Some Reflections on Method and Policy in the Crowded House of European Patent Law and their Implications for India

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Abstract

The patent regimes of several countries face an interplay of different obligations today which has made it difficult to discern the methodology adopted in answering questions of patentability. Consider India, where the regime witnesses the tussle between obligations under domestic legislation and Fundamental Rights, and those imposed by the Agreement on Trade Related Aspects of Intellectual Property Rights. Harmonization of these competing obligations raises important questions of an appropriate methodology, the absence of which would reduce the intricate complexities into an apparent jumble. In this article, the author takes up this issue in the European context, specifically positing her arguments against the backdrop of the debate surrounding the exclusion of natural phenomenon from patentability in Europe. It is argued that the European setting witnesses a lack of an appropriate methodology to determine the limits of patent law, which has rendered the inevitable convergence around some basic principles rather unsatisfactory and incoherent.

I. Introduction

II. The Patentability of Natural Phenomena and Fundamental Principles of European Law

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I. INTRODUCTION

The purpose of the United States (US) patent system is widely accepted as being to promote the progress of the useful arts, consistent with the terms of the constitutional clause by which Congress is empowered to “secure[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”

According to the US Supreme Court, this “clause is both a grant of power and a limitation” on congressional power in the field of intellectual property (IP); a view which explains its widespread treatment as the reference point for assessing substantive principles of US patent (as well as copyright) law.

This treatment of the US constitutional clause in national (US) patent jurisprudence raises important questions regarding the appropriate means for assessing the legal and normative legitimacy of non-US patent law principles. For

1. Article 1, § 8, The United States Constitution (empowering Congress to make laws “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”). As Justice Stevens remarked in Bilski v. Kappos, 561 US 23 (2010) [US Supreme Court], “[n]umerous scholars have suggested that the term “useful arts” was widely understood to encompass the fields that we would now describe as relating to technology or “technological arts”.


3. With respect to copyright law see, e.g., Grant v. Raymond, 6 Pet. 218, 241–242 (1832) [US Supreme Court] (patent “laws which are passed to give effect to this [constitutional] purpose ought ... to be construed in the spirit in which they have been made”); KSR Int’l Co. v. Teleflex Inc. 550 US 398 (2007) [US Supreme Court] (Kennedy J., for the Court: “The results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise, patents might stifle rather than promote the progress of useful arts.”); S. Chenette, “Maintaining the Constitutionality of the Patent System”, Hastings Constitutional Law Quarterly, 35 (2008), 221–62; P. J. Heald & S. Sherry, “Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress”, University of Illinois Law Review, (2000) 1119–97; all US Patent Acts before 1870 (which had the express purpose of “promoting the progress of the useful arts”). With respect to copyright law see, e.g., Feist Publications Inc. v. Rural Tel. Service Co. 499 US 349 (1991) [US Supreme Court] (O’Connor J., for the Court, describing the principle that “much of the fruit of the compiler’s labor may be used by others without compensation” as “a constitutional requirement”; the primary objective of copyright as being “[t]o Promote the progress of Science and the useful Arts”).

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example, adopting the US approach in Europe might lead one to have regard to the Treaty from which the European Union (EU) derives its patent authority and assess the resulting law with reference to its necessity to achieve the purpose for which that authority is conferred. However, this would be problematic for at least two reasons. One is that the European patent system is not a federal system in which the EU occupies the role of federal legislator, and the second is that the particular end to which the EU is empowered is the provision of uniform patent protection, which, when considered in isolation at least, is a manifestly unsuitable basis for assessing substantive European patent law principles. Hence the problem which US jurisprudence underlines, which is essentially one of methodology, namely, what is the appropriate method for establishing the limits of European patent law? The aim of this article is to consider that problem with reference to the exclusion from patentability of natural phenomena. It will be argued that in the crowded house of European patent law, “substantive convergence” around principles is inevitable but unsatisfactory: it will generally be the product of complex institutional dynamics as much as principled policy making, and in the absence of unified methodology and policy will fail to ensure coherence or consistency within the European patent system.

This argument has evident implications outside of Europe, where countries are subject to their own legal harmonization pressures. As the ongoing litigation in Novartis v. Union of India demonstrates, those pressures are particularly acute in India, which is caught between a tradition of granting limited patent rights in support of local industry, and an obligation to strengthen those rights in support of


5 In Novartis v. Union of India, a foreign company, Novartis, is challenging the TRIPS-compatibility of Indian law following the decisions of the Madras High Court (Novartis v. Union of India (2007) 4 MLJ 1153 [Madras High Court] [Hereinafter, “Novartis”] and Intellectual Property Appellate Board (I.P.A.B., June 26, 2009) that its life-saving cancer drug, Gleevec, is not patentable under Indian patent. The case is currently before the Indian Supreme Court.
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foreign industry under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).* Hence the relevance of the argument above, which is to validate the view of the Indian Legislature and courts regarding the scope which that obligation leaves for the persistence of national policy and methodology.

II. THE PATENTABILITY OF NATURAL PHENOMENA AND FUNDAMENTAL PRINCIPLES OF EUROPEAN LAW

The foundational principles of European patentability are contained in the Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions* (S.P.C.), on which the Convention on the Grant of European Patents* (E.P.C.) is also based. Article 1 S.P.C. establishes the obligation of Contracting States to grant patents "for any inventions which are susceptible of industrial application, which are new and which involve an inventive step". Article 2 S.P.C. creates exceptions to this for "inventions the publication or exploitation of which would be contrary to order public or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation", and "plant or animal varieties or essentially biological processes for the production of plants or animals" excluding "micro-biological processes and the products thereof". Both provisions have an E.P.C. counterpart - Article 1, S.P.C. in Article 52(1), E.P.C., and Article 2, S.P.C. in Article 53(a) and (b) - the only differences of current importance being that Article 52(2) E.P.C. defines an "invention" within the meaning of Article 52(1) to exclude "discoveries ... as such" (inter alia), and that Article 53(a), E.P.C. clarifies that an invention is not to be excluded from patentability on order public or morality grounds "merely because it is prohibited by law or regulation" in some or all of the Contracting States (emphasis added).

For the first 21 years of their co-existence, the S.P.C. and E.P.C. were the only operative European instruments concerned with substantive principles of

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6 Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round, vol. 31 (April 15, 1994, 33 I.L.M. 81). According to its Preamble, the purpose of TRIPS is "to reduce distortions and impediments to international trade, ... promote effective and adequate protection of intellectual property rights, and ... ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade" by (inter alia) introducing "new rules and disciplines concerning ... the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights".

7 (Strasbourg, November 27, 1963) E.T.S. 47.

8 (Munich, October 5, 1973) 13 I.L.M. 268 (as amended).
This gave the body responsible for implementing them – the E.P.C.-created European Patent Office (E.P.O.) – considerable freedom to fashion the values of the emerging European system. An important landmark in that regard was Howard Florey/Relaxin, involving an application for a patent for a D.N.A. sequence encoding for H2-relaxin which had been isolated from the human body for the first time using known recombinant techniques. The application was opposed on the ground that the sequence was a "discovery" the protection of which would confer excessive rights on the applicant, as well as concede the patentability of other "discoveries" such as "the moon (after the Americans landed on it in 1969), 'Otzi' (a mummified, around 5,000-year-old man found in ice in the Italian/Australian Alps), or a new animal found in some remote area". This argument was rejected by the E.P.O.'s Opposition Division with reference to a distinction between the acts of discovering a naturally occurring substance and isolating the substance from its natural environment. While the former did not result in an invention, the latter did, by reason of the technical nature of all acts of isolation and thus (it was said) of all isolated phenomena. It followed that provided an isolated phenomenon satisfied the other requirements of patentability it would be capable of supporting a European patent. It also followed that the scope of protection conferred by such a patent would extend beyond the method of isolation to the isolated phenomenon itself as the "invention" for which the patent had been granted. To the extent that this would give the patentee rights beyond the method which he had devised, it was regarded by the Division as "perfectly justified" in light of the phenomenon not having previously been made available to the public in a form in which it could be used. The decision broke with earlier United Kingdom (UK) authority including in its premise that the purpose of the system is to reward patentees, rather than to confer the consideration required by the social contact which a patent (on one view) represents.

Equally as a matter of doctrinal law, the importance of Howard Florey for the European patent system went beyond its restrictive view of the discoveries exclusion to its conception of patentability in general as appropriately extending to any subject matter which is technical in nature. That conception is also apparent from the E.P.O.'s interpretation of Article 53(b) E.P.C., and from the second part

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9 The Convention for the European patent for the common market (C.P.C.), 76/76/EEC (December 15, 1975) has never been ratified.


11 Howard Florey [5.4].

12 See Howard Florey [5.3].


of the Division's opinion in *Howard Florey* concerning the public ordre/morality exclusion. In the opponent's argument, D.N.A. sequences represent "life" the patenting of which is immoral and therefore prohibited by Article 53(a) E.P.C. The Division rejected this argument, finding instead that D.N.A. 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", and that "the opponents' general assertions concerning the alleged intrinsic immorality of patenting human genes ... 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) [which] assumption is false." For the E.P.O. to conduct its own enquiry into the morality of gene protection would be inappropriate, it said, having regard to the ambiguity of public views on the issue, and its limited remit to decide questions of law rather than morality. Consistent with this, and the E.P.O. Boards' repeated finding that exceptions to the general principle of patentability contained in Article 53(1) "are to be narrowly construed", the Division rejected the opponents' Article 53(a) argument. The earlier decision in *HARVARD/Onco-Mouse* — that the exclusion provided a mechanism for weighing the benefits and ethical risks represented by an invention — was all but rejected.

*Howard Florey* was decided nearly 20 years ago, four years before the EU entered the patent field with Directive 98/44/EC on the legal protection of biotechnological inventions (Biotech Directive). Building on the E.P.C. as implemented nationally, and reflecting its aim of harmonizing European patent standards, the premise of the Directive is the *Howard Florey* distinction between technical (and patentable) acts of isolation and non-technical (and unpatentable) acts of discovery. According to Article 3(2), for example, "[b]iological material which

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15 Howard Florey.
16 Howard Florey [6.4.3].
17 Howard Florey [6.4.4]–[6.5].
18 Howard Florey [6.2.1]. In the Division's opinion, this was presented as explaining and justifying the view of the exclusion "as a measure to ensure that patents would not be granted for inventions which would universally be regarded as outrageous" such as, it was suggested, a letter bomb.
19 See T_19/90 (HARVARD/Onco-Mouse) [1990] EPOR 501 [Technical Board of Appeal].
21 See Recitals 3, 5–7, 8.
22 The distinction is also recognized in US law. See, e.g., AMP v. USPTO (C.A.F.C., July 29, 2011) (reversing the district court's decision that isolated D.N.A. molecules are products of nature and therefore incapable of supporting a patent on the ground that "the molecules as claimed do not exist in nature" (p. 8). As reasoned by the court (at pp. 43–44), "...in nature, isolated D.N.A.s are covalently bonded to such other materials. Thus, when cleaved, an isolated D.N.A. molecule is ... a distinct chemical entity.")
is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature”. And similarly according to Article 5, while “[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements” are unpatentable, “[a] n element isolated from the human body or otherwise produced by means of a technical process” is patentable, “even if the structure of that element is identical to that of a natural element”.

In other respects, however, the Directive reflects markedly different values from those of Howard Florey. For example, its basis is a view of the European patent system as existing to support industry and research rather than technology per se, and as needing to accommodate “general principles of Community law”, viz., such “fundamental rights” as are guaranteed by European instruments or “the constitutional traditions common to Member States”. Of special importance in the Directive's recitals are the principles of health care and environmental protection, freedom of science, non-discriminatory patent protection, and the dignity and integrity of the person “in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented”. It is thus apparent that when the EU entered the field in 1998 it injected a new set of values into the then existing European patent system. Indeed, this was a central reason for the Court of Justice of the European Union's (C.J.E.U.'s) rejection of the Dutch challenge to the validity of the Directive as “undermining human dignity” by “reducing living human matter to a means to an end”, namely, that the Directive observes “the general principles of Community law”, including “the fundamental right to human dignity and integrity”. Ten years later that right was given a more explicit form and basis in the EU's constitutional fabric with the elevation of the European Charter on Fundamental

23 In relation to industry see Recitals 1, 20, 22, 24; Art. 5(3). In relation to research see Recitals 2, 10, 11, 14, 17, 18, 45.
24 Recital 43.
25 The source of this principle is Art 27.1, Trade-Related Aspects of Intellectual Property Rights.
26 See Recitals 16, 38. Cf Recital 34 (“Whereas this Directive shall be without prejudice to concepts of invention and discovery, as developed by national, European or international patent law".) While human dignity had been raised in argument in Howard Florey, the Division responded to the argument dismissively, due in part to its narrow conception of Article 53(a) generally. See Howard Florey [6.1], [6.3].
28 Netherlands [70]-[71].
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Rights of the European Union (Charter)²⁹ to the status of the EU Treaties,³⁰ and the imposition of an obligation on the EU to accede to the Council of Europe's Convention for the Protection of Human Rights and Fundamental Freedoms (E.C.H.R.).³¹

III. The Crowded House of European Patent Law and Its Convergence Around Substantive Principles

European patent law is an increasingly crowded house with no clearly defined boundaries and no clear hierarchy of legal norms. As mentioned above, its foundational legislative instruments are the S.P.C. and E.P.C., both of which are the products of intergovernmental agreements negotiated over a period of more than 20 years by the Council of Europe, the European Economic Community and two specially-convened diplomatic conferences.³² The E.P.C. is of particular importance due to its creation of a system for the grant of European patents and the E.P.O. to administer it. It was concluded in 1973 and later revised several times, including to incorporate the Biotech Directive.³³ Consistent with the nature of a "European patent" as a bundle of national (E.P.C. Member State) patents, it is implemented and supplemented by those States' national laws, at least some of which must be interpreted consistently with the Boards' interpretation of the E.P.C.³⁴ By its incorporation of the Biotech Directive, it is also the subject of EU jurisprudence, including decisions of the C.J.E.U., which take constitutional priority over decisions of national courts and the E.P.O. in all EU Member States, but which are not binding on the E.P.O. as a non-EU entity. Finally, and by its concern with property and

²⁹ OJ C 364/1 (December 18, 2000). See Arts. 1 ("Human dignity"), 3 ("Right to the integrity of the person"). See also of current relevance Arts. 13 ("Freedom of the arts and sciences"); 17 ("Right to property", including intellectual property), 35 ("Health care"), 37 ("Environmental protection").

³⁰ See The Treaty on European Union (T.E.U.) OJ C 83/13 (March 30, 2010) Art. 6(1) (recognizing "the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000" as having "the same legal value as the Treaties").


³² For the history see J. PILA, THE REQUIREMENT FOR AN INVENTION 126 (2010) et seq.

³³ See E.P.C. Implementing Regulations ch. V ("Biotechnological inventions").

³⁴ See, e.g., Patents Act, 1977 (UK) s. 130(7), transposed directly from the Resolution on the Adjustment of National Patent Law annexed to the C.P.C.
other "fundamental rights", it is the subject of decisions of the European Court of Human Rights, which, while not formally binding, are recognized as an important source of human rights jurisprudence, and the starting point for interpretation of the Charter.35

As this brief overview demonstrates, the European patent system comprises several overlapping European and national regimes, each of which differs in its basis and coverage. The Charter and E.C.H.R. deal with fundamental rights, including the rights of (intellectual) property. The Directive deals with the patenting of biotechnology, including issues of patentability and patent scope. The E.P.C. deals with the pre-grant aspects of a patent's life, and incorporates the provisions of the Biotech Directive. National laws deal with all pre- and post-grant aspects of a patent's life, and mostly incorporate and recognize the Biotech Directive and E.P.C., in addition to the Charter and E.C.H.R.36

The institutional complexity which this suggests is exacerbated by the opacity of the formal relationship between each of the relevant European and national regimes. The Council of Europe, E.P.O. and EU are all autonomous legal communities with their own claims to legal supremacy.37 And similarly most


36 Poland and the UK have sought to limit the application of the Charter in their respective countries; see Protocol (No. 30) on the Application of the Charter of Fundamental Rights of the European Union to Poland and to the United Kingdom.

37 The Council of Europe describes itself as "a pan-European human rights protection system" and "unique and powerful propagator of civilized values and democratic growth" committed to the goal of common standards. (Council of Europe, The Council of Europe: 800 Million Europeans: Guardian of Human Rights, Democracy and Law available at www.coe.int/AboutCoe/media/interface/publications/800_millions_en.pdf (last accessed January 29, 2012) p. 5). According to a 2009 decision of the E.P.O.'s Enlarged Board of Appeal, the European Patent Organisation comprises an autonomous legal community; "an international, intergovernmental organisation, modeled on a modern state order and based on the separation of powers principle, which the sovereign contracting states have entrusted with the exercise of some of their national powers in the field of patents." (G-03/08 (PRESIDENT'S REFERENCE/Computer program exclusion) [2011] O EPO 10, [7.2.1]). So too according to the C.J.E.U. in Costa v. Enelmore than 50 years ago, the EU comprises an autonomous legal community; "a community of unlimited duration, having its own institutions, its own personality, its own legal capacity and capacity of representation on the international plane and, more particularly, real powers stemming from a limitation of sovereignty or a transfer of
European states continue to regard themselves as autonomous and supreme within their territorial spheres, if only by virtue of their ability to denounce their regional commitments and memberships. In Europe there would thus seem to be two independent European patent systems, in addition to the two European human rights systems, and the (patents and human rights) systems of the various states, each of which interacts with the others in different and complex ways.

In the light of this, it is hardly surprising that the hierarchy of European patentability norms is also somewhat opaque. The formal position of European states is that such EU norms as exist take precedence over conflicting norms of the E.P.C. and national law, followed in most jurisdictions by the norms of the E.P.C. unless they (or the EU norms) are thought to be constitutionally or otherwise inappropriate. The formal position of the EU and E.P.O. is that their own norms take priority; the EU not being an E.P.C. Contracting State and the E.P.O. not being a Member of the EU. This, in combination with the facts that most European states will have divided E.P.C./EU loyalties, that EU patent law has limited coverage, and that the E.P.O. alone has technical and patent law expertise, make the reality even more complex than the formal position of states might suggest it to be. And this is without considering the E.C.H.R. and its associated jurisprudence, to which the Charter and some national laws are seemingly subordinate, nor indeed international norms and bilateral agreements.

On the European plane, the difficulties which potentially arise from the existence of (at least) four independent but overlapping European systems informed by different values and governing principles will be immediately apparent, particularly in an area as ethically sensitive and culturally embedded as the granting of property rights to scientific researchers in respect of elements of the human body. One need only consider the Directive’s extrapolation of the public ordre/morality

powers from the [member] states to the community” (C-14/64 Costa v. ENEL[1964] CMLR 425 (C.).E.U.) 455. See also Declaration 17 of the Lisbon Treaty concerning primacy.)

38 See Art. 174 E.P.C. (“Any Contracting State may at any time denounce this Convention. Denunciation shall be notified to the Government of the Federal Republic of Germany. It shall take effect one year after the date of receipt of such notification.”); for the UK, [LORD] T. BINGHAM, THE RULE OF LAW 164 (2010) (the curtailment by the European Communities Act 1972 of British parliamentary sovereignty “takes effect by express authority of the Westminster Parliament, which, at least theoretically, it retains the power to revoke.”)

exclusion to appreciate this. According to Article 6(2), that exclusion requires that...the following, in particular, shall be considered unpatentable:

a) processes for cloning human beings;

b) processes for modifying the germ line genetic identity of human beings;

c) uses of human embryos for industrial or commercial purposes;

d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

It is presumably in recognition of the difficulties which would result if the E.P.O. were to diverge on these exclusions that it has to date seemed intent on forging a common path by converging around the principles of the Biotech Directive. Evidence of that convergence ranges from the E.P.O.'s incorporation of the Directive's Articles into the E.P.C.\textsuperscript{40} to its recent embrace of the EU model of democratic governance based (\textit{inter alia}) on "the rule of law and respect for human rights".\textsuperscript{41} This embrace seems significant, and partly if not entirely to explain its 2008 decision in \textit{WARF/Stem Cells}.\textsuperscript{42} There the E.P.O.'s Enlarged Board of Appeal combined concern for human dignity with a conservative approach to statutory interpretation to find that the E.P.C. provision incorporating Article 6(2)(c) forbids the patenting of any subject matter the preparation or performance of which requires the destruction of human embryos. In the Board's analysis, the absence of a European definition of "embryo", the "straightforward" meaning of the exclusion "on its face", and the European legislators' concern to protect human dignity by preventing the commodification of human embryos, require an expansive interpretation of the exclusion to cover any patent application the teaching of which involves the use of an embryo for industrial or commercial purposes. Invited to support a more flexible interpretation which would enable the Office to weigh the benefits and risks of an invention in any individual case — in effect the approach of Onco-Mouse — the Board responded dismissively: "The legislators have decided, remaining within the ambit of Article 53(a) E.P.C., and there is no room for manoeuvre."\textsuperscript{43}

\begin{footnotes}
\item[40] For Art. 6 E.P.C. see Rule 28 E.P.C. Implementing Regulations.
\item[41] See President's Reference, [7.2.1] ("These principles have been subscribed to in substance at national level by all the E.P.C. contracting states, despite differing constitutional traditions and despite several reservations made by different states. As a democracy is prohibited from signing an international treaty which would undermine its citizens' constitutional guarantees, the E.P.O. must therefore support these fundamental principles either explicitly (e.g. Art.113 E.P.C. ("right to be heard and basis of decisions")) or implicitly (e.g. liberty, equality).")
\item[42] G_2/06 (WARF/Stem Cells), [2009] EPOR 15. [Hereinafter, "Warf"]
\item[43] Warf, [31].
\end{footnotes}
As I have elsewhere argued, there is reason to be skeptical about the E.P.O.'s purported respect for democracy, including for the limited constitutional remit of its Boards (and President). Consistent with this, it is ironic that the E.P.O. asserted its commitment to democracy and the rule of law in the very case in which it (unconvincingly) rejected an acteclaire doctrine under the E.P.C., thereby entrenching its Technical Board of Appeal as the first and last tribunal in the vast majority of European patent cases. And Warf may be viewed as further cause for skepticism, due to the means by which the E.P.O. achieved its particular end in that case. That means was to invoke some of the very factors invoked in Howard Florey to read the public ordre/morality exclusion down to read its "human embryo" subset up, in a dramatic reversal of European legal logic. Those factors include the absence of a consensus among Contracting States as to an aspect of the exclusion (in Warf the meaning of "human embryo"), and the appropriate interpretative approach to the public ordre/morality exclusion generally.

The EU's influence on the E.P.O. can hardly be doubted, and is perhaps unsurprising given the supremacy of EU law in most E.P.C. Contracting States, and its explicit concern to expand its involvement in the field of European patent law. That the EU has in turn been influenced by the E.P.O. is also apparent, not only from the terms of the Biotech Directive as discussed above, but also from subsequent C.J.E.U. cases. A key example is Brüstle v. Greenpeace, where the Court was asked to consider whether claims for purified and isolated neural precursor cells were invalid under Article 6(2)(c) of the Directive. Relying substantially on Warf, and the need to ensure that "the application of patent law ... respect the fundamental principles safeguarding the dignity and integrity of the person", it decided that they were, notwithstanding the applicant's intention to use the cells exclusively for

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45 G_3/08 came about as a result of a request by the UK Court of Appeal for a referral by the E.P.O. President of certain questions regarding patentability to the Enlarged Board. The link between that request and the acteclaire doctrine was made by Sir Robin Jacob in an unpublished paper delivered at a public conference in Oxford on January 8, 2012.

46 C-34/10 Brüstle v. Greenpeace eV [C.J.E.U.], [Hereinafter, "Brüstle"]

47 Brüstle, [32].
research, and on the basis of an expansive definition of "human embryo". Just as the E.P.O.'s decision in Warf seems to have been influenced by its concern to demonstrate its comfort with "human rights", so too it seems plausible to suggest that the C.J.E.U.'s decision in Brüstle was influenced, in part at least, by its concern to demonstrate its comfort with science and technology. Hence my suggestion, that "substantive convergence" around principles is inevitable but unsatisfactory, as it will generally be the product of complex institutional dynamics as much as principled policy making.

IV. DIVERGENCE OVER METHODOLOGY AND POLICY AS AN IMPEDIMENT TO COHERENT AND CONSISTENT EUROPEAN PATENT LAW

Following publication, Brüstle was criticized by scientists for failing properly to consider the needs of scientific and medical research and society as its beneficiary. The criticism connects with a certain expectation among academics regarding the consequences of "constitutionalising" intellectual property (I.P.), namely, that it would put I.P. on a par with other social and economic rights so as to permit, and indeed require, that they be "balanced" by tribunals in individual cases.

48 See Brüstle [35]-[36] (defining "human embryo" to include "any human ovum ... as soon as fertilized ... since that fertilization is such as to commence the process of development of a human being", and any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis). In Warf it was not considered necessary to define "human embryo" as the description of the invention made it clear that use of a pre-implantation embryo was necessary to produce the cells.

49 The C.J.E.U. is often criticized for alleged lack of technical expertise, particularly in patent law where such expertise is commonly regarded as essential. See, e.g., Department of Business Innovation and Skills, European Scrutiny Committee, "Documents Considered by the Committee on 20 December 2011: Draft Agreement on a Unified Patent Court and draft Statute", Paper 11533/l(December 20, 2011) [2.1] (reporting industry concerns that the currently proposed Unified European Patent Court would lack the technical expertise required to adjudicate matters of patent law).

50 See e.g., I. Sample, European Court outlaws patents on embryonic stem cell techniques. The ban will stifle research investment in potential stem cell treatments for conditions such as dementia, say scientists The GUARDIAN (October 18, 2011), available at www.guardian.co.uk/science/2011/oct/18/european-patents-embryonic-stem-cells (last accessed January 30, 2012). The criticism ignores that the effect of applying the public ordre/morality exclusion is not to constrain the freedom to research but to rather to decide that research may not be constrained by the grant of monopoly rights.

For some that expectation has been disappointed by the terms of the Charter, which have been said to promote a "maximalist conception" of I.P. and thereby unbalance the scales against society.\textsuperscript{52} The ambivalence reflects the difficulties inherent in any legal method which depends on a "balancing" of competing interests and principles, for what interests and principles are relevant and in "competition", what is required to "balance" them, and when and by whom are they appropriately to be "balanced"? These are difficult and contestable issues, and failing to engage with them directly can give the impression that appeals to "balance" are merely cloaking disagreement over method and policy.\textsuperscript{53} The suggestion of the decisions in Warf and Brüstle is that they ought to be answered as follows.\textsuperscript{54} First, the principles of primary relevance to patentability are the procedural principles flowing from the EU's restricted patent authority, including those of subsidiarity and respect for national sovereignty, and the substantive principles flowing from the E.C.H.R., the Charter, and the constitutional traditions of Member States, including those of the dignity and integrity of the person, health care and environmental protection, the freedom of the arts and sciences, and the protection of IP. Second, the balancing of these principles requires that their implications for patentability be considered and inform determinations of the content of substantive norms, which are then appropriately expressed statutorily. When reasoning from that content to a decision in a particular case, it is not appropriate for a tribunal to return to the relevant principles with a view to "re-balancing" them on the ground that they will already have been taken into account by the legislators. Central in that regard is the latters' decision as to how much weight the principles ought to have, and their relationship \textit{inter se}. From recital 16 of the Biotech Directive it is apparent that a principle of primary importance in European patent law is that of safeguarding the dignity and integrity of the person, and that this principle is the basis for the Article 5(1)


\textsuperscript{54} Even after \textit{Onco-Mouse}, references to the need to "balance" the competing interests in respect of an invention when applying the public order/morality exclusion received occasional support from the E.P.O., reflecting its continued ambivalence as to the proper method of determining the limits to European patentability. See, e.g., \textit{LELAND STANFORD/Modified Animal}, [2002] EPOR 2 [European Patent Office].
and 6(2) exclusions, in addition to informing the essential distinction between (inherently patentable) inventions and (inherently unpatentable) discoveries. It follows as a matter of methodology at least that criticisms of the Warf and Brüstle tribunals as having over-emphasised human dignity may be misconceived, for having considered all relevant (Charter and E.C.H.R.) principles, and in the absence of relevant constitutional constraints, the comparative importance of human dignity within the European patent system is a matter of legislative policy. What may be concerning is the use of identical considerations and principles – such as agreement between Contracting States (which may be linked to “respect for national sovereignty”) and the proper approach to interpreting patentability exclusions – in seemingly contradictory ways; unless human dignity is not merely the basis for the public ordre/morality exclusion, but the emergent foundation of the European patent system more generally, such that a shift in the policy and methodology of Howard Florey was not only appropriate, but necessary. While this suggestion may seem far-fetched, it draws attention to a peculiar feature of patent jurisprudence, which is its failure (in comparison with copyright, for example) to consider exactly how encouraging innovation benefits society, and what values beyond technology and research underpin the European patent system? If patent law were conceived as the engine rather than the competitor of human dignity – just as copyright is often conceived as the engine of freedom of expression and personal autonomy – it might even be possible to agree that the purpose of the European patent system is the appropriate reference point for assessing its substantive norms, as US courts and commentators would have it.

Whatever one's view on the relationship between patent law and human rights, one thing which emerges clearly from European patent law's treatment of natural phenomena is the importance which issues of legal methodology and policy have assumed in the European patent system. This supports the argument above that “substantive convergence” around principles is not enough to ensure legal coherence and consistency; one also needs a unified methodology and agreement over policy.55

V. CONCLUSION

The aim of this discussion has been to reflect on the importance which issues of legal methodology have in the European patent system, including the way in which the weight of legal norms is determined and decisions are presented (i.e., justified) to the public. The importance of these two aspects of legal method is particularly apparent in IP, where legal norms vary between jurisdictions in form,

55 The argument is consistent with at least some of the claims made in L. Alexander and K. Kress, Against Legal Principles, 82 IOWA LAW REVIEW, 739–86 (1996–1997).
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substance, and justificatory basis, and are accordingly weighted and presented differently by different law- and decision-makers. While copyright may remain the best source of examples of this phenomenon, the statement is true for patent law as well, as the recent decision in Human Genome Sciences Inc. v. Eli Lilly and Co. (H.G.S.) demonstrates. According to the UK Supreme Court in that case, the purpose of the patent system is to ensure the ability of companies to attract funding at an early stage of their research and development in order to be able to do the further work required to establish the value of their claimed discoveries. This view – which arguably informs the criticisms of Brüstle above – seems to have been important to the Court's decision in H.G.S. to accept the E.P.O. principle, that where the discovery is of a protein, the disclosure of an "educated guess" as to its use or benefit will satisfy the requirement for susceptibility of industrial application. The decision has relevance here for several reasons. The first concerns the Court's view that while European tribunals may reach different conclusions in parallel cases on procedural and evidentiary grounds, the lower courts' purported application of E.P.O. principles in H.G.S. was irreconcilable with their conclusion on the facts, justifying its reversal by the Supreme Court. The decision recognizes the difficulty of distinguishing substantive and methodological principles, and challenges the historical tolerance of methodological diversity among European tribunals. Second, by determining the content of the susceptibility of industrial application requirement with reference to the purpose of the system overall, the decision suggests agreement with the premise of the US approach, that substantive aspects of patentability ought properly to be determined having regard to that purpose, and without consideration of other relevant principles. Third, and consistent


57 Human Genome Sciences Inc. v. Eli Lilly and Co. (H.G.S.)[2011] UKSC 51 [UK Supreme Court]. Hereinafter, "HGS" Lord Neuberger delivered the main opinion and the citations below are from his reasoning.

58 HGS, [99].

59 HGS, [107], [123].

60 See HGS, [85] ("[T]he E.P.O. (or another national court) and a national court may come to different conclusions because they have different evidence or arguments, or because they assess the same competing arguments and factual or expert evidence differently, or, particularly in a borderline case, because they form different judgments on the same view of the expert and factual evidence.")

61 HGS, [105]–[111]. The lower courts had found that the use disclosed in the patent application was purely "speculative", and thus insufficient to justify a patent even applying those principles. For the decision of the Court of Appeal see [2010] EWCA Civ. 33 [England & Wales Court of Appeal].
with its "prospect" theory of patents, the decision supports a differentiated test of patentability according to the nature of the particular invention, and the rights required to enable the patentee to attract the funding required further research and development. And fourth, and notwithstanding its application of E.P.O. authorities, the decision sits uneasily with the provisions of the Biotech Directive "that the function of a patent is to reward the inventor for his creative efforts" (for the benefit of industry and research), that "the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology", and that "[t]he industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application" in order for the gene to be patentable. Hence my suggestion, that the case represents another example of "substantive convergence" in Europe masking a persistent divergence over methods and policy, and proving insufficient to ensure coherence and consistency in patent law. Hence also my suggestion, that there exists a need for greater consideration of both in the European patent system today.

Of course, the same suggestions may be apposite outside of Europe, with respect to the international patent system. For example, TRIPS is similar in its stated aims to the IP clause of the Treaty on the Functioning of the European Union; and while the World Trade Organization lacks the constitutional (and social rights) dimension of the EU, TRIPS itself recognizes the freedom of its member states to import that dimension from their national legal and constitutional systems. For these reasons alone, the Indian experience under TRIPS makes an interesting comparator to the experiences of European states under the E.P.C. and

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62 As Lord Hoffmann pointed out in his Hilary Term F.H.S. Patent Law seminars at the University of Oxford in 2012, the theory of patents supported by the Supreme Court in HGS is effectively that argued for in E. W. Kitch's classic work, The Nature and Function of the Patent System, 20 Journal of Law and Economics, 265-90 (1977), namely, that patents are prospects for developing technological opportunities.

63 See Recitals 46, 22; Art. 5(3) E.P.C.

64 Cf. ns 4, 6.

65 See TRIPS Arts. 7 & 8 ("The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations" (Art. 7); "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement" (Art. 8(1)), and its Preambles ("[t]hese objectives of national systems for the protection of intellectual property, including developmental and technological objectives" and "the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base").
EU law. For a UK commentator, India offers a particularly interesting case study because of its roots in the British patent system and through it in the English Statute of Monopolies 1623. As is well known, the Statute of Monopolies codified a constitutional prohibition against monopoly grants and a limited exception thereto for patents for “manners of new manufacture”. That exception had as its purpose the encouragement of local industry, and was subject to a proviso that the relevant manufacture “be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient”. With some important exceptions, the judicial assumption in the UK has been that the Government’s adoption of the E.P.C. in 1977 detached the UK system from its (Statute of Monopolies) roots and re-aligned it with the philosophy of the E.P.C., as subsequently developed by the Technical Boards of the E.P.O. The result has been the UK courts’ abandonment of certain important pre-1977 limitations on patent protection, such as the requirement for fairly based claims, the prohibition against patents for inventions in public use, and the narrow conception of products-as-inventions (and thus of the protection which product patents conferred), as well as a shift in their concern from promoting local industry to harmonization and technology (whatever that may mean!).

66 21 Jac 1 c. 3.
67 English Statute of Monopolies 1623 s. 6. For a detailed discussion see Pila (note 32) ch. 1.
68 Supra note 66, at S. 6.
69 See, e.g., Oakley Inc.v. Animal Ltd. & Ors, [2005] EWHC 210 (Ch) [23]–[25] [English and Wales High Court] (Mr Peter Prescott Q.C.: “According to the constitution of the United Kingdom the government (i.e. the Executive) cannot grant or regulate monopolies, or rights in the nature of monopolies, unless and to the extent that it has been authorised to do so by Parliament. This was established long ago: The Case of Monopolies, (1602) 11 Co Rep 84b; The Clothworkers of Ipswich Case, (1615) Godboll 252; The Statute of Monopolies, 1623 (21 Jac 1 c 3). Failure to respect that principle was one of the many causes of the English Civil War. ... The framing of legislation which governs trading monopolies requires the making of difficult policy choices. There are competing constituencies and a delicate balance has to be struck between them. ... The accommodation of all these interests is pre-eminently a matter for the legislature. Accordingly, patents, registered designs, copyrights and similar rights are regulated by Act of Parliament. For patents, we have the Patents Act 1977...”).
71 On the opacity of “technology” and related concepts, and their consequential inappropriateness as gatekeepers for patentability, see Pila (notes 32, 44).
By contrast, the same shift in patent (and social) policy seems not to have occurred in India following its entry to the World Trade Organization and TRIPS on 1 January 1995. Not only does Indian law maintain its pre-1995 skepticism with respect to patent rights, it continues to regard the Indian patent system as "a carefully crafted bargain that rewards an inventor in lieu of his contribution towards the society [in taking] the nation towards socio-economic prosperity". Consistent with this, local economic and social concerns – namely, "mischievous[ness] to the state", the "raising [of] prices of commodities at home" and "general[] inconvenience" – continue to provide legal and, indeed, constitutional grounds for refusing or limiting patent protection, including by denying injunctive relief, granting compulsory licences, and requiring a higher standard of inventive step in respect of pharmaceutical substances. Hence the statement by the High Court of Madras in Novartis, supported on appeal by the I.P.A.B., that the TRIPS Agreement "provides enough

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74 See e.g., Franz Zaver Huemer v. New Yesh Engineers (Delhi High Court, Nov. 11, 1995) (deciding that applications for injunctive relief must be decided having regard (among other things) to the impact of granting such relief on local investment and employment, public health (including public access to a life saving drug), and product quality and price); Hindustan Lever Ltd v. Godrej Soaps Ltd (Calcutta High Court, April 11, 1996) (refusing an application for injunctive relief on the basis in part of the patentee's failure to use the invention in India, and following the defendant's argument that if injunctive relief were to be granted, it would displace local workers and production); F. Hoffmann-LA Roche Ltd v. Cipla Ltd, (2009) 159 D.L.T. 243 [High Court of Delhi] [73], [79] (rejecting the plaintiff's argument that the grant of a patent must "be taken to be in the public interest" and deciding that "in a country like India where [the] question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of [an] injunction ... is likely to have, would have to be accounted for" by a court in deciding whether to grant such relief).

75 See e.g., Natco Pharma Ltd. v. Bayer Co. (Controller of Patents, March 9, 2012), [Hereinafter, "Natco"] discussed below.

76 See Patents Act 1970 (as amended) s. 3(d) ("the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. — For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.").

77 See Novartis v. Union of India (I.P.A.B., June 26, 2009) [Hereinafter, "Novartis"] especially p. 190. As noted in the Introduction, the decision in Novartis is currently before the Indian Supreme Court.
elbow room to a member country in complying with [its] obligations by bringing a law in a manner conducive to social and economic welfare and to a balance of rights and obligations”, and that the purpose of the Indian Patents (Amendment) Act 2005 was precisely to exploit that “elbow room” in order “to prevent evergreening, to provide easy access to the citizens of this country to life saving drugs and to discharge [the State’s] Constitutional obligation of providing good health care to its citizens”. On March 9, 2012, the same view was expressed by the Controller of Patents in support of his decision to grant the first compulsory licence ever to be granted to an Indian generic drug manufacturer under Chapter XVI of the Patents Act 1970 (as amended). The patent in question was for a liver and kidney cancer drug which the Controller found the US patentee, Bayer Corporation, to have made available “to a little above 2% of the eligible [Indian] patients” during the four years since its grant, and at a price that was (in the Controller’s opinion) “too high and simply unaffordable by the common [Indian] man”. Considering the implications of this decision for the TRIPS Agreement, the Controller stated as follows.

Even though the TRIPS Agreement marked a new era of obligations regarding the protection and enforcement of intellectual property, WTO Members retained important policy options, flexibilities and safeguards, including the liberty to determine the grounds for issuing compulsory licenses. In addition, certain key terms relating to TRIPS obligations are not defined in the Agreement itself, which leaves considerable discretion to WTO Members as to how to apply the criteria within their national laws. The use of these policy options and other flexibilities can directly or indirectly help the low and middle-income countries to achieve a balance between intellectual property protection and specific developmental priorities, including the attainment of national public health objectives.

78 Supra note 6 at 15, 19. See also 17 (describing the primary purpose of the Indian Patents Act 1970 as being the same as that of its predecessor, namely, “to safeguard the economic interests of [India]”, and as depending for its validity on its consistency with the Indian Constitution); R. Ayyanger, Report on the Revision of the Patent Laws (Government of India, 1959) (describing the main purpose of the Indian patent system as being “to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public”).

79 Natco.

80 Natco, 22.

81 Natco, 24.

82 Natco, 40–41.
Of particular interest for current purposes is the latter part of this statement, and that of the I.P.A.B. in *Novartis* quoted above, in which India’s national public health objectives and citizens’ right to health care services are invoked as limits on the reach of its patent protection. The primary source of the right to health care particularly is the protection of human dignity, which the Indian Supreme Court has interpreted Article 21 of the Constitution to confer. According to that Article, “[n]o person shall be deprived of his life or personal liberty except according to procedure established by law.” By relying on this constitutional guarantee to limit patent protection, India has, to date at least, met its international obligation to harmonize its laws without discarding the foundational values of its national system. It would be ironic indeed if the tempering effects of E.U. jurisprudence on the European patent system were to encourage a reversion within the UK to those values as well, by precipitating convergence around the principle of “human dignity.”

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83 On the right to life as including a right to human dignity see Frances Coralie Mullin v. Union Territory of Delhi (1981) 2 SCR 516 [Supreme Court of India]. On the right to human dignity as including a right to health care see Bandhua Mukti Morcha v. Union of India, (1984) 2 SCR 67 [Supreme Court of India]. For a discussion of these and other relevant cases see Centre for Enquiry into Health and Allied Themes (CEHAT), Legal Position Paper on Right to Health Care (Part II); available at http://www.cehat.org/rthc/paper3.htm (last accessed March 12, 2012).

84 See also Arts. 42, 47, Ch. IV, Constitution of India, 1950.
