manifestations of such activity (*i.e.*, useful inventions). Hence its appeal, which derives from the technological neutrality of the conception of patentability it appears to support.[77]

However, to the extent that the demise of eligibility reflects a concern to redefine patentability by reference to useful inventiveness over useful inventions it has not worked. Rather, it has left a conceptual gap in the landscape of biotech patenting that the non-threshold requirements are struggling to fill. This is reflected primarily in the failure of the inventiveness and utility requirements, on which such redefinition primarily depends, to have retained doctrinal form in the face of modern biotechnology.[78] Indeed, rather

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modern biotechnology that each reflects).

[77] The view of patent law as existing to protect useful inventiveness over useful inventions is reflected widely in European, U.S. and Australian patent law commentaries, consistent with the emphasis in those commentaries: (i) on technical teaching as the cornerstone of (Continental) conceptions of patentability (*see* discussion *supra* note 44); (ii) on promotion of the "useful arts" as the purpose of U.S. patent protection (*see* U.S. CONST., art. I, § 8, cl. 8); and (iii) on the historical focus in Australian jurisprudence on degrees of human intervention when determining a subject matter's suitability for patent protection (*see* discussion *supra* text accompanying notes 17-18). On (i) see, for example, Crespi, *supra* note 12, at 432; Schatz, *supra* note 23, at 4-5; Utermann, *supra* note 62. On (ii) see, for example, Phanesh Koneru, *To Promote the Progress of Useful Art[icle]s?: An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnological Research Tools*, 38 IDEA 625 (1998); Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CALIF. L. REV. 421 (1999). *Cf.* Karen F. Lech, Note, *Human Genes Without Functions: Biotechnology Tests the Patent Utility Standard*, 27 SUFFOLK U. L. REV. 1631 (1993); Thomas, *supra* note 61. On (iii) see, for example, Karinne Ludlow, *Genetically Modified Organisms and Their Products as Patentable Subject-Matter in Australia*, 1999 EUR. INTELL. PROP. REV. 298, 303. *See also* TRIPS art. 27(1), *supra* note 44 (requiring Member States to provide patent protection for all inventions, regardless of technological field).

[78] The failure of the utility and inventiveness requirements to have maintained form in the face of modern biotechnology has been reflected primarily: (i) in the dilution of the former to permit the patenting of biotechnological subject matter of prospective and–or speculative industrial applicability — particularly in the United States, where the requirement of actual utility, as explicated in *Brenner v. Manson*, 383 U.S. 519 (1966), is

innately more rigorous than the European standard of susceptibility of industrial application; (ii) in a test of inventiveness focused either on the structural identity of the relevant product (U.S.) or on the product's effect (Europe and Australia), independent of the means by which the product was derived; and (iii) in an increased acceptance of the use of functional limitations in patent claims to facilitate the granting of broadly scoped patents for recombinant products and other forms of modern biotechnology at an early stage in their development by reference to the special circumstances that prevail in the field of recombinant technology. Full explication of these points is beyond the scope of the present Article. On (i) see generally Forman, *supra* note 53, at 653-55 (describing the U.S. PTO and Federal Circuit's relaxation of the *Brenner v. Manson* standard of utility); Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1664 (2001) ("[B]eginning in the 1990s, the PTO and the Federal Circuit have backed away from the practical utility standard articulated in Manson, demonstrating greater willingness to recognize the patentability of human DNA sequences." (citations omitted)); Machin, *supra* note 77, at 434-36 (describing the malleability of the U.S. utility standard and its dilution by the U.S. Federal Circuit and PTO in the context of modern biotechnology since *Brenner v. Manson*); Andreas Oser, *Patenting (Partial) Gene Sequences Taking Particular Account of the EST Issue*, 30 INT'L REV. INDUS. PROP. & COPYRIGHT L. 1, 8 (1999) (noting the weakness of European standards of utility in the context of modern biotechnology on account of their ability to be satisfied by any subject matter that is capable of commercial manufacture, if only to be sold for further research purposes). *Cf.* Byron V. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments, and Licensing the "Useful Arts"*, 7 ALB. L.J. SCI. & TECH. 295, 314 (1997) (arguing that even under *Brenner v. Manson*, *supra*, the standard of utility was a de minimis one). On (ii) see generally Loots, *supra* note 5050, at 135 (describing U.S. law as "promoting the patenting of previously discovered sequences by simply altering a single amino or nucleic acid"); McInerney, *supra* note 3, at 20 ("In respect of inventiveness, the EPO seems ready to grant patents to patentees who have expended sufficient time, resources and money in winning the race to a new biotechnology discovery."); Rai, *supra* note 17, at 205, 206 n.18 (describing the U.S. Federal Circuit as having "virtually eliminated the nonobviousness standard with respect to DNA" such that "many biotechnology companies are seeking patents on hundreds of thousands of DNA sequences of unknown or speculative function that they have been able to isolate quickly through routine, automated methods"); Tim Roberts, *Broad Claims for Biotechnological Inventions*, 1994 EUR. INTELL. PROP. R. 371, 372 ("At present, the patentee [in the U.S. and Europe] has it both ways. In considering obviousness, he says that it is not obvious that his invention could be made successfully, or would work. Once over this hurdle, he then says that his few working examples make it clear that everything else within the scope of his claim will work."). *See also* Kern, *supra* note 65, at 257-58 (describing, in the context of inventiveness, the shift of U.K. courts away from their historical concern with the structure of inventions to "a more continental approach" focused on an invention's effect or result). On (iii) see generally Armitage, *supra* note 27 (analysing the use of functional claims in Europe and its impact in producing biotech patents of undue breadth); Huizenga, *supra* note 50, at 684 (analysing the European practice of granting very broad patents for recombinant proteins in order to cover all possible functional variants of the protein in its natural form); Roberts, *supra*. *See also* Forman, *supra* note 37 (noting the struggle of U.S. decision makers to derive a workable notion of utility in the context of modern science, and the failure generally of the eligibility and obviousness standards to have delimited the patentability of DNA sequences); John M.

than resetting the boundaries of patentability to embrace inventive results of practical utility, applications of those requirements have come close to dissipating those boundaries altogether.[79] As a consequence, removing eligibility and recasting patentability in the terms and manner described above has not freed the patent system of its prejudice and uncertainty as much as enslaved it to the immediate demands of specific forms of modern biotechnology.

What, then, can be concluded from the above? Primarily, that traditional understandings of the non-threshold requirements of patentability depend on a conception of patent eligibility that much modern biotechnology does not fit. As a consequence, whitewashing the eligibility criterion has not only failed to resolve the problems created for modern biotechnology by that conception, but

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Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 131 (2001) ("The patentability of most basic biotechnological products [in the United States] is now well established, and supposedly central requirements such as utility and nonobviousness have often merely nibbled at the margins of patentability's broad realm."); Charles R. McManis, *Patent Law and Policy Symposium: Re-Engineering Patent Law: The Challenge of New Technologies: Introduction*, 2 WASH. U. J.L. & POL'Y 1, 4 (2000) ("In the biotech field, in particular, both the utility and the nonobviousness requirements seem to have been increasingly watered down."). Finally, see the cases cited *supra* notes 57-58 (reflecting respectively the approaches of the U.S. Federal Circuit and EPO/Federal Court of Australia to issues of inventiveness and disclosure/enablement consistent with (ii) and (iii) above).

[79] *See id*. The most infamous example of the near dissipation of inventiveness and utility standards in the context of modern biotechnology is the acceptance in the late 1990s of the patentability of Expressed Sequence Tags [hereinafter ESTs], which went so far in effacing traditional standards of patentability as to have provoked widespread condemnation, even amongst biotech patentees, and a consequential reversion by the Council of the European Union and the U.S. PTO to a less generous principle. *See* EU Directive art. 5(3) (discussed by Sven J. R. Bostyn, *The Patentability of Genetic Information Carriers: The New E.U. Directive 98/44 on the Legal Protection of Biotechnological Inventions*, 1999 INTELL. PROP. Q. 1); U.S. PTO Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001) (discussed by Forman, *supra* note 53). The practical impact of that reversion remains to be seen, although a variety of factors — including the other provisions of the Utility Guidelines themselves (which, for example, eschew categorization of biotechnological products as "research tools" as confusing and unhelpful, despite the Supreme Court's view to the contrary in *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966)) — suggests it could well prove minimal. *See also* Gitter, *supra* note 78, at 1664-65 (querying the overall impact of the revised Guidelines for the scope of biotech patenting on other grounds); NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA § 3.36 (2002) (describing the revised Guidelines as still setting the threshold for utility too low in the context of ESTs on account of its standard of "credibility"). On the issue of patents for ESTs generally, see especially Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 53 (1995); Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1 (1995) (U.S.); David Keays, *Patenting DNA and Amino Acid Sequences — An Australian Perspective*, 7 HEALTH L.J. 69 (1999) (Australia); Oser, *supra* note 78 (Europe).

has relegated them to the obscure realm of factual enquiry and discretionary decision-making represented by the non-threshold requirements.[80] As a consequence, the whole issue of patent eligibility has in all jurisdictions become localised and fragmented, enabling decision makers: (i) to avoid being recast into an explicit discussion of what makes different forms of biotechnological subject matter suitable or unsuitable for patent protection; and (ii) to avoid express consideration of the implications of their individual decisions for that issue. However, the nature and depth of the questions raised by modern biotechnology for the patent system, including the way in which they are currently being resolved, is such that their effective resolution depends precisely on that discussion taking place. In addition, the occurrence of such a discussion now seems inevitable, and for reasons greater than those canvassed above. Specifically, there is the strong public opposition that exists in relation to biotech patenting, and the additional doctrinal and normative challenges presented by that opposition for modern biotechnology's ongoing claim to legitimacy. In order to appreciate those challenges and their impact the phenomenon of biotech patenting discussed thus far needs first to be considered more explicitly in its theoretical and jurisprudential context.

IV. THE EXPEDIENCY FUELLING BIOTECH PATENTING AND ITS THEORETICAL AND JURISPRUDENTIAL UNDERPINNINGS

The history of biotech patenting to date reflects an overriding concern amongst patent professionals to ensure the patentability of all forms of modern biotechnology. The immediate question that arises in this context is, why does this concern exist? The answer to this question is complex, and requires an understanding of the specific theoretical and jurisprudential context in which the biotech patenting debate has been conducted. It is, however, crucial to understanding both the nature of that debate and its ongoing significance for the patent system.

The reasons for the almost unwavering support amongst decision makers and commentators for the patenting of modern biotechnology are multifarious. Above all they include effective lobbying by the biotechnology industry and an almost universal belief, even amongst critics of biotech patenting, in the dependence of future biotechnological research and development on the promise of intellectual property protection.[81] Significantly, the emergence of

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[80] On the obscurity of the non-threshold requirements generally see, for example, Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2091-92 (2000) (noting the obscurity of the U.S. inventiveness standard as a result of its elaboration by the courts "in formulaic rules that shed little light on the underlying policy considerations at stake"); Sherman, *supra* note 48, at 279 (noting the obscurity of the European inventiveness requirement by reason of its concern with questions of fact and consequential embeddedness "within the confines of the judicial process").

[81] *See e.g.*, Angus J. Wells, *Patenting New Life Forms: An Ecological Perspective*, 1994 EUR. INTELL. PROP. REV. 111, 114 (expressing the view that the patent system encourages

these factors has coincided with a renewed focus on the socio-economic benefits of patent law generally[82] and with a new ambivalence in relation to those benefits.[83] Against this background the capacity of the patent system not only to accommodate but to embrace modern biotechnology has become a test of that system's ongoing strength and relevance; for if the patent system cannot be relied on to protect new forms of technology the future of which depends on it, of what use is it?

As reflected in the preceding discussion,[84] the specific interpretive and jurisprudential context in which this question has been posed has been significant. That context is provided by a century of legal formalism during which patent legislation became increasingly prescriptive and rule-complex, and the rules of patentability increasingly detached from historical considerations of patent law policy.[85] The emergence of modern biotechnology at the end of this period has been described as having "ruptured" the legal discourse that such period fostered, by precipitating a "change in orientation away from the rules of patent law towards a more instrumental or purposive rationality."[86] Hence the significance of the renewed concern with the purpose of patent protection that has coincided with and been facilitated by biotech patenting,[87] which lies in its having fuelled a wider challenge to the semantic nature of twentieth century patent law generally,[88]

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investment and innovation in the biotechnology industry despite having an ambiguous impact in other industries). The biotechnology industry's dependence on patent protection derives largely from the fact that much of its work product is of value only within that industry itself. *See supra* note 53 and accompanying text.

[82] *See*, *e.g.*, Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 840 (1990) (noting the very little attention paid before 1990 to the economic effects of patent scope). Since 1990 such attention has increased, and has reflected a particular concern with biotech patenting. *See*, *e.g.*, Forman, *supra* note 2; Ko, *supra* note 53; Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

[83] *See*, *e.g.*, Gladstone, *supra* note 3, at 230; Charles Lawson, *Patenting Genes and Gene Sequences in Australia*, 5 J.L. & MED. 364, 367-69 (1998); McInerney, *supra* note 50, at 16. The ambivalence in relation to the benefits of patent law has been caused in part precisely by its expansion into previously unprotected areas of research. *See* Eisenberg, *supra* note 80, at 2082 (noting the controversy provoked by the patent system's ascendancy and its implications for technological progress); Merges & Nelson, *supra* note 82 (noting that the economic impact of patent law varies between industries and types of subject matter).

[84] *See* discussion *supra* text accompanying notes 71-73.

[85] *See supra* notes 71-72; Winter, *supra* note 10, at 167-68 (attributing the twentieth century insularity of European patent law to the effect of late nineteenth century jurisprudential developments in having given the patent system an entrenched moral basis that "allowed new technologies to be discussed merely as doctrinal problems not as questions of economic policy").

[86] Sherman, *supra* note 48, at 285.

[87] *See* discussion *supra* notes 61-68 and accompanying text.

[88] *See* Sherman, *supra* note 48, at 285 (describing the increasing reliance in

and thereby provided the necessary interpretive support for bringing modern biotechnology within the patent system.[89] Specifically, by reasserting policy over principle as the ultimate justification for (and thus determinant of) patent law reform, supporters of biotech patenting in all jurisdictions have successfully undermined the very idea of per se exclusions from patentability and, with it, the need to define and conceptualise individual (alleged) inventions at all.[90] In so doing they have ensured the patent system's ability to accommodate subject matter that might not otherwise have been capable of accommodation, and have reasserted the relevance and importance of patent law in an era defined largely by its shifting technological and commercial paradigms.[91] It is thus the shift from formalism to instrumentalism that underlies the change in terms in which the biotech patenting debate has been conducted, from its early focus on whether biotech patenting was permitted by traditional doctrine to its subsequent focus on the reforms required to ensure such permission. More specifically, it is the shift from formalism to instrumentalism that has both enabled and been a central manifestation of the legal expediency that has driven biotech patenting.

Paralleling the change in terms in which the biotech patenting debate has been conducted has been a change in concern within patent law generally from protecting the doctrinal integrity or "internal efficacy"[92] of the patent system on one hand to establishing the patentability of modern biotechnology on the other. However, as the science of modern biotechnology has developed and standards of inventiveness and utility lowered to accommodate its

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contemporary patent law on purposive reasoning as reflecting either "a wider move towards policy style reasoning . . . or . . . a momentary change in direction as legal formalism undergoes a crisis of orientation" (citations omitted)).

[89] *See* discussion *supra* notes 61-68 and accompanying text. The role played by purposive/instrumentalist reasoning in encouraging a view that the eligibility criterion *should* be abolished is ironic given the role played by formalism in encouraging a belief that the criterion *could* be abolished. *Id*.

[90] In this way, the question of whether modern biotechnology is more accurately described as information or chemical compounds has become irrelevant, and the quandary identified above (text accompanying notes 37-39) eliminated. Compare the approach of the U.S. Federal Circuit which, by treating modern biotechnological products as structural objects so as to require disclosure of their structural identity, has transformed the fact-based requirements of inventiveness and enablement/disclosure into legal requirements for structurally defined subject matter that support threshold or "per se" exclusions of subject matter not thus defined. *See* Loots, *supra* note 50, at 135.

[91] *See* discussion *supra* text accompanying notes 51-54. The connection between the relevance and importance of patent law and its capacity to protect modern biotechnology has been cemented with the ascending economic importance of the biotechnology industry on account of that industry's peculiar dependence on patent protection. S*ee* discussion *supra* note 81.

[92] The phrase "internal efficacy" is used by McInerney to describe the House of Lords' approach to inventiveness and sufficient description in Biogen, Inc. v. Medeva, Plc., 36 I.P.R. 438 (H.L. 1996). *See* McInerney, *supra* note 3, at 20.

development, justifications of biotech patenting have become less convincing and the extent of modern biotechnology's disruption to the patent system's "internal efficacy" more apparent. The result has been a re-emergent uncertainty as to whether, and on what terms, patent law can and should protect modern biotechnology after all. Indeed, it is arguably such uncertainty that explains the Federal Circuit's (partial) defiance of the above jurisprudential trend, which defiance, paradoxically, has served only to underscore that uncertainty even more.[93]

In recent years the situation thus described has developed to the point of straining the commitment of the patent profession and biotechnology industry to the cause of biotech patenting.[94] It is moreover in the context of such strain that public concerns regarding biotech patenting have secured a foothold in patent law debates. That foothold has resulted in the politicisation of the patent system generally and in the diversification of its constituent voices, which have combined to weaken further the collective resolve of the profession and industry on the issue of biotech patenting.[95]

The immediate impact of this development has been positive to the extent of encouraging a renewed consideration of the fundamentals of contemporary patent protection.[96] An essential part of that consideration has been a

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[93] *See* discussion *supra* notes 50-53 and accompanying text.

[94] *See* discussion *infra* note 153. Principal issues of concern have included the patentability of ESTs and allowance of broadly scoped patents generally. On the former see, for example, Eisenberg & Merges, *supra* note 79; Andrew T. Kight, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of* Brenner, 73 IND. L.J. 997, 1015 (1998); Olsen, *supra* note 78. *Cf.* Chambers, *supra* note 79 (supporting EST patents); Machin, *supra* note 77, at 455 (propounding a conception of utility that "might" preclude patents for ESTs). On the latter see, for example, Armitage, *supra* note 27, at 54-57; Roberts, *supra* note 79.

[95] *See* discussion *infra* note 153.

[96] *See generally* Eisenberg, *supra* note 80, at 2097-98 (noting "the beginnings of a broader public debate about the patent system than [has been] seen in many years" and the opportunity it presents for scholarly interaction between lawyers and economists in order that the right questions be asked and the best means of addressing those questions identified); Golden, *supra* note 78 (arguing for a shift in academic attention from the legal work of doctrinal analysis to the institutional and social context in which innovation takes place in order to facilitate a reassessment of the balance currently struck between public and private rights by the patent system); Long, *supra* note 37, at 241-45 (arguing the need to revamp existing models of proprietary rights in order to reflect existing environments and create optimum incentives for scientific innovation); Winter, *supra* note 10, at 184 (advocating a debate on how patent law should be redesigned in the context of modern biotechnology, and arguing that such debate should proceed "not [as] a mere doctrinal discourse, where new phenomena are subsumed under stretched old legal forms, nor . . . a substantialist discourse where vitalists wage an idle war against materialist pervasiveness", but rather as "a functionalist argument where patentability, as opposed to other policy alternatives, is assessed with regard to social, economic and ecological effects"). In another context see also Lutz Van Raden, *Technology Dematerialised: Another Approach to Information-Related Inventions*, 1996 EUR. INTELL. PROP. REV. 384, 385 ("What we need

recognition that the role and impact of patents vary between industries and subject matter,[97] such that the very notion of a non-discriminatory or technologically neutral system of patent law is misconceived.[98] There has, in addition, been an increasing (and related) acceptance that resolving the issues created by modern biotechnology for patent law requires more than reflexive adaptation of existing principles and analogising from existing subject matter, and that the twentieth century approach to substantive patent reform — by which express provisions were inserted into patent codes to accommodate specific types of biotechnological subject matter — cannot work.[99] As a result, the contemporary biotech patenting debate is reflecting a further shift in concern from bringing all forms of modern biotechnology within the existing patent system, to considering whether that system offers the best policy alternative for encouraging biotechnological innovation after all.[100] Ironically, however, the same process of politicisation that has encouraged this shift has also threatened the future viability of the patent system. The purpose of the final two Sections is to consider this process and its impact on contemporary patent law.

V. BIOTECH PATENTING AND AND THE POLITICISATION OF PATENT LAW

Throughout the twentieth century the patent system has remained largely insulated from public scrutiny.[101] Biotech patenting has, however, challenged this insulation by exposing patent law to rigorous assessment by a diversity of persons representing a diversity of (legal and non-legal) interests and values. This increased interest in patent law was originally triggered by concerns regarding the ethics of biotechnological research and the use of its results. Before long those concerns extended to biotech patenting — partly because of the absence of other fora in which they could be expressed[102] — fuelling a view of such patenting as immoral, unethical, or otherwise contrary to public

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today is to rediscover patent law as a pragmatic law.").

[97] *See*, *e.g.*, Eisenberg, *supra* note 80, at 2083-85; Merges & Nelson, *supra* note 82; Long, *supra* note 37, at 245-46.

[98] *See* discussion *supra* note 77 and accompanying text.

[99] See, for example, the discussion above at note 79 regarding the response of the European Union and U.S. PTO to the outcry over the patenting of ESTs; Eisenberg, *supra* note 80, at 2085 (noting both the congressional practice of "mediat[ing] conflicts between industries that disagree about proposed changes in patent law by carving out special rules for particular fields", and the likelihood of such conflict increasing "as the subject matter of the patent system expands"); Winter, *supra* note 10, at 184 (see also cite at *supra* note 96).

[100] *See* sources cited *supra* note 96; Eisenberg, *supra* note 15, at 799-800 (questioning whether the patent system offers an appropriate model of intellectual property rights for protecting DNA sequences).

[101] *See* Julia Black, *Regulation as Facilitation: Negotiating the Genetic Revolution*, 61 MOD. L. REV. 621, 648 (1998); Winter, *supra* note 10, at 167-68.

[102] Black, *supra* note 101, at 650; The British Group of AIPPI, *supra* note 37, at 40. *See also* discussion *infra* note 154.

policy.[103] Primarily that view has manifested as arguments that granting patents for modern biotechnology sanctions unethical forms of research and development, and creates inappropriate monopolies in its underlying living and natural substrates.[104] It is through these arguments that various public groups have sought to enter patent discourse and to challenge its twentieth century insulation from political debate.[105]

The overwhelming response of decision makers and commentators to this situation has been unequivocal. They have dismissed concerns regarding biotech patenting as ill-conceived, pointing out that patents confer rights of exclusion rather than use[106] and are granted on the bases of novelty, utility and

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[103] Throughout this Article the terms "moral" and "ethical" are used interchangeably in accordance with their common language meanings. On the usage of those terms in patent law generally see Pila, *supra* note 71, at 421 n.1 (noting the change in Australian usage from "morality" to "ethics" and most recently "public policy" with no apparent change in intended meaning). *Cf.* Spranger, *supra* note 27, at 378–79 (distinguishing morality and ethics on the basis of the former's "philosophical provenance" and "concern[] with moral consciousness" in contrast with the latter's nature as "a legal concept that has been sufficiently clearly defined in physical terms by case law and theory").

[104] On the various ethical objections that have been raised against biotech patenting generally see NUFFIELD COUNCIL ON BIOETHICS, *supra* note 79, at §§ 3, 4; Black, *supra* note 101, at 647-48; Amy E. Carroll, Comment, *Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law*, 44 AM. U. L. REV. 2433, 2474–75 (1995); Crespi, *supra* note 62; Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals*, 5 Health L.J. 147 (1997). For an example of the use of ethical objections to oppose the grant of a patent see Leland Stanford/Modified Animal, Application No. 88312222.8, 2002 E.P.O.R. 2 (Opposition Div. 2001) (opposing the grant of a patent for an immunocompromised mouse implanted with human hematopoietic tissue (*i.e.*, an 'animal-human chimera') on ethical grounds in reliance on EPC art. 53(a)).

[105] The emergence of a public debate on the ethics of patenting living and natural phenomena so late in the history of biochemical patents is often remarked upon, and is explicable by reference to the historical presumption, however valid, that living and natural phenomena were not patentable (*see* discussion *supra* Section II), and to the changed consciousness of contemporary society on ethical (including ecological) issues generally (Spranger, *supra* note 27, at 377).

[106] *See*, *e.g.*, Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 935 n.15 (Fed. Cir. 1991); Schatz, *supra* note 23, at 12; Spranger, *supra* note 27, at 378; *Leland Stanford/Modified Animal*, 2002 E.P.O.R. at 2, ¶ 48; Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541, 550–51 (Opposition Div. 1994); Harvard/Onco-Mouse, Application No. 85 304 490.7, 1991 E.P.O.R. 525, 526 (Examining Div. 1991). *Cf.* Plant Genetic Systems/Glutamine Synthetase Inhibitors, T356/93, 1995 E.P.O.R. 357, 371 (Technical Bd. App. 1995) ("A patent confers on its owner(s) for a specified time an excusive right to exploit the subject-matter of the claims, that is, to manufacture, use and market it, and to prevent others from doing the same."). Reliance on the exclusionary nature of the right conferred by patents to reject an explicitly ethics-based criterion creates problems for the argument, made by some of the same commentators (*see*, *e.g.*, Schatz, *supra* note 23, at 12-13), that the public ordre/morality exclusion of EPC art. 53(a) should be interpreted restrictively on account of its concern with actual (and not potential) uses of an invention.

inventive merit rather than ethics.[107] In addition, to the extent that such concerns reflect a view of patents as inappropriate for application in the life sciences they have been dismissed on the same grounds as the living and natural phenomena arguments were dismissed decades earlier,[108] and on the additional ground that such view embodies an emotive[109] and inherently

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[107] *See*, *e.g.*, Crespi, *supra* note 62, at 435 ("[P]atenting cannot be classified as wrong, or even right, but can be put into the category of the *ethically neutral*.") (emphasis in original)); Spranger, *supra* note 27, at 378–79 (describing the patent examination process as "inherently neutral" and patent law as having a "basically neutral orientation"). *Cf.* Plant Genetic Systems/Glutamine Synthetase Inhibitors, T 356/93, 1995 E.P.O.R. 357, 371 (Technical Bd. App. 1995), discussed *infra* note 129.

[108] *See* discussion *supra* Section II, especially text accompanying notes 17-22. Since the advent of biotech patenting, arguments that patents are not appropriate for application in the life sciences have been interpreted and resolved in two central ways. First, by construing them as embodying an ethical objection to the patenting of life, and responding that biotech patenting does not involve the patenting of life. *See*, *e.g.*, Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541, 551 (Opposition Div. 1994) ("DNA is not 'life', but a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be medically useful."). And second, by construing them as embodying an ethical objection to the promotion of inherently unethical and/or "risky" technologies, and responding: (i) that denying patents to new technologies in order to prevent their development and thus avoid their inherent risks would be futile (*see*, *e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980) ("[L]egislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides"); *Animal Legal Def. Fund*, 932 F.2d at 935 ("[W]ere we to enjoin issuance of patents for non-naturally occurring animals, the requested relief would not prevent the development of such animals.")); and (ii) that risk is an inherent part of all new technologies and does not justify a negative attitude thereto (*see*, *e.g.*, Harvard/Onco-Mouse, 1991 E.P.O.R. at 527 ("The development of new technologies is normally afflicted with new risks; this is an experience mankind has made many times in the past. The experience has also shown that these risks should not generally lead to a negative attitude vis-à-vis new technologies. . . .)). Note the effect of the second of these responses which, by linking ethical objections to (the risks associated with) new technologies, ascribes to those objections the same inherent prejudice of eligibility per se (discussed *supra* text accompanying notes 61-66). *See*, *e.g.*, *Chakrabarty*, 447 U.S. at 315-17 (reasoning from the purposes of patent law in protecting unforeseen technologies to the futility of denying patents in order to prevent undesirable technological developments); Plant Genetic Systems/Glutamine Synthetase Inhibitors, T 356/93, 1995 E.P.O.R. 357, 369 (Technical Bd. App. 1995) (rejecting an argument that plants are unpatentable under EPC art. 53(a) on the ground that "plant biotechnology per se cannot be regarded as being more contrary to morality than traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation, namely to change the property of a plant by introducing novel genetic material into it in order to obtain a new and, possibly, improved plant.").

[109] *See Chakrabarty*, 447 U.S. at 316 (referring to the "gruesome parade of horribles" advanced by the petitioner in support of its argument against the patentability of micro-organisms); Helen W. Nies, *Patent Protection of Biotechnological Inventions — American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 480, 480 (1990)

arbitrary ideological assertion the truth of which can never be substantiated.[110]

However, rather than protecting patent law from unwelcome scrutiny by outside commentators this response has served only to fuel objections to biotech patenting, and to draw the people heralding those objections into deeper engagement with the patent law community. An essential part of that engagement has been the translation of early visceral responses to biotech patenting into the less emotive language of patent law theory and doctrine.[111] Ironically, in undertaking this task the public has been able to exploit the patent profession's own use of instrumentalist methodology and the window it offers for importing policy into an otherwise closed, doctrinal environment.[112]

("'Biotechnology' — One cannot say the 'B' word in serious conversation without producing an emotional reaction from the listener [that] may range from great hope and applause to fear and rage."). For a description and "debunking" of some of the more emotive arguments against biotech patenting see Crespi, *supra* note 62, especially at 431-32. The emotiveness of the debate on the ethics of biotech patenting is inevitable given the central charge, on which it is based, that biotech patenting is part of a wider phenomenon involving the commodification of life. For a discussion of that phenomenon generally see Andrew Trew, *Regulating Life and Death: The Modification and Commodification of Nature*, 29 U. TOL. L. REV. 271 (1998).

[110] *See*, *e.g.*, Crespi, *supra* note 62, at 435; Spranger, *supra* note 27, at 378–79; Straus, *supra* note 23, at 949. *See also* Julian Kinderlerer & Diane Longley, *Human Genetics: The New Panacea?*, 61 MOD. LAW REV. 603, 620 (1998) (arguing that only society can decide "the degree of importance to be attached to the benefits, hazards and impact" of biomedical techniques). "Legal certainty" was one of the grounds advanced in the application for annulment of the EU Directive made by the Netherlands (with the support of Italy and Norway) by application of 19 October 1998. That application was dismissed by the Court of Justice of the European Community on 9 October 2001, following the advice of the Advocate-General of 14 June 2001. *See* Pays-Bas v. Parliament & Council, Case 377/98, (E.C.J. Sept. 10, 2001), *available at* http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&docrequire=alldocs&numaff=C-377%2F98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100.

[111] *See* Winter, *supra* note 10, at 177. For an excellent analysis of the communicative dimension of the biotech patenting question generally see Black, *supra* note 101, *especially* at 644-50.

[112] The connection between instrumentalist theory and ethical considerations offers one possible explanation for why bioethical concerns have found a more receptive audience amongst European than Anglo patent specialists; the non-semantic tradition of European patent philosophy having perhaps made that jurisdiction more amenable to public policy style arguments. On the growing place of ethics in European patent jurisprudence see *infra* note 116; Spranger, *supra* note 27, at 377; Van Overwalle, *supra* note 71, at 284. *See also* Robin Beck Skarstad, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. PA. J. INT'L ECON. L. 353 (1999) (contrasting the place of ethics in European and U.S. patent jurisprudence); Tade Matthias Spranger, *Europe's Biotech Patent Landscape: Conditions and Recent Developments*, 3 MINN. INTELL. PROP. REV. 235, 244 (2002) (noting the support amongst German and French scholars for strengthening patent law's ethical provisions). *See also* Black, *supra* note 101, at 649 ("Essentially, insiders see patents as objective, technical and legal, and so in express contrast to ethics which are malleable, subjective and emotive.").

This has been done in three central and related ways. First, by challenging directly the claim that generous protection for modern biotechnology is in the public interest, however defined.[113] Second, by arguing that the test of patentability should be recognized as incorporating a criterion of ethics.[114] And third, by criticizing the expedient means by which biotech patenting has to date been achieved.[115]

Through these arguments ethical considerations have been successfully maneuvered into patent discourse, and public engagement on the use of the patent system to protect modern biotechnology enabled.[116] The terms of the ensuing debate on such use can be crudely summarized as follows. On one side "opponents" of biotech patenting have claimed that the doctrinal impediments to allowing patents for modern biotechnology are insurmountable, and that the arguments relied on to make them appear otherwise are a disingenuous attempt to override the dictates of patent law theory and reality. Specifically, the charge has been that biotech patenting is irreconcilable with traditional patent law policy and doctrine, not to mention contemporary values, and has been engineered with the aims of driving economic competitiveness and protecting the private interests of biotech patentees.[117] The response from the other side has been that such charge itself proceeds from an ill-conceived and misguided concern with semantic and

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[113] Some commentators have argued that even if "public interest" is defined exclusively by reference to the social good of encouraging innovation, it is not met by granting patents for modern biotechnology, because biotech patents stifle innovation by stifling scientific research. *See*, *e.g.*, Keays, *supra* note 79, at 89; sources cited by Morin, *supra* note 104, at 184 n.238. See also Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987), for an analysis of this issue.

[114] Biotech patenting has been said to reveal the weakness of patent law's historical claims to ethical neutrality — recalling the argument that modern biotechnology reveals the inherent weaknesses of traditional patent doctrine per se see discussion at above text accompanying notes 61-66. *See*, *e.g.*, Peter Drahos, *Biotechnology Patents*, *Markets and Morality*, 1999 EUR. INTELL. PROP. REV. 441, 447; Wells, *supra* note 81, at 112-13; Winter, *supra* note 10, at 167.

[115] Consistent with the view described immediately above, biotech patenting has been portrayed as reflecting an indulgence in ex post facto rationalization that has harmed and continues to harm patent doctrine and policy. *See*, *e.g.*, Drahos, *supra* note 114, at 443-44.

[116] Ethics play an increasingly prominent role in European patent law and jurisprudence. See, for example, the work done by the European Parliament, the European Group on Ethics in Science and New Technologies of the European Commission, and the European Group on Life Sciences, discussed in the context of the EU Directive in *Report from the Commission to the European Parliament and the Council — Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, COM/2002/0545 final (Oct. 7, 2002), *available at* http://europa.eu.int/eur-lex/en/com/rpt/2002/com2002_0545en01.pdf.

[117] *See generally* sources cited *supra* notes 113-15. *See also* McInerney, *supra* note 3, at 20 (describing the EPO's approach to biotech patenting as reflecting a concern with promoting "the international competitiveness of the European patent system and the European biotechnology industry").

ethical considerations that have no place within contemporary patent jurisprudence.[118] From these terms what began as a debate on biotech patenting has evolved to a much wider debate regarding the nature and purpose of patent law generally including, in particular, the relevance of public values to conceptions of patentability and of eligibility per se. In arguing these issues opponents and supporters of biotech patenting have delved deep into theory and doctrine in a bid to cover the high ground on biotech patenting and thereby rebut or confirm the suitability of modern biotechnology for patent protection.

In its generic terms the debate regarding the relevance of ethics to substantive questions of patentability has run along six broad lines. According to the first, the link between ethics and patentability is inherent in the nature of the patent grant itself as an "interventionist instrument of the State designed to foster progress."[119] Hence the argument that the relevance of ethics to patentability is not a question of "ought", it just "is", as the fact of biotech patenting itself reveals.[120] Similarly cast is the second line of argument, which posits the link between ethics and patentability as inhering in the public ordre/morality exclusion of EPC article 53(a),[121] as well as the (threshold and non-threshold) requirements of patentability themselves — either directly by prescription of their substantive principles, and-or indirectly through the interpretive processes required for their application.[122] The third line of argument moves from the "is" to the "ought", and asserts that ethics should as a matter of policy inform determinations of patentability because of the social and economic impact of patent law.[123] And the fourth, fifth and sixth are

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[118] *See generally* sources cited *supra* notes 106-10.

[119] Winter, *supra* note 10, at 167. *See also* Wells, *supra* note 81, at 112 ("[P]atent regimes have continually acted as a social and moral filter, allowing certain forms of culture to pass into mainstream commercial life and blocking others.").

[120] *See* discussion *supra* note 114.

[121] *See supra* note 44. *Cf.* Spranger, *supra* note 27, at 378–79 (arguing that ethics have no place in EPC art. 53(a) for the reason discussed above note 103). *See also* Black, *supra* note 101, at 648 (describing EPC art. 53(a) as having been dormant until the arrival of modern biotechnology). *But see* Schatz, *supra* note 23, at 12 (attributing EPC art. 53(a)'s historical lack of use to the fact that the only inventions to which it (properly) applies are unlikely to be tradable in the market place and thus unlikely ever to be the subject of a patent application).

[122] *See*, *e.g.*, Drahos, *supra* note 114, at 441; THE GROUP OF ADVISERS TO THE EUROPEAN COMM'N ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY [hereinafter European Group on Ethics], *Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, Opinion No. 8 ¶ 2.2 (Sept. 25, 1996), *available at* http://europa.eu.int/comm/european_group_ethics/gaieb/en/opinion8.pdf; Keays, *supra* note 79, at 79; Ludlow, *supra* note 77, at 310–11. In the United States, the courts have interpreted the utility requirement of 35 U.S.C. § 101 as excluding inventions that are "injurious to the well being, good policy, or good morals of society." *See* Lowell v. Lewis, 15 F. Cas. No. 1018 (C.C. Mass. 1817) (No. 8,568) (Story, J.), *quoted in* Tol-O-Matic, Inc. v. Proma Produkt-und Marketing Gesellschaft M.b.H., 945 F.2d 1546, 1552 (Fed. Cir. 1991).

[123] *See*, *e.g.*, sources cited *supra* note 114.

essentially retorts to the first three, and state respectively: (i) that ethics are fundamentally inconsistent with the nature of the patent grant and its substantive requirements;[124] (ii) that patent law is an inadequate means of ethical regulation and should not therefore be burdened with any regulatory function;[125] and (iii) that, for the sake of legal clarity and certainty, patentability should not depend on the satisfaction of subjective, ideologically-based criteria.[126]

The last of these arguments has been the one most forcefully presented in the case against importing an explicitly ethics-based criterion into patent law, and underlies the widely-held view that the patent system is an inappropriate forum (and patent law an inappropriate mechanism) for addressing ethical issues. With one notable exception this view has been expressly supported by decision makers, who have repeatedly justified their unwillingness to entertain ethical considerations when determining issues of biotech patenting on the ground that to do so would constitute an inappropriate incursion into the domain of the (democratically elected) legislature.[127] The exception is the

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[124] *See*, *e.g.*, sources cited *supra* note 107.

[125] *See*, *e.g.*, The British Group of AIPPI, *supra* note 37, at 40; Crespi, *supra* note 62, at 441; Moufang, *supra* note 12, at 824. *See also* Black, *supra* note 101, at 650 ("The attempt to use patent law to prevent unwanted commercial exploitation is . . . simply to use an instrument which is badly fashioned for the task."). This view has also been adopted by governments and decision makers. *See*, *e.g.*, Parliament of the Commonwealth of Australia, *Genetic Manipulation: The Threat or the Glory?: Report by the House of Representatives Standing Committee on Industry*, *Science and Technology*, A.G.P.S., Feb. 1992, ¶ 7.99; Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980); Nies, *supra* note 109, at 481; Leland Stanford/Modified Animal, Application No. 88312222.8, 2002 E.P.O.R. 2, ¶¶ 47-48 (Opposition Div. 2001). The view of patent law as an inadequate means of ethical regulation has led some commentators to support the creation of a special regulatory regime in respect of modern biotechnology. *See*, *e.g.*, Kinderlerer & Longley, *supra* note 110, at 620; Carolyn Oddie, *Bio-Prospecting*, 9 AUSTL. INTELL. PROP. J. 6, 20 (1998). Others, however, have noted the problems that would be created for such a regime as a result of the different paces at which science and patent law advance (on which see Eisenberg, *supra* note 15, at 784; Michael Kirby, *Challenges of the Genome*, 20 UNIV. NEW SOUTH WALES L.J. 537, 539 (1997). *See*, *e.g.*, Winter, *supra* note 10, at 183. *See also* Dianne Nicol, *Should Human Genes Be Patentable Inventions Under Australian Patent Law?*, 3 J.L. & MED. 231, 247 (1996) (criticising approaches to biotechnology that would result in "each new technology [being] given its own system of protection in a piecemeal fashion.").

[126] *See*, *e.g.*, sources cited *supra* note 110.

[127] *See*, *e.g.*, *Chakrabarty*, 447 U.S. at 317 ("What is more important is that we are without competence to entertain these arguments [on the potential social hazards of genetic research] — either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot."); Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541, 550, 553 (Opposition Div. 1994) ("Obviously recognising that the EPO is not the right institution to decide on fundamental ethical questions, the opponents requested that the EPO carry out a referendum to find out what the

(now discredited) decision of the EPO's Technical Board of Appeal in *Plant Genetic Systems/Glutamine Synthetase Inhibitors*,[128] which, for its principle rather than its conclusion,[129] is viewed by many commentators as a reminder of the dangers of entrusting ideological criteria to individual decision makers.[130]

The claim that patent offices and courts are inherently ill-suited to determine matters of ethics is substantively compelling — particularly when regard is had to the impact of ethical considerations on patent law historically.[131] Methodologically, however, it is hard to view that claim as anything other than a further manifestation of the legal expediency that has driven so much of biotech patenting to date.[132] This is particularly true of those decision makers

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public in the Contracting States really wants to be patented."); Leland Stanford/Modified Animal, 2002 E.P.O.R. at 2 ¶ 47 ("[T]he EPO is not vested with carrying out the task of monitoring and estimating [the risks associated with granting patents in the field of xenotransplantation]; this is rather a matter for the numerous regulatory authorities charged with regulating research and medical practice."). There is nothing new in this view, nor in the disinclination of decision makers expressly to consider ethical objections to patentability. *See infra* note 132.

[128] 1995 E.P.O.R. 357 (Technical Bd. App. 1995).

[129] In *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, *id*., the Board interpreted public ordre and morality as having specific meanings in the context of EPC art. 53(a) independent of (and thus unaffected by) the legal and regulatory codes of individual Contracting States. *See id*. at 367. According to the Board, the effect of EPC art. 53(a) was to position it "at the crossroads between science and public policy" (*id*. at 371), and thereby entrust it with responsibility for ensuring that "inventions the exploitation of which is *not* in conformity with the conventionally-accepted standards of conduct pertaining to [the culture inherent in European society and civilisation] are to be excluded from patentability" (*id*. at 366-67). The Board's approach in *Plant Genetic Systems* has since been superseded by subsequent decisions. *See*, *e.g*., Howard Florey/Relaxin, 1995 E.P.O.R. at 550, 553 (deciding that EPC art. 53(a) excludes only such subject mater that it is probable would be regarded by "the public in general . . . as so abhorrent that the grant of patent rights would be inconceivable"); Leland Stanford/Modified Animal, 2002 E.P.O.R. ¶ 51 (confirming the provisions of EPC art. 53(a) as having been "intended to exclude from patentability not subject-matter that is controversial, but rather that kind of extreme subject-matter (*e.g*., letter-bombs and anti-personnel mines) which would be regarded by the public as so abhorrent that the grant of a patent would be inconceivable").

[130] *See*, *e.g*., Schatz, *supra* note 23, at 15; Straus, *supra* note 23, at 929-34, 948-50.

[131] *See*, *e.g*., Pila, *supra* note 71 (analysing the impact of ethical determinations regarding medical methods on the development of twentieth century U.K. and Australian patent law).

[132] The whole history of decision makers' treatment of public policy in the context of patent eligibility reflects this legal expediency — at times more overtly than others. *See*, *e.g*., A. & H.'s Application, 44 R.P.C. 298, 298 (Sol. Gen. 1927) ("Even if, as to which I express no opinion, [use of a contraceptive device] is consistent with morality, I am not prepared to exercise on behalf of the Crown the Crown's discretion in favour of the grant of a patent in respect of it . . . I express no opinion as to whether the use of these articles is consistent with morality, because I am not aware that the law has laid down what the exact standards of morality are. I am a Court of Law, and not a Court of Morality. All I say is I think these are not articles for which, whether the specification be amended or not, the

whose preparedness to consider policy-based objections to patentability has varied depending on the subject matter in question.[133] Even at a general level, however, the same plea when used to avoid the consideration of ethical issues is identical in form and effect to the arguments relied on to avoid the consideration of eligibility, discussed above.[134] In form it relies on the inherent uncertainty and prejudice of the concept of "ethics" to support a view of ethics-based exclusions as undermining the capacity of the patent system to fulfil its purpose of promoting innovation within a changing technological landscape.[135] And in effect it relegates the issues addressed by that concept to a site where their restrictive impact on patentability can be negated. In the case of ethics that site has been described as the complex and fragmented realm of general regulatory law[136] — just as in the case of eligibility it is the complex and fragmented realm of the non-threshold requirements of patentability per se.[137]

Crown can be expected to exercise its discretion by way of granting a patent."). *See also* Pila, *supra* note 71, especially at 459–61 (noting that the refusal to consider explicitly ethical issues in the context of medical methods has supported different conclusions in different contexts).

[133] See for example the decisions of Heerey, J. of the Federal Court of Australia in *Bristol-Myers Squibb Company v. F. H. Faulding & Co., Ltd.*, 41 I.P.R. 467 (Fed. Ct. Austl. 1998), *rev'd*, 46 I.P.R. 553 (Full Fed. Ct. Austl. 1999) and *Welcome Real-Time S.A. v. Catuity, Inc.*, 2001 F.C.A. 445 (Fed. Ct. Austl. 2001) respectively. In the first of these cases, his Honour found a method of treating cancer to be ineligible for patent protection on the basis, among others, of the effect that granting a patent would have in restraining medical practice. *See Bristol-Myers Squibb*, *supra*, at 480. In the second his Honour rejected a claim that a business method was ineligible for patent protection because of the effect that granting a patent for the method would have in restraining commonplace ways of doing business, on the principle that "if an invention otherwise satisfies the [statutory requirements of patentability] it can hardly be a complaint that others in the relevant field will be restricted in their trade because they cannot lawfully infringe the patent. The whole purpose of patent law is the granting of monopoly." *See Welcome Real-Time*, *supra*, ¶¶ 131–32.

[134] *See* discussion *supra* notes 61-68 and accompanying text.

[135] *See*, *e.g.*, discussion *supra* note 108 & text accompanying note 110. On the equivalent view expressed in the context of the eligibility criterion see discussion *supra* text accompanying notes 65-66. This view is also reflected in the criticism of EPC art. 53(a) and EU Directive art. 6 as discouraging investment in the European biotechnology industry and thereby putting Europe at risk of becoming technologically dependent on jurisdictions in which no equivalent provision exists. *See*, *e.g.*, Skarstad, *supra* note 112, at 355–56, 384; Straus, *supra* note 23, at 949.

[136] Drahos, *supra* note 114, at 446.

[137] *See* discussion *supra* text accompanying note 80. Note also the impact of the EPO's construction of EPC art. 53(a) as importing a factual inquiry (and as thus not supporting any threshold exclusions from patentability per se) in relegating the issues addressed by that article to the same realm of factual inquiry and discretionary decision-making to which issues of eligibility have been relegated. *See*, *e.g.*, Plant Genetic Systems/Glutamine Synthetase Inhibitors, T 356/93, 1995 E.P.O.R. 357, 367-68 (Technical Bd. App. 1995)

The debate on biotech patenting has come a long way in the years since it first commanded the attention of patent specialists and called into question the (un)patentability of living and natural phenomena. As a consequence it now commands the attention of a wide range of legal and non-legal communities and embraces a wide range of issues from age-old questions concerning the nature of an invention, to more contemporary questions of patent jurisprudence and methodology that have arisen specifically from the way in which modern biotechnology has been accommodated within the patent system. A critical effect of the debate thus described has been to propel patent law down the path of international harmonization. The purpose of the final Section of this Article is to consider this effect, including the reasons for it and its likely outcome.

VI. HARMONIZATION: THE FUTURE OF PATENT LAW IN THE LIGHT OF BIOTECH PATENTING

Biotech patenting has been a consistent theme in both formal and informal patent law harmonization initiatives to date, providing at once an incentive for those initiatives and a sticking point in their realisation. That this should be the case is perhaps obvious given the uncertainty and controversy that presently surrounds biotech patenting, and the purpose of legal reform in responding

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(citing the factual nature of the public ordre–morality inquiry to reject an argument that EPC art. 53(a) supports a threshold exclusion from patentability covering plant genetic resources and other living matter); Howard Florey/Relaxin, Application No. 83 307 553.4, 1995 E.P.O.R. 541, 552 (Opposition Div. 1994) ("As for the opponents' general assertions concerning the alleged intrinsic immorality of patenting human genes, these are founded on the premise that there is an overwhelming consensus among the Contracting States that the patenting of human genes is abhorrent and hence prohibited under Article 53(a). This assumption is false."); Leland Stanford/Modified Animal, Application No. 88312222.8, 2002 E.P.O.R. 2, (Opposition Div. 2001) (rejecting a public ordre-morality opposition to a patent for an immunocompromised mouse implanted with human hematopoietic tissue (*i.e.*, an "animal-human chimera") on the ground, among others, that it would be presumptuous for the EPO to interfere in an unresolved public debate on the patenting of xenotransplantation technology by acting as moral censor and invoking the provisions of EPC art. 53(a)). *But cf*. Press Release, U.S. PTO, *Facts on Patenting Life Forms Having a Relationship to Humans* (Apr. 1, 1998) (on file with author, and available at http://www.uspto.gov/web/offices/com/speeches/98-06.htm) ("It is the position of the [U.S.] PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement."); Jasemine Chambers, Note, *Patent Eligibility of Biotechnological Inventions in the United States*, *Europe*, *and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 226-27 (2002) (referring to the U.S. PTO's rejection of a patent application directed to a human–nonhuman chimera on the ground that "Congress did not intend to allow patents on humans or on creatures that are essentially human when it passed the Patent Act in 1952.", (quoting Rick Weiss, *U.S. Ruling Aids Opponent of Patents for Life Forms*, WASH. POST, June 17, 1999, at A2.)).

precisely to such uncertainties and controversies.[138] Not obvious, however, is why it is the case in the particular context of biotech patenting and international law.

The creation of a global patent system is increasingly seen as both necessary and achievable.[139] Its necessity is generally attributed to the realities of globalisation and developing technologies, both of which conspire to make the traditionally territorial nature of patent law anachronistic and impractical.[140] This effect of globalisation and technological developments has been particularly underlined by modern biotechnology for two combined reasons. First, a universal stake in modern biotechnology and a related dependence of all countries on international transacting to secure it, has made the biotechnology industry a truly global one in need of correspondingly global regulation.[141] And second, the peculiar dependence of the biotechnology industry on strong patent protection has translated inevitably to a view that the primary aim of that regulation must be to provide such protection.[142] Indeed, ongoing differences in national standards of patentability are a constant source of complaint within the biotechnology industry, both because of the legal (and thus commercial) uncertainty they create,[143] and the risk they pose of technological piracy in countries offering lesser standards of protection.[144]

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[138] *See* Heinz Bardehle, *A New Approach to Worldwide Harmonization of Patent Law*, 29 INT'L REV. INDUST. PROP. & COPYRIGHT L. 876, 877–78 (1998) (discussing the 1995 harmonization initiatives of the World Intellectual Property Organization [hereinafter WIPO], the pursuit and failure of which were attributable largely to the "first-to-file"/"first-to-invent" issue).

[139] Compare the expressions of pessimism that followed the failure of the initial draft of the EU Directive (Common Proposal of the European Parliament and the Council of Ministers for a Directive on the Legal Protection of Biotechnological Inventions (Doc. COM (88)) 196 final — SYN 159, October 17, 1988, O.J. No. C, January 13, 1989) [hereinafter draft EU Directive]). *See*, *e.g.*, Nicol, *supra* note 125, at 247 (doubting the possibility of any international agreement on the issue of what constitutes patentable subject matter, and arguing that whilst an international discussion on that issue should occur, "ultimately the solutions must be achieved at the national level within the existing patenting framework").

[140] *See* Irene Park, *Patents Without Borders: The Future of Patent Harmonisation*, 12 AUSTL. INTELL. PROP. J. 32, 32–33 (2001).

[141] *See* Bardehle, *supra* note 138, at 876–77; Carroll, *supra* note 104, at 2455.

[142] *See*, *e.g.*, Commission of the European Communities, *supra* note 116 at Annex 2. *See supra* note 81 and accompanying text.

[143] Legal uncertainty is generally regarded as the "greatest enemy of patent law," particularly in the context of modern biotechnology. *See*, *e.g.*, Stephen Crespi, *Recombinant DNA Patents in Litigation: A Comparative Study of Some EPO and UK National Court Decisions*, 28 INT'L REV. IND. PROP. & COPYRIGHT L. 603, 622 (1997). *See also*, Commission of the European Communities, *supra* note 116, Annex 2 ¶ 3; Kern, *supra* note 65, at 247; Nicol, *supra* note 125, at 247; discussion *infra* note 159.

[144] *See* Morin, *supra* note 104, at 166-67 (noting the economic costs to biotechnology companies of technological piracy in countries in which strong patenting regimes do not

Hence the continuing push by nations that house biotechnology companies (and that derive significant revenue from exportation of those companies' products) for a commitment from their trading partners to recognise the same high level of patent protection for modern biotechnology as they themselves provide.[145] In addition, whilst the position of developing nations without strong biotechnology industries is far more complicated,[146] it includes support for a harmonized system of some sort in order to secure those nations' own stake in modern biotechnology; a stake that derives, above all, from their (often rich) and commercially valuable genetic and other biological resources, and from their dependence on the pharmaceutical and other products that research into and development of those resources gives rise to.[147] There is also the ongoing political pressure on all countries to yield to international standards, and the fear that if they do not they will become technologically dependent on (and exploited by) their trading partners.[148]

Alongside this compelling account of the need for global harmonization in the light of modern biotechnology is, however, a less compelling account of its achievability. Confidence in such achievability is attributable to the almost unanimous support that harmonization commands, as reflected in the number of formal and informal moves that have already been made in pursuit

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exist, and the support for harmonization that they (and the fear of piracy) encourage).

[145] *See* Carroll, *supra* note 104, at 2439 (discussing the U.S. policy of "promot[ing] globalization of stringent and broad patent protections similar to those found in the United States" and the justifications therefore); Drahos, *supra* note 114, at 446 (describing a self-perpetuating situation in which lead patent jurisdictions are continually driving up standards of patent protection).

[146] *See* Carroll, *supra* note 104, at 2465–68; Scalise & Nugent, *supra* note 25.

[147] *See* Oddie, *supra* note 125, at 9.

[148] *See* Carroll, *supra* note 104, at 2465–68. *See also* Keays, *supra* note 79, at 88 (attributing the failure of biotech patenting reform initiatives in Australia to an (explicit) fear of technological dependence on other countries); Andrew Scott, Comment, *The Dutch Challenge to the BioPatenting Directive*, 1999 EUR. INTELL. PROP. REV. 212, 212 (attributing European support for the EU Directive to a fear of technological dependence on American and Japanese industries); Skarstad, *supra* note 112, at 355 (describing the EU Directive as precipitated by a recognition in Europe that "it had fallen far behind the United States in the competition for biotechnology dollars"); Kirby, *supra* note 125, at 539 (citing as anecdote the concern of an Argentinean lawyer, that "patenting would permit industry in some developed countries to effectively take control of scientific and medical developments based upon components of human life common to all human beings in all countries. It would render humans in developing countries hostages to medical knowledge about the human species owned by particular individuals or corporations."). *See also* Commission of the European Communities, *supra* note 116, Annex 2 ¶ 3 (Oct. 7, 2002) (considering the comparative industrial competitiveness of the European and U.S. biotechnology industries); McInerney, *supra* note 3, at 15 (describing patent rights as "commodities which compete with each other in the international market-place" and individual nations as competing to provide protection for their national biotechnological industries).

thereof.[149] As with the effects of globalisation and technological developments themselves, these moves are self-perpetuating in two ways. First and most obviously they keep harmonization a live issue. And second, to the extent that they have succeeded, they underline its all-or-nothing nature. The central example of this latter point is the EPC, by which substantive principles and procedures relating to the search and examination phases of a patent's life have been harmonized across Europe. Nearly thirty years after its creation, however, the central lesson of the EPC has been that successful harmonization, whether of substantive patent law principle or of procedure, and whether amongst countries of shared or differing values and interests, requires a centralised enforcement mechanism from which can be generated a single body of law and jurisprudence. The reason is that allowing individual nations to retain their own decision-making infrastructure can only lead to divergences in substantive law, however prescriptive the code they are applying and however closely aligned their economic and social interests appear to be, thereby perpetuating the problems of uncertainty and potential piracy described above.[150] Thus effective harmonization at any level requires a truly global

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[149] *See*, *e.g.*, Park, *supra* note 140, at 43 (describing the history of patent agreements as indicating an inclination of international patent law towards harmonization). *Cf.* Scalise & Nugent, *supra* note 25, at 117 (noting the failure of the "enormous amount of energy expended attempting to achieve international patent law harmony pertaining to biotechnologies" to have generated many results). The greatest successes of harmonization to date have been those aimed at streamlining patent procedures in order to reduce costs. Indeed, formal attempts at harmonizing patent law at the level of substantive principle have repeatedly been abandoned out of concern to prevent the political issues that inevitably plague those attempts from destroying the prospects of agreement on such procedural matters. *See* Bardehle, *supra* note 138 (regarding the 1990 WIPO Basic Proposal); Carroll, *supra* note 104, at 2458 (regarding WIPO harmonization initiatives in general). Compare the work currently being undertaken by the WIPO Standing Committee on the Law of Patents on the Substantive Patent Law Treaty, discussed in Commission of the European Communities, *supra* note 142, ¶ 2.2 (Oct. 7, 2002).

[150] *See supra* note 144 and accompanying text. The greatest divergence of approach to the EPC to date has involved the U.K. and EPO. Initially such divergence was the result of the U.K. Court of Appeal's narrow construction of EPC art. 52(2). *See*, *e.g.*, Genentech, Inc. v. Wellcome Found., 1989 R.P.C. 147 (Eng. C.A. 1988). However, even the reversal of that construction by the House of Lords in *Biogen, Inc. v. Medeva, Plc.*, 36 I.P.R. 438 (H.L. 1996), did not bring the U.K. position on biotech patenting completely into line with that of the EPO — despite the House of Lords' explicit statement in *Biogen* to the contrary (*see id.* at 459). *See generally* Crespi, *supra* note 143, at 619-22; McInerney, *supra* note 3, at 17–20. Differing opinions on biotech patenting have also been reflected amongst other Contracting States — as, indeed, the experience of the (draft and current) EU Directive itself reflects. *See* Pays-Bas v. Parliament and Council, Case 377/98, (E.C.J. Sept. 10, 2001), *available at* http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&docrequire=alldocs&numaff=C-377%2F98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100 (regarding the application for annulment of the EU Directive by certain Contracting States); Llewellyn, *supra* note 65, at 191 (discussing the protection of biological material in general); Schatz, *supra* note 23, at 14-15 (discussing the use of

patent system.[151] In addition, the truth of this conclusion has been particularly apparent in the context of biotech patenting.[152] The reason is that by destabilising traditional patent doctrine and policy in the ways described above, biotech patenting has provided fertile ground for divergent interpretations and applications of identically or equivalently framed principles and provisions, and looks set to continue to do so as ethical considerations cement their place in its jurisprudence.

The intrusion of ethics, and growing importance generally of judicial discretion within contemporary patent discourse, have also strengthened the incentive to harmonize in ways other than by creating an increased uncertainty and propensity for divergent standards of protection.[153] Specifically, those

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animals in scientific research and human germ line therapies and its implications for EPC art. 53(a)); Straus, *supra* note 23, at 945-46 (discussing the draft EU Directive). *See also* Commission of the European Communities, *supra* note 142, Annex 4 ¶¶ 1-4 (Oct. 7, 2002) (noting the requests by Contracting States for clarification of, among other things, the meaning of the distinction between discoveries and inventions in EU Directive art. 5). As Huizenga has shown, the identically framed principles of U.S. and European law on sufficient description have also supported diametrically opposed applications. *See* Huizenga, *supra* note 50. *See also* Gitter, *supra* note 78 (discussing other differences in U.S. and European approaches to biotech patenting). Explanations of the reasons for these various divergences of approach to modern biotechnology have included: (i) different scientific understandings of modern biotechnology (*see*, *e.g.*, Huizenga, *supra* note 50, at 669-70 (U.S. and EPO); *see also* discussion *supra* notes 57-58 and accompanying text); (ii) different cultural values and norms (*see*, *e.g.*, Nicol, *supra* note 125, at 247 (Europe); Gitter, *supra* note 78 (U.S. and Europe)); (iii) different policy objectives (*see*, *e.g.*, Gitter, *supra* note 80 (U.S. and Europe); Huizenga, *supra* note 50, at 670-71 (U.S. and EPO); McInerney, *supra* note 3 (U.K. and EPO); Peter E. Montague, *Biotechnology Patents and the Problem of Obviousness*, 4 AUSTL. INTELL. PROP. J. 3, 29 (1993) (U.S. and U.K.)); and (iv) different languages (*see*, *e.g.*, Walter Moser, *Exceptions to Patentability Under Article 53(b) EPC*, 28 INT'L REV. INDUST. PROP. & COPYRIGHT L. 845, 847 (1997) (noting the discrepancies of meaning imported by the official French, German and English texts of EPC art. 53(b)); Christian Franceries/Traffic Regulation, T16/83, 1998 E.P.O.R. 65, 69 (Technical Bd. App. 1985) (noting the discrepancies of meaning imported by the French, German and English texts of EPC art. 52(2)(c))).

[151] *Cf.* Crespi, *supra* note 143, at 603 ("So long as conflicting decisions [under the EPC] are not too frequent, such an event must on occasion be expected and does not amount to a crisis of our European legal institutions.").

[152] *See* Power, *supra* note 28, at 214-15 (referring to the conclusion of the Committee for Scientific and Technological Policy of the Organization for Economic Co-operation and Development that in "no other field of technology, old or new, do national laws vary on so many points and diverge so widely as they do in biotechnology", as reported by F. K. BEIER, R. S. CRESPI & J. STRAUS, BIOTECHNOLOGY AND PATENT PROTECTION, AN INTERNATIONAL REVIEW 89 (1985)).

[153] The pursuit of a strong biotech patenting regime is now also seen by some commentators as threatening the strength of the biotechnology industry and biotechnological innovation generally as a result of the potential it creates for a reversion: (i) amongst patent law decision makers and commentators to a less generous approach to biotech patenting

factors have given rise to a cynicism regarding the capacity of domestic reform mechanisms adequately to address the issues surrounding biotech patenting, and to a related perception that the current state of those issues is such as to require international action.[154] Thus harmonization is viewed by many as a means by which non-economic considerations can be introduced within the closed patent systems of nation states[155] and, in the words of one commentator, as representing the only hope for "stemming the current tide of patent law expansion that continues to occur as a result of biotechnology."[156] The immediate significance of this for the current discussion is three-fold. First, it underlines the fact that it is not merely governments and patent law enthusiasts who stand to benefit economically from an international regime of biotech patenting that support harmonization. Second, it explains why biotech patenting is likely to dominate the agenda of future harmonization initiatives, with much of the interest in harmonization deriving from an interest in biotech patenting itself. And third, and as a result of this likely dominance, it suggests that the debate on harmonization will progress along the same lines as the biotech patenting debate generally, thereby devolving into an argument about

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(*see*, *e.g.*, Montague, *supra* note 151, at 29; *see also* discussion *supra* note 79 (giving an example of such reversion)); and (ii) amongst biotechnology companies to traditional technologies (*see*, *e.g.*, Llewellyn, *supra* note 65, at 196 (attributing such reversion to the concern of bioscience companies to avoid being tainted with the image "of corporate concerns taking precedence over public and environmental safety")). Some commentators have also expressed concern that the European practice of granting broadly scoped patents will assist the case against biotech patenting. *See*, *e.g.*, Crespi, *supra* note 62, at 441. *See also* discussion *supra* note 94 (regarding principal causes of disquiet amongst patent professionals and the biotechnology industry in relation to biotech patenting).

[154] One reason that international action on biotech patenting is supported is because of the potential it offers for participation by non-specialist interest groups. But note the concerns that some commentators have expressed regarding the possibility for the ongoing exclusion of such voices (including those of developing countries) even in the international arena, and the (paradoxical) effect that such participation can have in affording certain voices greater legitimacy than others. On the former see, for example, Carroll, *supra* note 104, at 2493; Winter, *supra* note 10, at 186-87. On the latter see, for example, Black, *supra* note 101, at 651-52.

[155] *See* Drahos, *supra* note 114, at 448–49 (advocating the introduction of an international biotech patenting "framework convention" with express provision for morality-related issues as a means of creating "the potential for the evolution of more concrete obligations further down the track, a contracting space for further [international] action"). *See also* Spranger, *supra* note 27, at 374 (noting the effect of the EU Directive in providing a platform for ethical issues not previously accorded serious consideration in the patent law debate).

[156] Keays, *supra* note 79, at 89. Note the additional political and legal impediments to national reform arising from the risk that restricting patentability would: (i) harm local biotechnology industries; and/or (ii) place the reforming nation in breach of its obligations to provide technologically neutral protection for inventions under TRIPS art. 27(1), discussed above note 44. On the second of these points and its implications for the EU Directive see Commission of the European Communities, *supra* note 116, Annex 2 ¶ 2.1.

conceptions of patentability and the values they reflect. The innately difficult and controversial nature of these issues is such as to make the already fraught task of achieving international consensus on matters of substantive patent law impossible.[157]

This is particularly so given the further political reality created by past harmonization initiatives in respect of those matters, the lessons of which will inevitably inform approaches in the future.[158] Those lessons are likely to unite both sides of the debate in rejecting the historical tendency to leave ethical and other policy-based considerations, including conceptions of eligibility through which they are expressed, to the discretion of future (national or international) decision makers in the interests of securing immediate agreement.[159] The reason is that such compromise undermines much of the reason for substantive harmonization by deferring resolution of the very matters of substance in respect of which certainty is most needed, thereby creating a risk of future unfavourable decisions (and methods of decision-making) and, in the event that territorial decision-making is retained, exacerbating the current problem of divergent interpretations of identically or similarly cast principles and provisions.[160]

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[157] *See* Carroll, *supra* note 104, at 2480 ("The fact that IP rights have been addressed recently in both TRIPs and the Biodiversity Convention, two pieces of international legislation with vastly different outlooks and objectives points to the conclusion that an international consensus on biotechnology patents, if possible, will not be easily obtained."); Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1 (2001) (arguing that the provision for ethical restrictions in the EU Directive will preclude substantive patent law harmonization because of the propensity they create for divergent interpretations). *See also infra* note 160.

[158] *See*, *e.g.*, Moufang, *supra* note 12, at 830-31 (describing EPC art. 53(b) as the result of political compromise); Nicol, *supra* note 125, at 247 (citing the failure of the draft EU Directive as evidence of the need for clear guidelines to overcome the problem of legal uncertainty created by leaving too much scope for judicial interpretation); Thomsen, *supra* note 65, at 856 (expressing concern that the EU Directive not be permitted to replicate the interpretive problems created by EPC art. 53(b)).

[159] *See*, *e.g.*, Bostyn, *supra* note 79, at 35–36 (arguing the need for Contracting States to provide explicitly for the patentability of specific types of biotechnological inventions and to implement the EU Directive by the direct enactment of its literal terms in order to ensure legal certainty and avoid future interpretive problems); Nicol, *supra* note 125, at 247 (advocating the introduction of clear guidelines to mitigate against the uncertainty created by the European judiciary's "tendency . . . to give exclusions from patenting a very narrow reading"); Spranger, *supra* note 27, at 379 (criticising the EU Directive's introduction of ethical considerations into patent law on account of the "uncertainty" thereby introduced "into the inherently neutral examination process, to the detriment of the objectives of patent law"). *See also* Montague, *supra* note 151, at 30 ("[L]ong-established principle is a better guide to patent decisions than is contemporary policy.").

[160] *Cf.* Commission of the European Communities, *supra* note 116, Annex 2 ¶ 6, Annex 4 ¶¶ 1-4 (noting the ongoing risk of divergent biotech patenting standards under the EU Directive, and the request by certain Contracting States for clarification of (among other

The result, methodologically, is likely to be a strong push for highly prescriptive and semantic provisions that do not share the legal uncertainty or "wiggle room"[161] of existing concepts so denigrated by supporters and detractors of biotech patenting alike. However, such provisions will not only be impossible to secure agreement upon, but will also contribute to the very formalism that has been so undermined by the history of biotech patenting to date. Hence the fundamental dilemma facing patent law harmonizers, which is that any system harmonized at the level of substance must be both "flexible" — meaning (for some) capable of future application to new technologies and (for others) capable adequately of accommodating a public policy-based criterion, and "certain" — meaning bare of criteria requiring linguistic or policy considerations that invite subjective or discretionary decision-making.[162] At the heart of this dilemma lies a further tension between the perceived need for patent law to be both non-discriminatory and thus capable of accommodating all forms of technology, and attuned to the special needs of modern biotechnology. This tension replicates the historical tension, explored

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things) the meaning of the invention-discovery distinction in EU Directive art. 5, but nonetheless asserting that "the European legislator has succeeded [through the EU Directive] in creating a functional system which respects the major ethical principles recognised within the European Community.").

[161] *See* J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 28 (1997) (describing TRIPs as "leav[ing] developing countries ample 'wiggle room' in which to implement national policies favoring the public interest in free competition").

[162] The tension between the need for patent law to be both flexible and certain was a central issue in the Netherlands application for annulment of the EU Directive (*see supra* note 110). *See* Pays-Bas v. Parliament and Council, Case 377/98, (E.C.J. Sept. 10, 2001) ¶¶ 35-49, *available at* http://www.curia.eu.int/jurisp/cgi-bin/form.pl?lang=en&Submit=Submit&docrequire=alldocs&numaff=C-377%2F98&datefs=&datefe=&nomusuel=&domaine=&mots=&resmax=100. The same tension is also reflected widely in academic discussions of biotech patenting and its harmonization. *See*, *e.g.*, Byrne, *supra* note 65, at 299 (praising the Australian definition of "invention" for its flexibility, and yet lamenting the absence of any equivocal definition of "living" to elucidate the eligibility or otherwise of living phenomena); Kern, *supra* note 65, at 254, 255 (simultaneously praising patent law for having demonstrated its unique capacity to adapt to the special characteristics of patent law, whilst criticising the eligibility criterion for its promotion of "flexibility" and judicial subjectivism); Nicol, *supra* note 125, at 247 (criticising the "express and detailed list of exclusions from patenting" contained in European law as "clearly inflexible", whilst at the same time recommending the introduction of "clear guidelines . . . in the form of legislative amendments or policy statements" to overcome the legal uncertainty created by leaving issues of patentability to judicial interpretation). That tension is also reflected in the EU Directive itself, which was introduced to clarify the role of ethical considerations within European biotech patenting jurisprudence, but which has been perceived instead to have created further uncertainty in respect of such role because of the inherent vagueness of its provisions and the propensity they create for divergent interpretations. *See*, *e.g.*, Gitter, *supra* note 157, at 3-4; Morin, *supra* note 104, at 161; Skarstad, *supra* note 112, at 355–56; Straus, *supra* note 23, at 949.

above,[163] between treating modern biotechnology as essentially different from historically patentable subject matter, so as to require an overhaul of the traditional doctrine built around such subject matter, and as essentially identical to historically patentable subject matter, so as to be patentable according to the dictates of traditional doctrine.

In the meantime there remains the possibility of informal harmonization through patent office information exchange programs such as the ongoing Trilateral Cooperation Project between the United States, Europe and Japan.[164] However, and as the experience of the Trilateral Project itself reflects, the likelihood of programs of this nature producing any tangible results is doubtful — and not only because of "the lack of conformity of fundamental norms" within the relevant jurisdictions.[165] There is, in addition, the lack of certainty and transparency that exists in relation to those norms as a result precisely of the approach to biotech patenting described above. Specifically, the concealment of eligibility issues in the largely factual and discretionary enquiries of the non-threshold requirements makes differences in understandings of patent suitability — and of the reach of patent law generally — difficult to identify, thereby compromising the possibility of any meaningful "exchange of work results" on biotech patenting.[166]

VII. CONCLUSION

Modern biotechnology dominates much of the contemporary discussion about patent law, and promises to dominate future discussion about its substantive harmonization to a greater extent. As has been seen, the reason for the centrality of modern biotechnology to current patent law debate derives not only from the extent of its dependence on patent protection, but also from its

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[163] *See* discussion *supra* Section II.

[164] *See* About Trilateral Cooperation, TRILATERAL WEB SITE, http://www.uspto.gov/web/tws (1998).

[165] Bardehle, *supra* note 138, at 877. *See also* Chambers, *supra* note 137, at 240 ("Major discrepancies in the scope of patent-eligible biotechnological inventions remain between the patent systems of the United States, Europe, and Japan. At a recent meeting in Tokyo, the heads of patent offices from several key developed countries, including the United States, Japan, and the European Commission, acknowledged the growing significance of intellectual property rights of advanced technologies. Although the participants affirmed that they would use best efforts to achieve international harmonization of patent systems in each country, they did little to narrow the gaps among them." (citations omitted)).

[166] *See* Bardehle, *supra* note 138, at 877 ("The noticeable creativity of the individual states in inventing specific formal requirements and peculiarities not only prevents the exchange of work results of the patent offices [in the case of the Trilateral Cooperation Project], it also leads, in a case in which protection is sought for an invention in a number of states, to considerable efforts in revising an underlying patent application to meet the requirements of the individual countries. This results in considerable costs to the applicant. Only with the help of specialists can the organisation and handling of a series of patent applications in foreign countries on the basis of an underlying patent application be mastered.").

role in having exposed the fundamental uncertainties that plague the theory and principles of such protection worldwide. Indeed, it is partly in order to resolve such uncertainties that harmonization is required, which is one reason why future harmonization initiatives are likely to be dominated by biotech patenting. This confirms the nature of biotech patenting as a site in which deeper questions regarding patent doctrine and policy are being played out. That those questions are still far from being resolved in turn underscores the implausibility of securing international consensus on matters of substantive patent law in the near future.