From Engagement to Re-Engagement: The expression of moral values in European patent proceedings, present and future

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**Abstract**
In the regulation of new technologies, publics are often left questioning the value of their contribution to the final regulatory content, or feeling excluded from the regulation-making loop altogether. Dissatisfaction with upstream participation naturally results in stakeholders looking further downstream for influence. In the biotechnology arena, patent proceedings represent a participatory tool for stakeholders who may have been left out of or failed to achieve their goals upstream. Although they may have a reduced capability for shifting paradigms or shaping policy formulation, downstream expressions of values can be lively, and the acceptance or rejection of stakeholder positions by downstream regulators can be of great significance. Here the use of the morality provision in EPO proceedings is contrasted as between earlier and more recent decisions. It suggests which values have been given expression in this forum, how they have changed over time and how a wider pool of values might be incorporated into the existing system.

**Keywords**
Health research, stem cells, governance, engagement, participation, patents, bioethics, values, solidarity, WARF, Edinburgh.
INTRODUCTION

Biotechnologies are more important than ever before. Fluctuations in research funding influence (positively and negatively) scientific workforces and innovation and productivity trajectories. Advances drive social change and economic growth; new products and processes increasingly play a central role in our daily lives, shaping communication, information processing, health.\(^1\) With respect to health, biotech research is resulting in increasingly sophisticated analyses of living matter, and is expected to lead to targeted therapies for simple and complex diseases, common and rare. Promoting and regulating biotech research and innovation, and determining the social uses to which it is appropriately put, is an important and sensitive undertaking which must include the public. We are currently in transition both with respect to how publics are engaged in this policy-making process and how the engagement outcome (law) deals with biotech innovation.

This paper has the dual purpose of examining both the engagement and the expression of values during engagement exercises in the context of the Biotechnology Patenting Directive 98/44/EC (“BPD”),\(^2\) which, given the ubiquity of patenting in the biotech field,\(^3\) and the disputed consequences of patenting for its future development,\(^4\) will be of increasing importance. Part I outlines the engagement transition and examines the engagement processes and moral perspectives associated with the formulation of the BPD. Part II outlines European patent law and examines the primary values and moral approaches identifiable in the BPD as a substantive output of a participatory exercise. The premise of Part III is that statutorily permitted legal interventions represent a participatory tool through which stakeholders can re-engage with policy and other stakeholders, reiterating their policy positions and influencing not the formulation of policy but the execution of policy and the realisation of rights.

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and benefits thereunder. The intervention examined is genetic patent proceedings at the European Patent Office (“EPO”), which necessitate decisions on/at the commercialisation stage of innovation. Part IV queries how the moral base for such decisions might be broadened to give practical effect to some of the idealistic rhetoric in recent international instruments.

As a preliminary matter, it is appropriate to state the reasons for assessing EPO decisions. First, although the EPO is not an EU institution and is not bound by the BPD, its functions mirror the BPD’s purpose. Indeed, it has amended its Examination Guidelines and its Implementing Regulations to the EPC, both of which serve as interpretive aids for the European Patent Convention (“EPC”), to conform to the BPD. As such, it represents the first and foremost institution to adopt the BPD. Second, recognizing that patents are tools for promoting and regulating biotechnology innovation, EPO proceedings, particularly morality-based opposition proceedings, have become an important forum for stakeholder participation, as evidenced by the following:

1. The EPO has a clear morality mandate under the EPC and has become a crucible for morally-based challenges to scientific innovation and commercialisation.

2. Opposition decisions constitute governmental action which sets boundaries, provides science with legitimacy, and shapes conduct (influencing research programs and economic fortunes).

3. Whereas the morality provision was originally viewed as an unremarkable and infrequently used but necessary safeguard at the margins of the system, it was not written to reflect that desire and has evolved into an increasingly-utilised tool for managing/influencing innovation.

4. Oppositions have similarly evolved: in 1985, the EPO stated that it

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would be wrong to regard oppositions as contentious proceedings between warring parties where the deciding body takes a neutral position; by 1993, it described oppositions as “contentious proceedings between parties normally representing opposite interests, who should be given equally fair treatment”.

Ultimately, although EPO rulings are not binding on EPC signatories or EU members, they are persuasive to policy-makers, and courts tend to accept their authority, making them a worthy subject for an assessment of the trajectory of European policy.

I. ENGAGEMENT: THE PUBLIC IN THE POLICY-MAKING PROCESS

(1) Overview of Public Engagement Practices

Public participation was traditionally viewed (by policy-makers and scientific authorities) as a means of educating the public – instilling greater understanding of science. It was hoped that this transfer of knowledge would alleviate some of the ambiguity around science and relieve the “crisis of trust” surrounding biotechnologies and their regulation. This was the general approach adopted during the controversial attempt to introduce genetically modified foods in Europe. The perception that authorities used public engagement processes as an ex post facto attempt at public legitimation spurred demands for greater transparency in governmental processes which touch on human biotechnologies and their regulation.

Repeated calls for a shift from “government” to “governance” and an increased role for public participation in policy-making transformed the one-way educational model into a two-way dialogue; a more active public engagement

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characterised by information exchange. However, this new model was criticised as occurring too far “downstream” (ie: after the innovation process was set, leaving little potential to influence the shape of that process or consider much less answer broader social/political questions surrounding the subject biotechnology). A common criticism:

… Processes of engagement tend to be restricted to particular questions, posed at particular stages in the cycle of research, development and exploitation. Possible risks are endlessly debated, while deeper questions about the values, visions and vested interests that motivate scientific endeavour often remain unasked or unanswered.

Thus, even within the context of the governance model, the manner and function of participation needed to evolve.

Stakeholders thus tried to move public engagement “upstream” – before key development decisions (such as R&D priority-setting) are made and stakeholder positions entrenched. “Upstream” mechanisms such as deliberative polling and mapping, focus groups, citizens’ juries, consensus conferences and stakeholder study circles, were seen as capable of doing much more than simply examining the impacts, risks and consequences of the subject biotechnology. If appropriately integrated into political decision-making, they could better address broader social/political

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questions like:16 (1) For what purposes are we developing this biotechnology? (ie: what needs/desires are driving its development?) (2) Who should own/control biotechnology and related knowledge? (3) Who has responsibility for it and what is that responsibility? (4) Who benefits from the biotechnology?

Presumably having learned from the GM foods debacle, authorities moved discourses concerning human biotechnologies further “upstream”. And although these discourses were widely viewed as improved, they still suffered from a lack of demonstrable impact. Some of the new “upstream” participatory models provided:

… legitimacy to political decisions without requiring decision-makers to enact its recommendations when they ran counter to government policy. … [O]ne report of a consultation listed the issue of reproductive cloning as one where both government policy and the consultation results agreed. It then described an issue where they disagreed … then moved seamlessly on to reject the possibility of amending existing legislation to reflect this response …17

In short, participants wanted to know that their participation affected policies and trajectories of innovation, but were frequently left questioning the real value of their input; they had no way to measure the influence or efficacy of their contribution to the final regulatory content.18

So where does the policy-making process used for the BPD fall on this public engagement spectrum?

(2) Engagement Activities Surrounding the BPD

Although patents originated in an era of mechanisation, they have been extended to new areas of innovation (ie: chemicals, pharmaceuticals, software).19

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16 M. Kearns et al., supra, note 12.
17 M. Jones & B. Saltier, supra, note 9, at 33, and DEMOS, supra, note 13, at 18. Commentary, “Going Public” (2004) 431 Nature 883, reports that, in 2003, the UK government held a public debate on genetic modification and “is widely believed to have ignored the results”.
jurisprudence, the door for patenting biotechnology was opened in 1980 by *Diamond v. Chakrabarty*, an American case wherein the patentee produced a bacterium which fed on oil. The Court held that a live, man-made micro-organism is patentable, saying that, “anything under the sun made by man” could be patented. After *Chakrabarty*, the US biotech industry positively bloomed.

Motivated by the diminishing competitiveness of European biotech companies, and the threatened relocation of European companies to the USA due to the perceived disadvantages of Europe’s patchwork biotech patenting rules, the European Commission (“EC”) sought to clarify patenting principles re: biotechnology and harmonise them across member states. The EC’s draft directive (initially prepared with little public debate) proved to be the first step in a long and acrimonious 10-year political struggle characterised by intense stakeholder activity all along the “stream” of development, from first presentation to final promulgation (though it is questionable whether much of that activity was planned at the outset).

The initial and subsequent drafts were supported and promoted by industry stakeholders, who consulted with the EC from early stages and continued to campaign/lobby as the process progressed. Adopting a primarily economic utilitarian approach, they argued, *inter alia*, that patents:

- incite firms/individuals to invest and create;
- protect the value of the knowledge that resides in advances/inventions;
- encourage economic growth and competitiveness and therefore jobs;
- are properly available for any invention with a commercial potential; and
- have a natural and direct relationship with (medical) cures.

whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” The first patent on living matter was granted in Finland in 1843 and then by the US in 1873 (to Louis Pasteur for a yeast free from organic disease): EGE, “Opinion on Ethical Questions Arising from the Commission Proposal for a Council Directive on Legal Protection for Biotechnological Inventions” (1993), at www.eu.int/comm/european_group_ethics/gaieb/en/opinion3.pdf (Feb. 22/06).

The drafts were condemned by anti-legislation stakeholders who advanced a plurality of moral approaches. They argued, *inter alia*, that the granting of private monopolies over living material:

- is fundamentally immoral and contrary to human dignity;
- is undemocratic and blocks access to fundamental resources (including food and medicine) to which all humans have rights;
- stifles research by driving up research costs and complicating the research arena, creating inefficiency and disincentives; and
- dilutes the patentability criteria, leading to the patenting of mere discoveries and the expansion of biopiracy.

The political storm, powered by divergent interests and visions of acceptable scientific endeavour, involved the use of public meetings and conferences, open letters and resolutions, submissions to MEPs, and tireless pamphleteering, picketing, lobbying and negotiating, and was punctuated by allegations of sharp practice and dishonesty (usually directed at pro-BPD industry).

A consequence of the moral plurality was that stakeholders negotiated concessions to morally informed positions in their attempts to secure the inclusion of

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23 This loose alliance included hundreds of agencies, including the Green Party, Greenpeace, Friends of the Earth, GRAIN, ETC Group, ActionAid, European Farmers’ Coordination, European Christian Environmental Network, European Ecumenical Commission for Church and Society, Church of Scotland, Misereor (German Catholic Bishops), EKD (German Evangelical Church), and more.


26 The horse-trading resulted in the original draft being amended to include (1) a statement that the human body is not patentable, (2) a requirement that function must be disclosed in the patent application, (3) a limited farmers’ privilege to reuse the product of the harvest, (4) a power of referral to an ethics group, and (5) a morality provision with express reference to inventions which cannot be patented.27 Attempts to include other limitations were abandoned as expediency required. For example, provisions (1) prohibiting the development and patenting of genetic weapons, (2) directed at limiting the possibility of biopiracy, and (3) broadening the scope of the farmers’ privilege, all failed.28

In 1998, after multiple drafts and votes, a conciliation procedure, and the use, for the first time, of the European Parliament’s veto power, the BPD was adopted.29 Reflecting its difficult birth, it constitutes a hodgepodge of moral approaches, including utilitarian, human rights and dignitarian.30 The utilitarian approach weighs probable benefits and harms/dangers in determining whether a particular course should be pursued. The particular utilitarian approach advanced is informed by neo-liberal capitalist ideology; it assumes that securing financial reward/gain is a “good”, and adopts the traditional wisdom that permissive patentability encourages the “good” of economic growth and scientific advancement for the (potential) benefit of humanity (ie: corporate self-interest results in socially beneficial outputs). The human rights approach generally emphasises human agency and individual autonomy (ie: physical, psychological, economic and legal liberty and freedom from coercion). The dignitarian approach has been described as follows:

[T]he dignitarian view gives voice to the interests of conservatism, constancy and stability [and] the articulation of the concern that we

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27 S. Emmott, supra, note 22, at 382.


should … have the opportunity to hang onto those parts of the human condition that are familiar and reassuringly ‘human’. … [D]ignitarians can claim to represent a kind of ethical last stand. At the moment, safety concerns allow the ruling synthesis to echo dignitarian disgust at the idea of human reproductive cloning. However, once it becomes a significant option for some humans, there will … be just one voice of opposition – that of the dignitarians.  

Generally, it laments human interference with the genetic building blocks of life, which are viewed as common assets of humanity, and the privatisation and commercialisation of life-based processes/products.

(3) Summation: Moving Public Engagement “Upstream” and the BPD’s “Upstream” Course

Although one can debate how far “upstream” the BPD-related participation took place (ie: the EC had already prepared a draft text and opponents fought a rear-guard action to amend and/or kill it), there can be little doubt that it constituted public mobilisation and engagement. Drafting and adopting the BPD involved multiple steps and a host of diverse and competing stakeholders from government officials to industry operators to religious bodies to environmental activists, who engaged in a wide range of activities. When the BPD was finally adopted, it settled the legality of biotech patenting, but failed to settle the controversy, even becoming a nexus of controversy itself. The process or the outcome or both failed to satisfy certain stakeholders, who now strive to express their values and advance their agendas further “downstream”.

R. Brownsword, ibid, at 20-21.

Although legally bound to translate the BPD into domestic law, member states balked on moral grounds, and some 8 members had to be referred to the ECJ for failure to implement. One such case is Commission v. Italy, [2005] EUECJ C-456/03 (ECJ) The French National Bioethics Committee, the G8 Ministers of Research and a number of lobby groups expressed concern over the BPD: T. Schweiger, “Update on the EU Patenting Directive” (2000), at www.gene.ch/genet/2000/sep/msg00024.html (Mar. 8/06). Subsequent legal instruments have recommended revisiting the issue: see Council of Europe, “Report on Biotechnology and Intellectual Property”, Doc. 8459, July 9, 1999, and European Parliament “Joint Resolution on Patents for Biotechnological Inventions”, RC/586117EN.doc, October 24, 2005, which (1) alleges lack of clarity as to whether a DNA patent, which must articulate a function, covers only the application function or other functions as well, and (2) requests that the EPO introduce a body to consider the ethical aspects of ethically sensitive patents prior to issuance.
II. ENGAGEMENT OUTCOMES: VALUES AND MORAL APPROACHES IN THE (NEW) PATENTING REGIME

(1) Overview of European Patent Law

In principle, patents encourage and promote innovation and economic growth. Claims to that effect are frequently made as justification for expanding the role of patents in the economy.33 In much of Europe, patenting is governed by domestic laws which conform to the EPC.34 Under the EPC, patents afford patentees a nationally-bounded, exclusive, 20-year monopoly to exploit an invention in exchange for public disclosure of that invention.35 Patents may be granted by domestic patent offices, but are more commonly granted by the EPO, which administers the EPC.36 The EPO’s general function is to support innovation, competitiveness and economic growth, and to strengthen cooperation and create standard rules of treatment and procedure,37 which function evolved out of the original premises of the EPC.38 An invention can be registered/patented in multiple countries via a single process overseen by the EPO, thereby forming a bundle of patents.

Under the EPC, post-grant challenges to the validity of a patent may be initiated in the Opposition Division (“OD”) of the EPO. Such proceedings are not an extension of the examination procedure.39 They are a review of the acceptability of inventions on one or more of three grounds specified in Article 102 EPC.

33 See EPO, Mission Statement (2001), at www.european-patent-office.org/epo/pubs/brochure/general/e/mission_e.htm (Jan. 20/06). However, there is little empirical evidence to support this claim: R. Gold et al., supra, note 4, O. Mills, supra, note 5, at 12, K. Liddell, supra, note 26, and CIPP, Genetic Patents and Health Care in Canada: An International Comparison of Patent Regimes of Canada and its Major Trading Partners (Montreal: McGill, 2005). States that did not adopt patent systems in the 19th century experienced impressive economic and technological advancements, leading to accusations at the time that the patent system was “parasitic” and a “playground for plundering”: G. Dutfield, supra, note 8, at 50-53.

34 The EPC has 31 signatories. In the UK, it is given effect by the Patents Act 1977 (UK). Articles 1-11 of the Biotechnology Directive are incorporated into the Patents Act 1977 (UK) via the Patents (Amendment) Act 2000 (UK).


36 With respect to the latter functions, see Preamble, EPC. For more on the EPO’s purpose, see www.european-patent-office.org/epo/pubs/brochure/general/e/epo_general.htm (Feb. 2/06).


(patentability, clarity of disclosure, and over-inclusiveness).\textsuperscript{40} Oppositions, which must be instituted within nine months of issuance of a patent,\textsuperscript{41} represent an exception to the rule that competence over granted patents is transferred from the EPO to domestic institutions. Although they can be paper reviews, oral hearings are not uncommon.\textsuperscript{42} Oppositions have liberal standing rules: any natural or legal person can participate on payment of the requisite fee;\textsuperscript{43} they can be filed on behalf of other persons;\textsuperscript{44} and they are transferable \textit{via} succession law.\textsuperscript{45} In addition to the initial opponent(s) and the patentee, oppositions can involve interested third parties, offering the panel a larger pool of information upon which to base its decision.\textsuperscript{46} The OD must render a decision based on the grounds of the opposition and the evidence tendered.\textsuperscript{47} It must affirm, amend or revoke the patent, and its decision is unique in that it applies to the whole bundle of patents.\textsuperscript{48} Where the decision is appealable, it must be “reasoned” and “written”.\textsuperscript{49}

Article 53 EPC authorises the EPO to refuse patents (or revoke them where granted and opposed) where the publication or commercial exploitation of the invention would be contrary to \textit{ordre public} or morality.\textsuperscript{50} It is not to determine the

\textsuperscript{40} EPC Articles 52-57 (patentability), 83 (clarity of disclosure), 61 and 123 (over-inclusiveness), Clauses D-III-5 and D-V, EPO Guidelines, and “Note on Opposition Procedure in the EPO”, [1989] O.J. EPO 417. Although considered a “streamlined” procedure, oppositions take years from filing to completion: S. Thorley \textit{et al.}, \textit{Terrell on the Law of Patents} (London: Sweet & Maxwell, 2000).

\textsuperscript{41} Article 99(1) EPC.

\textsuperscript{42} For more on the OD and opposition procedures, see EPC Articles 19, 99-104 and 113-126, \textit{Implementing Regulations}, Parts D and E, Guidelines, and G. Paterson, \textit{The European Patent System: The Law and Practice of the European Patent Convention} (London: Sweet & Maxwell, 1997), Ch. 4.B.

\textsuperscript{43} Articles 58 and 99(1) EPC, and Clause D-I-4, Guidelines.

\textsuperscript{44} GENENTECH / Opposition on Behalf of Third Person, [1999] O.J. EPO 245 (OD).


\textsuperscript{46} Article 115 EPC. \textit{PPG INDUSTRIES / Heat Processable Metallic Appearing Coatings}, [2004] E.P.O.R. 331 (EAD), in addition to the patentee and opponent, the AD heard from another 5 industry organisations with no direct interest in the subject patent.

\textsuperscript{47} Article 113 EPC. For more on admissibility and evidence, see Article 117 EPC, \textit{Implementing Regulations}, Clause E-IV-1, Guidelines.

\textsuperscript{48} Article 102 EPC. Traditional infringement/enforcement proceedings are initiated in the domestic court of each country in which the patent is registered and infringed: Article 64(3) EPC.

\textsuperscript{49} Rule 68, \textit{Implementing Regulations}.

\textsuperscript{50} Article 53(a) EPC states that “patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to \textit{ordre public} or morality”. Article 6(1) BPD states that “inventions shall be considered unpatentable where their commercial exploitation would be contrary to \textit{ordre public} or morality”. Theoretically, the EPC offers a broader exception to patentability. My view is that the difference is immaterial. It is unlikely that the publication of an invention will be contrary to \textit{ordre public} or morality where the commercial exploitation is considered compliant with \textit{ordre public} and morality; in short, the decision will always turn on commercialisation. Indeed, the EPO has reported that amending the EPC to remove “publication” and bring it in line with the BPD would have no real impact on its current practice: Cabinet Chaillot, “Revision of the European Patent Convention” (2003), at \url{www.chaillot.com/en/pages/p9.html} (Feb. 22/06). Neither does the EGE
morality *per se* of biotechnologies, but rather the morality of their commercial exploitation and the extent to which a patent should be granted as part of that exploitation.\textsuperscript{51} Arguably, this is a patent law assessment well within the EPO’s expertise (whose skill is in understanding how patent application claims translate into potential products/processes). Although the EPC offers no guidance as to the appropriate interpretive approach to applying Article 53,\textsuperscript{52} the EPO has formulated its own guidance as follows:

The purpose … is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour. Obvious examples … are letter-bombs and anti-personnel mines. In general, this provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public … would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.\textsuperscript{53}

This clearly sets the bar for EPO intervention on morality grounds extremely high. One might question whether the EPC wording warrants such a restrictive approach, but it follows from the patent community’s (and EPO’s) partiality toward patentability,\textsuperscript{54} and the parallel marginalisation of morality in patenting by legal bodies.\textsuperscript{55} Unfortunately, the guidance offers no insight into how the EPO will arrive at a conclusion as to what “society” views as “abhorrent”.

So how does the BPD fit into this regime, what values have found expression in the BPD, and, importantly, what has it added?


\textsuperscript{51} This diminishes the persuasiveness of allegations that the EPO lacks the expertise in moral theory, ethics and public policy necessary to apply the morality provision, as suggested by the Nuffield Council, *The Ethics of Patenting DNA: A Discussion Paper* (London: NCB, 2002), at para. 6.18.

\textsuperscript{52} This shortcoming and the various theoretical approaches that could be taken are discussed in D. Beyleveld & R. Brownsword, *Mice, Morality and Patents* (London: CLIP, 1993), at 56-73.

\textsuperscript{53} Clause C-IV-3.1, *Guidelines*.


(2) The Expression of Moral Values in the BPD

Using the moral approaches advanced by the stakeholders and identified in Part I, some of the BPD’s key provisions can be explored.

(a) Utilitarian Approach

This approach weighs risks/harms against benefits such as individual financial reward, economic development, and scientific advancement which may promote better healthcare and greater health.\(^{56}\) This pro-patenting approach is apparent in Recitals 10 and 11, which precede the formal, operative provisions of the BPD:

10. Whereas regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground … ;

11. Whereas the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world [and] the patent system should likewise be used to encourage research in these fields … .

Examples of its reification can be found in Articles 3 and 5. Article 3(2) clearly/explicitly extends patentability to biotechnologies:

3(2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

\(^{56}\) See Recitals 1, 2, 3, 7, 8, 17, and 46, which generally state that biotechnology and the patenting of same plays an increasingly important role in economic wellbeing and the development of the internal market.
Article 3(1), together with Recitals 22, 24 and 34, quite practically, preserves the existing legal test for patentability (as established in Articles 52-53 EPC) and applies it in the biotech context:

- **Novelty:** The invention must be new and not form part of the existing “state of the art”, nor can it be something that exists in nature and is merely “discovered”. In the genetic context, a gene/sequence must be purified, isolated from the body and characterised, after which natural counterpart cannot destroy its novelty.

- **Inventiveness:** The invention must not be obvious to someone skilled in the field. If someone so skilled would consider it obvious to go from what is known to what has been claimed/invented, then inventiveness is lacking. Genomics researchers must consider the invention not routine or ordinarily achievable. A gene/sequence which shares the same function and is closely related structurally to an existing sequence/invention will fail for lack of inventiveness.

- **Industrial Applicability:** The invention must be capable of production and/or practical use in some industry. An isolated gene/sequence must have some practical probability (as opposed to a theoretical possibility) of application/function in some industry. This utility must be disclosed in the patent application.

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57 The term “state of the art” comprises all matter (product, process, information about either) that has at any time before the date of the application been made available to the public by written or oral or other means: see ss. 2(2), 2(3) and 2(4) of the Patents Act 1977 (UK) and Article 54 EPC.


61 For more, see C. Martinez & D. Guellec, *supra*, note 19, at 19.


63 The importance of functional claims not being too broad was expressed in *MYCOGEN / Transgenic Animal*, [1998] E.P.O.R. 114 (AD), and *ICOS / Transmembrane Receptor*, [2002] 6 O.J. EPO 293-308 (OD), which held that DNA sequence applications must disclose a credible function, which is not achieved where it claims sundry possible uses and the method for ascertaining the protein function.. Nonetheless, numerous (speculative) patents have been granted for genetic sequences whose full or even partial use is not known: Ontario, Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare (Toronto: Ontario Government, 2002), at 35.
Article 5(2), which is supported by Recitals 20-22, states:

5(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

This provision basically deems that the isolation and purification of natural substances are capable of being inventions. Pragmatically, they loosen the “inventiveness” criteria and blur the line between discoveries and inventions (and thereby reject the US requirements for patentability originally enunciated in Chakrabarty).64

The primary value which underlies the utilitarian approach is corporate/researcher autonomy (self-governance and freedom of will). However, this approach is not uni-dimensional. It limits patentability where harms/dangers are seen as too great, thereby endorsing a certain level of precautionism and a vision of justice. Such concessions to justice and/or decency are found in some of the Article 6(2) exceptions to patentability, notably human cloning, germline gene therapy, and industrial and commercial uses of the embryo.

(b) Human Rights Approach

This approach is sprinkled throughout the BPD. Recital 26, with no enforceable counterpart in the operative part of the BPD, states:

26. Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had

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64 Chakrabarty grounded patentability on the fact that the bacterium had (1) “markedly different characteristics from any found in nature”, and (2) the obvious potential for significant utility. This is stricter than the BPD’s requirement that an element isolated from the body may constitute a patentable invention, even if its structure is identical to that of a natural element. Thus, although the EC cited Chakrabarty as its authority [EC, Final Report: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering (Brussels, EC, 2002), at 17], it broke from the Court’s stipulation that biological material, though isolated and purified, remains an unpatentable product of nature: see L. Palombi, “Patentable Subject Matter, TRIPS and the European Biotechnology Directive: Australia and Patenting Human Genes (2003) 9 UNSW L.J. 26-35.
an opportunity of expressing free and informed consent thereto, in accordance with the law.\(^{65}\)

Recital 43 notes that fundamental rights as contained in the European Convention on Human Rights (1950) and member state constitutional traditions must be protected. More concretely, Article 11 stipulates that farmers can use the product of a harvest based on patented material for further propagation, and Article 12 stipulates that breeders can apply for compulsory, non-exclusive use of a patented invention. These provisions, which permit the limited redistribution of the benefits of genomic advances, expose values of justice and autonomy (which rest on the broad notion of valuing the worth of human beings).

\textit{(c) Dignitarian Approach}

This approach is exposed by a number of Articles which endeavour to limit the patentability of genetic material. Article 5(1) states that “the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions”. As evidenced by Recital 16, this is directed at establishing limits to biotech patentability based on personal integrity and human dignity. Article 6(1), supported by Recital 37 and substantively equivalent to Article 53(a) EPC, states:

\begin{quote}
6(1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to \textit{ordre public} or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
\end{quote}

Article 6(2) offers some guidance by stating that the following are unpatentable: (a) processes for cloning human beings,\(^{66}\) (b) processes for modifying the germline

\(^{65}\) For a discussion on the (potential) role of consent in patent law, see G. Laurie, “Patents, Patients and Consent: Exploring the Interface Between Regulation and Innovation Regimes” in J. Homsen (ed.), \textit{Regulating Biotechnology} (London: Edward Elgar, 2006).

\(^{66}\) Although “human cloning” is not defined in the operative part, Recital 41 limits the ban to reproductive cloning.
The dignitarian approach clearly emphasises the sanctity of life value (ie: human life and health above all other life and weighed equally as against other human life). It emphasises an interpretation of human dignity which holds that the human race’s sense of its own importance should be maintained by affording it greater protection than other entities. It seeks to preserve humanity’s place in and relationship to nature, and to avoid the instrumentalisation of human life (ie: treating humans solely as a means to an end). It also supports autonomy, but not to the extent that individuals are entitled to choose courses that compromise human dignity.

(3) Summation: Patenting Processes and the Hodgepodge Status of the New Regime’s Morality

As evidenced by the fact that some of the BPD’s provisions could be re-allocated differently amongst them, these moral approaches are not watertight categories. They overlap; it is their emphasis of particular values which varies, with the result that they promote different (and conflicting) rights/obligations. One might argue that a plurality of moral approaches within a single instrument is neither fatal nor even particularly harmful. However, in the case of the BPD, it has been problematic. The dearth of guidance regarding how these approaches (and values) are defined and properly balanced, particularly where they are implicated by new technologies outside those listed in Article 6(2), makes it difficult for decision-makers to know how to apply the BPD. It offers them broad discretion and a legal basis for contradictory outcomes, which hinders the BPD’s capability to harmonise laws/practices across jurisdictions. Indeed, the BPD’s validity was immediately challenged in part on the

67 Recital 40 also addresses germline genetics and the consensus within the EC that it offends human dignity.
68 Recital 42, which states that it does not affect inventions for therapeutic or diagnostic purposes which are applied to human embryos and are useful to it, is relevant.
lack of legal certainty caused by this plurality.\textsuperscript{70} This ambiguous outset suggests that the EPO is unlikely to adopt a robust and critical approach to the morality provision. At the least, however, one would expect it to (1) acknowledge and articulate competing interests and their underlying moral theories, (2) arrive at a means of measuring society’s abhorrence to the commercialisation of opposed products/processes, and (3) use its “moral compass” to formulate a comprehensible and cross-jurisdictional commercialisation morality.\textsuperscript{71} Let us see.

III. RE-ENGAGEMENT: GIVING VALUES PRACTICAL EFFECT THROUGH EPO DECISIONS

(1) The Early EPO Jurisprudence

The attitude and reasoning of the EPO in the “early” genetic cases which consider morality can be described as “circumspect”. Generally, the EPO:

- adopted a restrictive view of the morality provision’s functions and its role with respect to them, stating that the exceptions to patentability (eg: Article 53 EPC; Article 6 BPD) should be interpreted strictly/narrowly even where living matter is concerned;

- failed to articulate any broad, widely-held moral values (such as those which informed the BPD) other than to express the view that patenting is socially useful and to be encouraged;

- failed to engage in any real moral discussion beyond endorsing the need for a “common European morality”\textsuperscript{72};

- failed to invoke any of the touchstone values explicitly, though it implicitly


\textsuperscript{71} A. Warren-Jones, supra, note 54, at 114, suggests that the EPO does not need expertise in moral philosophy, simply a “moral compass” which accords with society.

\textsuperscript{72} PLANT GENETIC SYSTEMS / Glutamine Synthetase Inhibitors, [1995] E.P.O.R. 357 (AD).
elevated the sanctity of human life above other considerations, and was compelled by compliance with the autonomy value;

- held that Article 53(a) EPC (Article 6(1) BPD) requires a “standard of outrageousness test”, but gave no guidance as to how an opponent might show the overwhelming consensus on the issue amongst the contracting states that it demanded, even rejecting polls/surveys;

The reasoning in these cases is summed up in the following comments:

… [It cannot be the role of the EPO to act as moral censor and invoke [Article 6] to refuse on ethical grounds … a patent … directed to an invention indisputably associated with medical benefits … . The technology underlying the present invention is undoubtedly controversial and the subject of intensive discussion … . However, there is at present no consensus in Europe … about … this technology, and public opinion is still being formed … . It would be presumptuous for the EPO to interfere in this debate. The [morality] provisions … are intended to exclude from patentability not subject-matter that is controversial, but rather that kind of extreme subject-matter … which would be regarded … as abhorrent.

In each case, the EPO granted the patent, albeit sometimes on more limited claims. One could conclude from them that oppositions are not a fruitful means of re-engagement. Opponents have not been successful in (1) encouraging a consistent interpretation/application of the morality provision, (2) identifying what values the EPO relies on, or (3) revoking genetically-related patents. Additionally, lack of clarity as to the basis of decisions makes it difficult for stakeholders to confidently predict outcomes and to strategise appropriately to bring about desired outcomes.

So how do more recent cases involving new biotechnologies compare with the

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76 *LELAND STANFORD*, para. 51. This patent was opposed by Bio-Pharmaceuticals, C. Then *et al.*, and Bundeszentrale der Tierversuchgegner Österreichs.
approach adopted in the early precedents?

(2) The Recent EPO Jurisprudence

In *EDINBURGH / Animal Transgenic Stem Cells*, the patentee sought protection for a process for genetically modifying animal stem cells such that they had a survival advantage over differentiated cells (thereby overcoming the need to culture massive cell populations comprised largely of unwanted cells). The fourteen opponents and five third-parties all objected to the patent, in part, on the morality provision, arguing that the term “animal stem cells” could include human embryonic stem cells (“ESC”), thus falling afoul the patentability exclusion relating to industrial and commercial use of embryos.

After an oral hearing, the OD defined morality as relating to the belief, founded on the deeply held norms of a particular society, that some behaviour is right and acceptable and some behaviour is wrong and unacceptable. It identified the subject society as European society/civilisation. Thus, inventions the exploitation of which is not in conformity with conventionally accepted norms of European culture are excluded from patentability. With respect to identifying “conventionally accepted norms”, it stated:

Neither the evaluation of the national legislation nor the assessment of the conventionally accepted standards of conduct of European culture has revealed a uniform approach with regard to human ESC, and … even a uniform estimation of the situation for all contracting states … would not automatically [suffice] under Article 53(a) EPC [to render an invention unpatentable]. …

It determined that the case turned on whether Rule 23d(c) (Article 6(2)(c) BPD) should be interpreted narrowly to ban patents on human embryos as such or broadly to

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78 Human stem cells can be cultured from adults or embryos. Embryonic stem cells are cells cultured from early embryos, and have the potential to develop into a wide variety of specialised or differentiated cells.
79 Germany, Italy, Netherlands, and 11 other parties ranging from individuals (Dr. Tippe, Dr. Kaiser) to organisations (Greepahe, *Aktion Leben Österreich*, *Alliance pour les Droits de la Vie*, etc.).
80 *EDINBURGH*, para. 2.5.3.
ban patents on human embryos and the cells retrieved therefrom by destruction of the embryos (ie: ESC). In answering this question, the OD noted:

- Patent law must be applied so as to respect the fundamental principles of dignity and integrity.\(^81\)

- The illustrative list of unpatentable inventions is not exhaustive and can expand to processes for producing chimeras from “totipotent cells”\(^82\) of humans and animals.\(^83\)

- Although inventions using human embryos for industrial/commercial purposes are unpatentable, inventions for a diagnostic or therapeutic purpose which are applied and are useful to embryos are acceptable.\(^84\)

It concluded:

If the legislator had intended … to exclude from patentability only the human embryos as such, he would not have introduced both … Article 5(1) and Article 6(2)(c) … .

The fact that [Article 6(2)(c)] refers to “uses” for “industrial or commercial purposes” is not of relevance in the given context. If patent applications are being filed there is always an industrial or commercial purpose implied because the only function of a … patent is to stop others from commercially/industrially exploiting the invention. Moreover, the reference to “use” … cannot have a bearing in considerations of an ethical nature. If the patenting of a product is ethically unacceptable, it is hardly conceivable that the patenting of

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\(^81\) Recital 16 BPD.
\(^82\) “Totipotent” cells have the capacity to form an entire organism. They have “total potential”. In humans, the fertilised egg forms a single totipotent cell. Only after approximately 4 days and several division cycles do they begin to specialise into “pluripotent” cells (which give rise to most tissue necessary for foetal development) and pluripotent cells into “multipotent” cells (which give rise to cells with specific functions).
\(^83\) Recital 38 BPD.
\(^84\) Recital 42 BPD.
“uses” of this product can be judged differently. Thus, it is considered that the exclusion of human embryos from patentability … also pertains to the “uses” of human embryos for whatever purpose.

In consequence, [Article 6(2)(c)] in order to have a purpose exceeding the one of [Article 5(1)] has to be interpreted broadly to encompass not only the industrial or commercial use of human embryos but also the human ESC retrieved therefrom by destruction of human embryos.85

Breaking from precedent, the OD held that a broad interpretation of the exclusion is appropriate (ie: morality bars patents on human embryos and the ESC retrieved therefrom). It concluded that the claim was described such that it was caught by Article 6(2)(c). However, it upheld the auxiliary request which related to animal and human stem cells but excluded ESC. It concluded that stem cells isolated from adults or aborted foetuses are akin to any other cell isolated from an organism, which is patentable by operation of Article 5(2) BPD and Recitals 20 and 21.

The OD’s decision – in particular its outright consideration of the patent’s morality and its assessment and rejection of the EGE’s ethical opinion – suggests that the OD has come a long way since the early cases in which it appeared happy to avoid engaging the morality question at all. That is not to say that its moral analysis represents the ideal. The OD conflated its legislative review and its assessment of conventionally accepted standards of (moral) conduct. It held that the lack of uniformity of ESC research regulation in Europe (ie: the patchwork of legality, illegality and legislative silence) confounds any attempt to identify conventionally accepted standards of conduct. So it neglected to try, arriving at its moral conclusion on the wording of the BPD. As such, the values it relied on are easy to identify – non-instrumentalisation and personal integrity. It exhibited a cautious (almost dignitarian) approach in that, despite dealing with pluripotent cell lines which could not develop into embryos, it invalidated the original patent on the basis of the Article 6 ground that the use of embryos for industrial/commercial purposes is immoral.

85 EDINBURGH, para. 2.5.3.
In *WARF / Primate Embryonic Stem Cells*, the patentee sought protection for ESC cultures derived from rhesus monkeys and marmosets. Reference to “primate” was interpreted to include “human”, although the generation of human ESC cultures was not exemplified in the application. As in *EDINBURGH*, the invention’s patentability under Article 53(a) EPC and Rule 23d(c) (Article 6(2)(c) BPD) was questioned, although this time by the ED.

After an oral hearing, the ED noted that, although the application related to cell cultures, the method for their creation was included in the claim and the final product inherited technical features from its starting material – a preimplantation embryo. Thus, it must take into consideration the starting material and the process as well as the end product claimed:

Since no alternative starting material is given but preimplantation embryos, the disclosed cultures … are inseparable from the methods that generate them and from the use of an embryo as starting material.

In addition, it held that the description of the invention implicated human embryos by its claim that the process could equally be used to create human ESC cultures. The use of (human) embryos as starting material for the generation of products with industrial application is, it held, equal to industrial use of the embryo.

Having established the indispensability of embryos to the invention and the industrial use to which they are put, the ED considered the BPD’s Recital 42 exception to the exclusion from patentability (ie: the industrial use exclusion “does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it”). It held that this invention did not fall within the exception because the generated ESC cultures served no diagnostic/therapeutic purpose useful to the originating embryo:

… According to the application … [these cell lines] are highly desirable for the study of human pregnancy with a view to

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86 Patent Application No. 96 903 521.1 – 2401, July 13, 2004, Examination Division. This case was appealed to the Technical Board of Appeal, which, by decision T 1274/04 – 3.3.08, dated November 18, 2005, has referred the appeal to the Enlarged Board of Appeal.

87 *WARF*, para. 10.
understanding the mechanisms involved and for … treating … human infertility. However, none of these goals relate to therapeutic or diagnostic purposes useful to the embryo that gave rise to said cells, although it is not disputed that achieving said goals would probably benefit the development of *in vitro* fertilisation methods and/or infertility treatments. ...\(^88\)

It dismissed the patentee’s caution that such an approach would exclude from patentability all products traceable to ESC and thereby gravely endanger biotech innovation, stating that this position failed to appreciate that such products may be developed through methods that do not include direct use of human embryos. In denying allegations that it adopted an erroneously broad interpretation to the exclusion, it stated:

… The relevance of [Article 6(2)(c)] in assessing the patentability of the claimed subject-matter is not from a broad interpretation of said [Article] but rather from the significance of the teachings of the entire application (use of a human embryo and culture method) which are indispensable for the generation of the claimed subject-matter (human ESC cultures).\(^89\)

The ED concluded by saying that the clear wording of the BPD and its direct applicability to this invention made resort to moral philosophy unnecessary.

Although the EPO denied adopting a broad interpretation of the morality provision, it certainly gave it more work to do by holding that the application was not limited to the claimed subject matter, but to the invention in its entirety, including all aspects that make it available to the public:

… [T]he ED in *WARF* rejected [a strict] approach, preferring an holistic consideration of the totality of the inventive process and not just of the claimed invention. The message from the ruling is that the moral concern goes far beyond patenting itself and extends to general

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\(^88\) *WARF*, para. 11.  
\(^89\) *WARF*, para. 12.
instrumentalisation. It implies that mere involvement – use – of embryos in the research and development of an invention is sufficient to bar the patentability of that invention.\textsuperscript{90}

Unfortunately, the decision does not offer any reliable insight into the direction of the EPO’s moral leaning or the underlying values being brought to bear. It specifically declined to enter into any moral discussion or to offer any guidance as to what evidence (of morality) might prove persuasive in future cases.\textsuperscript{91} It limited itself to reading the claims and offering an almost literal interpretation of the legal provisions without elucidating any overt morality. However, by adopting a more holistic approach which more readily implicates the exclusions to patentability, one can argue that it has given greater life to the sanctity and dignity values emphasised by the dignitarian approach, which decries human embryonic research, and has eroded the economic utilitarian dominance, which claims that commercialisation decisions are properly that of the researcher. In short, it has shifted its perspective slightly and this may bring hope to stakeholders who oppose genetic patents.

(3) Summation: EPO Conduct and Stakeholder Engagement in Transition

Regardless of how oppositions were originally viewed, they are now “legal battles” fought by socially conscious NGOs in the trenches of commercialisation.\textsuperscript{92} Indeed, their liberal standing rules and the number and scope of participants in the cases reviewed suggests that oppositions could and should be a useful forum for lively re-engagement (ie: for the exploration of fundamental moral and commercial questions in the context of specific inventions). The early cases were not. The latter cases moreso; they represent a shift in the EPO’s view of its role, but not a drastic shift. EDINBURGH and WARF were not decided by balancing competing visions of


\textsuperscript{91} WARF, para. 12. However, at the oral hearing, it stated that the applicable moral standards are those evidenced by national laws and common religious beliefs in EPC states existent at the date of filing: WARF, Minutes, paras. 4.1 and 4.2.

\textsuperscript{92}T. Schweiger, “Patenting Life” (1999), at http://archive.greenpeace.org/geneng/reports/pat/pat002.htm (Mar. 8/06).
science and morality, but by an interpretive approach which gave greater effect to the wording of the BPD (albeit for the first time). The EPO did not (1) acknowledge and articulate competing interests and their underlying moral theories, (2) arrive at a means of measuring society’s abhorrence to the commercialisation of opposed products/processes, or (3) use its “moral compass” to formulate a comprehensible and cross-jurisdictional commercialisation morality. In the result, even the latter cases have been described as “crude” and “absolutist” and open to ethical criticism. 93 Stakeholders are still left with real questions about what moral approaches and values motivate the EPO. Indeed, recognising the lack of clarity on this issue and the controversy surrounding its own decisions, the EPO has announced a moratorium on applications involving human ESC technology. 94 As such, questions remain as to where the new cases leave the patent system.

IV. FUTURE ENGAGEMENT: EXPANDING THE VALUE POOL

(1) Adopting the Orphan Value

Modern healthcare is transitioning towards “genomic medicine” and is increasingly reliant on biotechnological advances. 95 Solidarity is a core value of modern healthcare (and the welfare state) and has been described as essential for redressing the growing global healthcare deficit. 96 Given that intellectual property rights play an ever-expanding role in both healthcare and genomic research, the solidarity value is surely relevant to the patenting regime and ought to play a role in the EPO’s morality-based deliberations.

Solidarity may have been advanced by some of the stakeholders during the “upstream” negotiations, but it found little expression in the final version of the BPD. This value is grounded in compassion, fraternity and an interest in the well-being of others. It recognises that individuals are naturally and irrevocably embedded in social contexts and therefore emphasises the creation and preservation, through personal and

93 G. Laurie, supra, note 90, at 9.
95 WHO, Genetics, Genomics and the Patenting of DNA: Review of Potential Implications for Health in Developing Countries (Geneva: WHO, 2005).
collective action, of a just and decent global society. This socially-connected and
common-action-promoting notion of solidarity is recognised in religious and
philosophical thought and in a host of international instruments.

With respect to its interplay with intellectual property and commercialisation,
the value is embodied at international law in the characterisation of Antarctica, space,
culture, the moon, and the seabed as the “common heritage of mankind” warranting special protection and special rules of exploitation. It is
implicated in the genomics field through the characterisation of the genome and
genomic information as the “heritage of humanity”. Characterising the genome as
the “heritage of humanity” underlines human unity and implies the following
elements: (1) non-private/national appropriation; (2) common or international
management; (3) use only for peaceful and socially useful purposes; (4) equitable
sharing of benefits (just distribution); and (5) protection/preservation for future
generations. The interrelationship between the “heritage of humanity” concept
and solidarity is obvious: they share notions of global community, shared social purpose,
common resources and intergenerational justice.

The realisation of these aspirational elements is thrown into doubt by
corporate practices and research-stifling patent thickets of the economic model that
governs society and corporate scientific activity, limits commercial/political

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100 UN Convention for the Protection of the World Cultural and Natural Heritage (1972).
101 UN Agreement Governing Activities of States on the Moon & Other Celestial Bodies (1979).
102 UN Law of the Sea Convention (1982).
imagination, and shapes the nature and direction of genomic research.\textsuperscript{105} Some suggest that this individualistic, market/profit-driven model is fundamentally incompatible with the genome as the “heritage of humanity”.\textsuperscript{106} The same might be argued in relation to the solidarity value, particularly in its purest and most robustly defined form. However, I am not concerned with the deeper philosophical debate about the compatibility of solidarity fundamentalism with the economic model.\textsuperscript{107} Given the entrenchment of the economic model and this paper’s modest aim of looking at engagement and morality within that model (ie: the patent regime), I wish to limit the analysis of the solidarity value to its potential application within the model by the EPO.

So what might be the practical effect for commercialisation if the EPO were to adopt solidarity as one of its moral touchstones?

(2) \textbf{Solidarity on the Ground}

One could argue that solidarity has already been translated into action through prohibitions on (1) human cloning, (2) germline gene therapy, and (3) owning genes in their natural state, and (4) through the recommendation to benefit-share, and is therefore already realised in the patenting regime and enforceable in EPO jurisprudence. I would argue that these actions, which are equally informed by the dignitarian and the human rights approaches, do not adequately reflect the deeper meaning or significance of solidarity. Something more is needed. Having said that, the following suggestions are not reflective of solidarity in its purest form. They are rather a means of advancing notions of solidarity within a system with which the value interacts uncomfortably.

Recognising that solidarity does not despise self-interest where it enhances the

\textsuperscript{105} With respect to sharp practices and greed, note the conduct of Myriad Genetics Inc. and Human Genome Sciences Inc. With respect to research-stifling tangles of IP rights, note that gene patents number well over 355,000 and surveys indicate that researchers are deterred from working on particular gene targets due to fear of infringement actions and/or expensive licenses: J. Sulston, \textit{ supra}, note 3, and P. Gepts “Who Owns Biodiversity and How Should the Owners be Compensated?” (2004) 134 Plant Physiology 1295-1307. For more on the economic model and the operation of the biotech market, which has been described as “morally perverse”, see L. Cahill, “Genetics, Commodification and Social Justice in the Globalization Era” (2001) 11 Ken. Inst. Ethics J. 221-238.


\textsuperscript{107} That is not to say that such ideological/philosophical debates are not important. If we only strive to be practical within the confines of the existing economic model, we will never explore alternate world views or change the dominant frame of reference.
greater good, and accepting (with a grain of salt) the common wisdom that patents promote innovation and healthcare advances, the simplest and most direct action the EPO might take in support of solidarity would be to reinvigorate the patenting criteria of novelty, inventiveness and industrial applicability (ie: take seriously its gatekeeper function). The distinction between a discovery and an invention has been so blurred and the patentability criteria so diluted as to be almost meaningless in the gene patenting context.  

It is widely argued, even by scientists, that the routine purification and replication of gene sequences outside the body does not properly constitute an invention:

The essence of a gene is the information it provides – the sequence. Copying it into another format makes no difference. It is like taking a hardback book written by someone else, publishing it in paperback and then claiming authorship because the binding is different.

Conceding that the BPD adopts the position that isolation/purification can result in an invention (despite its own Recital 34), the EPO could nonetheless stiffen the burden of proof imposed on applicants. Indeed, it could adopt a “substantial transformation test” whereby a product must be substantially transformed such that it has a new and distinct character or use before it can obtain patent protection. Only a substantive transformation justifies granting an individual monopoly, which necessarily infringes solidarity broadly described. Although other values might be supported by the adoption of such a test (or the more rigorous application of the patentability criteria), solidarity is enhanced because, presumably, fewer patents would be awarded. This would serve to keep more information in the pre-competitive public domain and would expand the freely available prior art, both consequences which are supportive of the collective notions embodied by solidarity. Given that patents are not the primary motivation for innovation, and that patents would still be available for end-

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109 J. Sulston, supra, note 3.
110 Recital 34 states that the BPD “operates without prejudice to concepts of invention and discovery as developed by national, European and international law”.
111 P. Gepts, supra, note 105, at 1301.
products, research should not be hindered and the EPO would still be performing its innovation/economy promoting function.

In the absence of this front-door approach, the EPO is given a back-door approach – the morality provision. The effective and legitimate use of this option for giving legal effect to the full range of moral values (including solidarity) would require the EPO to sharpen its moral analysis, adopting a more contextual approach. As previously stated, the crux of the EPO’s function is to determine the moral acceptability of the state sanctioning a single entity to commercially exploit an invention. Thus, as foreshadowed above, in undertaking this process, the EPO should explicitly:

(1) acknowledge and articulate competing interests and their underlying moral theories/values;

(2) arrive at a means of measuring society’s abhorrence to the commercialisation of the invention (which may entail considering the source materials and underlying processes of an invention and determining the nature and scope of the application/claims and the morality surrounding the science as a means of grounding or contextualising the assessment); and

(3) articulate a comprehensible and cross-jurisdictional commercialisation morality which adopts solidarity as one of its guiding values (ie: heeds the manifold claims in international instruments and by NGOs and scholars that genes are the “heritage of humanity”).

In doing so, the EPO would have to recall (1) the special position of the genome to modern healthcare and in the human psyche, (2) the legal/moral obligation to use genetic information for the benefit of humanity, and (3) the moral responsibility to preserve it (and its utilisation) for future generations, and embed them into its Article 53 morality assessments. So oriented, it could justify the preservation of much genetic knowledge as a global common resource which transcends national (and corporate) boundaries and which imposes on stakeholders duties akin to the five
elements described above.\textsuperscript{113}

(3) Summation: New Values for the New Regime and More With Which to Engage

Much can be done to ameliorate the more harmful effects of the economic model and to enhance the patenting process as a useful site of re-engagement for stakeholders without concluding that IPRs are absolutely wrong and must be prohibited in the biotech field or that patent proceedings will hijack more explicit policy-making fora. Just one possibility is to expand the moral values in play in patent proceedings (ie: “cosmopolitansit” the moral options where patents converge with genomics so they are less homogenous/limited). Reliance on the solidarity value (implicated in this field by the rhetorical description of genes as the “heritage of humanity”) would serve to enlarge the EPO’s ethical resource base and, where it is called upon to render morality-based decisions, make those decisions more reflective of the moral positions being advanced in law and society.

CONCLUSION

Parts I and II demonstrated that meaningful public engagement opens up questions, provokes debate, exposes differences, interrogates assumptions, and can lead to more versatile policy decisions.\textsuperscript{114} That is not to say that the foundational tenets upon which a law is built will necessarily weaken when challenged “upstream”; despite the vociferous challenges to the morality of patenting living matter, neither the economic model nor the patent regime’s inexorable march to expand its reach could be shaken. Part III demonstrated that, where stakeholders are ineffective at achieving their ends “upstream”, they will turn to “downstream” mechanisms to advance their agenda. Early patent proceedings, which proved as ineffective at stemming the bio-patenting tide as “upstream” mechanisms, show hints of the moral approaches implicated by the BPD, but very little overt recognition. However, the EPO has recently exhibited a greater willingness to undertake analyses of the morality of inventions (as measured


\textsuperscript{114} DEMOS, supra, note 13, at 40.
against the legal texts rather any particular moral theory). If the shift continues, it will undoubtedly offer hope to stakeholders that oppositions could become more valuable as an avenue for multiple stakeholder re-engagement. As it stands, they are still left without any real sense of which values will be upheld and which defeated in any given case. This vagueness poses a problem for legal legitimacy and continuity. In the expectation that the shortcomings identified in Part III can be addressed, Part IV offered the solidarity value as a legitimate moral touchstone in patent proceedings. It recommended its adoption as a means of expanding the EPO’s moral menu and suggested some possibilities for its reification within the confines of the dominant economic model.

The above makes clear that steps should also be taken by legislators to reform the patenting regime so that it better reflects and more equitably performs its role in human health, global biodiversity and scientific advancement. Thought should be given to how it could enhance our idealistic rhetoric. An important aspect of this reform could be the restructuring of patent proceedings in recognition of their importance as “downstream” mechanisms of engagement. Some options include:

- The examination, opposition and appeal processes could be more transparent and judicial. The EPO could institute comprehensive reporting of decisions, which should all be written, and the roles of examiner, opposition arbitrator and appeal division member could be clearly separated.  

- The role of morality in the patenting process could be strengthened by making an ethical evaluation a mandatory part of the patent application process. An EPO which embraces its statutorily mandated morality function, in addition to soliciting opinions from the EGE, might train its examiners/arbitrators in moral thought. Practice in this area exposes the fallacy of the ECJ’s claim that the patent regime operates separate from other regulatory systems (separate from what happens before and after the patent grant), so adequately

\[115\] The EPC allows members to sit at different levels, though not on the same case.

arming EPO members working at the front lines seems reasonable.  

- The BPD (and EPO rules) could be amended to exclude specific examples from the morality-based exclusions to patentability. Although inventions relying on reproductive cloning or germline therapy may be reasonable examples of what society currently considers immoral, specific examples date in this quicksilver field. A morality-based exemption which better defines the terms “ordre public”, “morality” and “commercial exploitation” and which identifies the values sought to be protected (eg: dignity, sanctity, autonomy, justice and solidarity) may be more beneficial. The substance of the morality being applied could be also made more transparent by enumerating admissible sources for measuring public attitudes toward biotechnologies (ie: international instruments, domestic laws, polls, surveys, referenda, etc.). Presumably, such a morality framework would require the EPO to consistently articulate those values and consider them in the context of specific inventions, and to be more exacting in its analyses of what commercial exploitation is or might be for an invention and what society considers immoral.

With respect to giving solidarity some impact on the ground, legislators could amend regulatory instruments to recognise two categories of research: (1) that directed at and resulting in findings concerning genetic structure and function; and (2) that resulting in products and processes with demonstrated practical applications. The former could be open, free and unpatentable (thereby eliminating barriers to knowledge circulation and research tools), whereas the latter could be patented. Other options include shorter monopolies on biotechnology patents (in recognition of their special nature and their importance as research tools in pursuits aimed at improving human health), the restriction of biotech patents to those inventions which have a direct consumer market, or the strict banning of “reach-through” claims (ie: patent claims that could

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117 Extending the research regulatory regime and requiring researchers to obtain consent from research participants before seeking a patent is explored in G. Laurie, supra, note 65.  
extend to future inventions or which reach beyond the patented invention or platform to seize a share of revenues from another’s future end-product sales.  

Regardless of the specific options chosen to reify our moral values and give stakeholders a more effective voice in the patenting process, it is clear that no field of law (particularly where it governs genomics and human and environmental health) can ignore its responsibility to facilitate, not only human understanding, but justice, equality and community. It has been stated that:

… [E]ach generation receives a natural and cultural legacy in trust from previous generations and holds it in trust for future generations. This relationship imposes upon each generation certain planetary obligations to conserve the natural and cultural resource base … and also gives each generation certain planetary rights as beneficiaries of the trust to benefit from the legacy of their ancestors.

We must take a hard look at how the patent regime (and the economic model) fails to recognise this and falls short of the conduct necessary to both preserve and best exploit our common genetic resource.

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119 For more on such claims and strategies, see R. Eisenberg, “Reaching Through the Gene” (2003), at http://law.wustl.edu/Academics/Faculty/Bios/Kieff/HGPIP/Final/GEN_50_CH10.pdf (June 19/06).