Ethics and Law of Intellectual Property

Current Problems in Politics, Science and Technology

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Chapter 13

The Institutional Nature of the Patent System: Implications for Bioethical Decision-Making

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The relationship between law and morality is particularly fraught in the sphere of patent law. There is reluctance to concede that morality and patentability intersect, and a number of legal scholars have argued that patent law was not intended to encompass moral or ethical judgments on inventions.[1] Although it is possible to historically trace moral concerns within legal doctrine, for example in the controversy over patenting playing cards in the 19th century, and more recently over the protection of contraceptives,2 patent systems in Europe and the United States[3] remain largely unreceptive to bioethics. In a European context this remains true, despite the existence of the Biotechnology Directive. On the one hand specific exclusions from patentability in the Directive seems to deflect meaningful bioethical debate on the interpretation of the more general prohibition against the patenting "of inventions the exploitation or publication of which would be contrary to ordre public or morality" under Article 53(a) of the European Patent Convention (EPC). On the other hand, the bright line exclusions are closed categories and make it harder to reopen or question established interpretations in patent law that fall under the rubric ofbioethics.

Bioethical decision-makint in the patent system is a subset ofthe normal process of change, transition and reform. Unearthing the dynamics of the general process of

1 In the present context I use the two terms "morality" and "ethics" interchangeably. For a discussion see R. Brownsword, "The Ethics of Patenting: A Legal Perspective", paper presented at the Roundtable on the Bioethical Issues of Intellectual Property Rights, March 28-29, 2003, University of Cambridge. Available at http://www.shef.ac.uk/ipgenethics/roundtable/papers/RBrownsword.pdf, accessed on March 30, 2006.

2 See S. Thambisetty, "Understanding Morality as a Ground for Exclusion from Patentability under European Law", *Eubios J Asian and 1ntf Bioethics,* March 12, 2002, pp. 48-53.

3 In the U.S. there is no equivalent statutory exclusion for patentability on ethical grounds.

4 I use the term "bioethical decision-making" to refer to a range of circumstances where ethical and moral concerns generated by biotechnological inventions are addressed. This includes substantial patent examination at the patent office, opposition proceedings at the European Patent Office (EPO), and litigation.

change and shifting legal doctrine in patent law provides clues as to why the system is so limited in its approach to bioethics. The circumstances under which moral questions are raised by the research on biological material and the application of that research impinges on patent matters can and has been varied. It includes "inherent patentability" issues about naturally occurring substances such as proteins and cells,5 concerns about the monopolization of subject matter "essential" for biomedical advances,6 the questionable ethics of patenting higher life forms as products,7 and the international distributional effects of the patentability of biotechnological inventions including agricultural biotechnology.8

There are at least two characteristics common to all such debates. Firstly, the cases are framed by decision-making bodies such as patent offices and the courts as a question between competing forces - the pressure to increase the scope of "inherent patentability" and allow new biological subject matter, and the contrary and restraining force of a cautious (risk averse) and value laden approach to scientific research and development. Secondly, resolution of the controversies requires critical discussion and debate. Typically, bioethical controversies in patent law have been "resolved" by incorporating additional subject matter. Thus the animal and plant variety, and gene patentability debates have all been settled in favor of the granting of expansive patent rights. Furthermore, in most cases (with one notable exception[9]) the controversy has been "settled" with little purposive debate about patentability and bioethics in patent law itself. What are the features within the patent system that load the dice in favor of expansive patent rights rather than a more measured approach? Are there any systemic factors that undermine the level of debate, or influence the responsiveness of the system to bioethical concerns?

The patent system today is a configuration of complementary institutions in which the behavior of each is affected by the existence and performance of the other, often in ways that are poorly understood. It is submitted here that complex causal reasons within the institutional nature and function of the patent system often undermine assessments based on social optimality. With respect to bioethical concerns, it elicits a standard response, framing and resolving the problem in favor of expansive patentability. Without judging the outcome on its ethical content, it is possible to evaluate the existence of endemic factors within the system that favor more property rights over fewer, and undermine the possibility of informed debate about alternative

5 Howard Florey/Relaxin, [1995] EPOR 541.

6 See S. Basheer, "Block Me Not: Are Patented Genes 'Essential Facilities'?" *ExpressO Preprint Series,* April 3, 2005, Working Paper No. 577, available at http://law.bepress.com/expresso/eps/577'; see also M. Helier, R. Eisenberg, "Can Patents Deter Innovation: The Anticommons in Biomedical Research", *Science* 1280(5364) (1998), pp. 698-701.

7 See T 0315/03 Transgenic animals/HARVARD (July 6, 2004) and *Harvard College v. Canada (Commissioner of Patents),* [2002] 4 SCR 45.

8 See Commission on Intellectual Property Rights, Chapter 4, and S. Thambisetty, "Human Genome Patents and Developing Countries", Study Report 10, Commission on Intellectual Property Rights, U.K. Government (2002), available via http://www. iprcommission.org/.

9 Harvard College v. Canada (Commissioner of Patents), [2002] 4 SCR 45 (see discussion below).

intellectual approaches. Based on illustrative examples form the European and U.S. legal systems, and an institutional approach to bioethical decision-making,1O I submit that the normal and general course of change in patent systems lead inevitably to increased patentability irrespective of deontological concerns.

In the first and second sections, I discuss the "reformed" role of patent offices and courts in modem legal systems and how they impact on the general process of change and transition in the law. **In** the third section, I explore an institution that is not normally regarded as being part of the patent cluster. Research funding bodies such as the National Institutes of Health (NIH) in the U.S. act as powerful "norm-setting" institutions that play an effective role in the exploitation of intellectual property. The absence of an equivalent entity in Europe is a significant factor for the patent system that has so far been inadequately explored. **In** the final section, I conclude that the institutional inter-relationships in the patent this cluster reveal latent aspects that may have a credible impact generally on the social optimality of inventions and specifically on bioethical decision-making.

Patent offices

Administration

In order to maintain the integrity of the patent system and avoid political interference in individual applications, the "statutory person" model for patent offices is quite popular, especially in commonwealth countries. A "comptroller" appointed by the government usually heads the statutory office.[11] The United States Patent and Trademark Office, a federal agency under the Department of Commerce, *de facto* adheres to this model; the actual appointments are political. **In** the U.K. the patent office is an executive agency of the department of trade and industry and became a self-financing trading fund in 1991.[12]

Since the late 1980s and 1990s patent offices in a number of countries have changed their status, role and functions remarkably. Most of them now have executive agency status with greater powers over their finances, personnel and other operations. Self-funding offices, including in the U.S. and U.K., have been

10 "Institutional ism" includes a variety of theoretical strands. I refer here to an approach that emphasizes patterns of group behavior and recognizes the need for political intervention to change entrenched habits. Although the institutional approach is uncommon in legal scholarship it can be used very effectively to explain complex causal relationships. As an illustration see R. Fujikawa, "Federal Funding of Human Stem Cell Research: An Institutional Examination", *Southern California Law Review* 78(1075) (2005).

11 As is the case in Ireland, for example. See http://www.patentsoffice.ie/About-uS.htm!.

12 A trading fund is part of government established by means of a Trading Fund Order under the Government Trading Fund Act 1973. Trading Funds in the U.K. include the Land Registry Office, Meteorological Office and the Queen Elizabeth 11 Conference Centre. See http://www.hmtreasury.gov. uk/spendingJeview /spendingJeview _ 2000/associated_ documents/spend _ srOO _ ad _ ccrappd.cfm.

transformed from inward-looking and isolated entities[13] into nimble customer oriented agencies, with unexpected repercussions. The notion that paying customers, in the form of applicants rather than the public, are the intended beneficiaries of the patent system is an indefensible position for a quasi-judicial administrative agency entrusted with issuing patents in the public interest. According to Mark Lemley, this has resulted in greater numbers of patents in the U.S. without regard to quality of the subject matter. [14]

The pressures of revenue-raising for patent offices can also lead to changes in the social benefits of intellectual property. Patent renewal fee structures are an integral part of patent offices as revenue-generators.[15] The life of a patent is the patentee's choice in return for fees. Since it is not worth paying renewal fees on a patent that is not being used, renewal fees can ensure that patents of lesser social value are valid for a reduced length oftime.[16] However, distortions can arise in a self-funded patent office, due to conflict between the fee structure that would optimize the social value of innovation and that which would maximize revenue for the patent office.

One study theoretically predicts that a financially constrained, self-funded patent office can be expected in course of time, to reduce renewal fees and increase initial application fees in a bid to increase revenue. If the patent renewal fees do not rise steeply enough, more inventors wilI be encouraged to renew their patents. Reducing renewal fees also increases the inventor's expectation of profits that can then be appropriated through initial high application fees[17]. The model predicts that over a period of time the rebalancing of fees by self-funded patent offices could result in two unforeseen detriments to social welfare: it will discourage the filing of some patents while extending the effective life of others.

The U.S. Federal Trade Commission has reported that a patent examiner in the U.S. spends 18 hours on average per application reading a patent application, searching for and reading prior art, writing one or more provisional rejections,

13 B. Doern, "Global Change and Intellectual Property Agencies" (London: Pinter Publishers, 1999), p. 31.

14 M. Lemley, "Rational Ignorance at the Patent Office", Berkeley Olin Program in Law and Economics, *Working Paper Series 1021* (Berkeley: Olin Program in Law and Economics), fu 3, p. 2.

15 Renewal fees have been in operation in European countries now for over forty years. See U.K. Patents Act 1977, s. 25 (as amended). All U.S. patents issued on patent applications filed after December 1980 must be maintained by payment of renewal fees in increasing amounts at varying intervals. Failure to pay is effective abandonment of the patent, as the patent holder can no longer sue: 35 USCA, s. 41. Canada also requires payment of "maintenance fees" as defined in s. 46(1) of the Patents Act. The Canadian Intellectual Property Office is a "revenue generating agency ... financed ... entirely by intellectual property services rendered":
CIPO, *Intellectual Property - Innovation on a Global Scale,* Annual Report 2001-2002, p.2.

16 S. Scotchmer, "On the Optimality of the Patent Renewal System", *RAND Journal of Economics* 30(2) (1999), pp. 181-196.

17 J. Gans, S.P. King, R. Lampe, "Patent Renewal Fees and Self Funding Patent Offices", *Legal Studies Research Paper* No. 64 (Melbourne: University of Melbourne Faculty of Law, 2004), p. 14. Also see discussion at p. 9, available at http://ssrn.comJabstract=515162.

reviewing responses and amendments, often conducting an interview with the applicant's attorney and writing a notice of allowance. Against this backdrop there are constant demands to increase productivity, often issuing from the patent office itself, such as the 2004 USPTO Annual Report, which set the goal of accelerated processing times through "more focused examination".ls While it is the job of the patent office to grant patents for suitable inventions, it is also to weed out unsuitable inventions. Robert Merges notes that in the U.S. requiring examiners to write up reasons for rejection but not allowance gives them psychologically more incentive to allow rather than reject a patent. The volume of patent applications that arrive also mean that an examiner is more likely to be rewarded for getting quantity rather than quality correct. [19]

Patent quality problems have also been experienced in the European Patent Office (EPO). Recently, according to staff surveys, examiners at the EPO are losing confidence in its ability to ensure the quality of the patents that it issues. In a devastating indictment to have two-thirds of the 1,300 patent examiners state that productivity demands within the EPO did not allow them "to enforce the quality standards set by the European Patent Convention".20 One can safely say that this translates into more patent rights for questionable inventions rather than fewer.

Policy role

Explicit policy-making roles and opportunities have also been structured into the new institutional incarnation of patent offices. For example the United States Patent and Trademark Office (US PTO) Corporate Plan undertakes to perform a "leadership" role in policy development; the primary performance goal being to "help protect, promote and expand intellectual property rights systems throughout the United States and abroad".21 The United States Trade Representative also uses regional and multilateral trade initiatives such as the North American Free Trade Agreement to "promote and *extend* (emphasis added) the protection of intellectual property".22

The Intellectual Property Policy and Innovation Directorate of the U.K.
Patent and Trade Mark Office works to "facilitate and improve the international competitiveness of British industry".23 In 2001 a new body, the Intellectual Property

18 http://www.uspto.gov/web/offices/com/annuaI/2004/0402 yerformance.html.

19 R.P. Merges, "As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform", *Berkeley Technology Law JournaI577(14)* (1999).

20 The survey also noted that 90% of the patent examiners did not have time to keep up to date with advances in their scientific field. See A. Abbott, "Pressured Staff 'lose faith' in Patent Quality", *Nature* 429 (2004), p. 423.

21 V.S. Patent and Trademark Office, *Corporate Plan* (2000), p. 17; *Corporate Plan* (200 I), p. 71. Also see U.S. Patent and Trademark Office, *Corporate Plan* (200 I), p. 66.

22 http://www.ustr.gov/Trade _ Sectors/Intellectual_Property/The _ Work _ oC USTR__ Intellectual_ Property.html.

23 http://www.patent.gov.uk/about/ippd/whatwedo/index.htm.

Advisory Committee (IPAC) was set up in the U.K.24 to meet the needs of the patent office for external advice on "policy making" at a variety of levels, provide a forum for consultation with interest groups, and provide the government with high-level "independent" advice on intellectual property issues.[25] There are *prima facie* at least a couple of problems with this set up.

Firstly, this committee is sponsored by the patent office - a body that is widely perceived to be supportive of and hospitable to the strengthening of intellectual property rights. A review of the IPAC was instituted in October 2004 due to concerns about the ambiguous remit of the organization. The provisional recommendations include considering whether the patent office should continue to be the sole sponsor of this body given the need to avoid the perception of conflict of interest between the Patent Office's Policy Role and its relationship with IPAC.26

Without going into the legitimacy of these roles taken on by the patent office, it is obvious that this represents an expansion of institutional capacity. **In** the United States and the United Kingdom there has been no political debate on whether the patent office prejudices its statutory obligations by positioning itself as an advocate for expanding intellectual property systems.27 It seems obvious that a real conflict of interest is created by such an expansion of institutional capacities. It is also questionable whether patent offices truly have the dynamic ability to adapt lessons learnt from their "expanded" role, given other pressures that emanate from their revenue generating work.

The second, more generic, concern is the proliferation of "interest group" politics in intellectual property. Clearly the last few decades have seen a net expansion in all types of intellectual property rights. Landes and Posner analyze some of the reasons for this hospitable climate from the perspective of public choice theory.28 Using this rubric they argue convincingly that there is an inherent asymmetry between the value that creators of intellectual property place on having property rights and the value that would-be users place on the freedom to use without obtaining a license

24 The IPAC replaced The Standing Advisory Committee on Industrial Property (SACIP) following a review in the context of patent office consultation. See *Review of the Standing Advisory Committee on Industrial Property (SACIP) in the Context of Patent Office Consultation.* Available at http://www.intellectual-property.gov.uk/ipac/pdf/sacip.pdf.

25 http://www.patent.gov.uk/about/ippd/ipac/index.htm. Particularly on the strategic policy questions about the proper scope of IP rights in areas such as biotechnology, computer software and business methods. Recommendation contained in the Quinquennial Review of the Standing Advisory Committee on Industrial Property, p. 2; available at http://www. intellectual-property.gov. uk/ipac/std/about.htm.

26 See Provisional Conclusions and Emerging Recommendations No. 12, available at http://www.patent.gov.uk/about/ippd/ipac/review-summary.htm.

27 See B. Kahin, "The Expansion of the Patent System: Politics and Political Economy", *First Monday* 6(1) (2001), p. 7.

28 Public choice theory sees legislation and political processes generally from the point of view of demand and supply. Legislations are "non excludable" goods in that everybody can enjoy them without having contributed to their creation. The theory focuses on the role of interest groups in solving the resultant free rider problem. See D.A. Farber, P.P. Frickey, *Law and Public Choice: A Critical Introduction* (Chicago: University of Chicago Press, 1994).

from the patent holder. This makes it easier to organize interest groups to demand an expansion of intellectual property rights than it is to get would-be users to Oppose such an expansion.[29]

When patent and trademark offices avow the expansion of intellectual property rights explicitly or implicitly as part of their functional responsibilities, they in effect function as a powerful interest group that drives up the demand for greater and stronger intellectual property rights. The "technical" and often opaque nature of the subject matter also means that patent offices or advisor bodies associated with them are less likely to be interfered with by other government agencies, further strengthening their *de jure* and *de facto* independent status. Given that patent offices are at the forefront of the application of patentability standards during examination of applications, and additionally in the case of the EPO, of litigation,30 an accurate appreciation of the role of the patent office has to include consideration of the distinctive interests the office promotes.

Coriflicting institutional competencies

The question of institutional competencies in a European context is often more complicated than in the United States. Illustratively this can be seen in the awkward co-existence between the European Commission (EC) and European Patent Office (EPO), which is a non-European Union (EU) organization. The Biotechnology Directive[31] is a EU document and has no direct legal basis under the European Patent Convention, although some of the patentability standards were clearly based on EPO practice and Board of Appeal decisions. Soon after the Directive was legislated the EPO stated that it would use the Directive as a supplement to interpretation of the European Patent Convention (EPC).32

This apparent symbiosis is not uncontroversial. The failed Directive on Computer Implemented Inventions initiated by the European Commission[33] was widely perceived as little more than consolidation of the tortured legal interpretation

29 Absence of serious opposition to the bill that became the Sonny Bono Copyright Term Extension Act is provided by the authors as evidence of this persistent asymmetry. W.M. Landes, R.A. Posner, *The Political Economy of Intellectual Property Law* (Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies, 2004), available at http://www.aei. brookings.org/admin/authorpdfs/page. php?id=985.

30 As per s. 91 (I) of the U.K. Patent Act 1977, U.K. courts are required to take judicial notice of the EPC and any decision of a "relevant convention court", a phrase that is defined in s. 130 of the Patent Act 1977. The definition includes any department of the EPO that has jurisdiction under the EPC, and includes EPO Boards of Appeal.

31 Directive for the Legal Protection of Biotechnological Inventions No. 98/44/EC.

32 After some amendments made by the EPO Administrative Council, the Directive was introduced into the Implementing Regulations of the EPC in 1999. See C. Baldock, O. Kingsbury, "The Biotechnology Directive and its Relationship to the EPC", July 2000 (Boult Wade Tennant), available at http://www.boult.com/information/ArticleDetails. cfm? ArticleID=31.

33 European Union Directive on the Patentability of Computer Implemented Inventions (2002/0047/COD).

on computer-related inventions adopted by the EPO.34 The Economics and Social committee (ESC) of the E.C. noted that it would be preferable for the EC to take the initiative away from the EPO and develop it in other intellectual directions. The reason for this is that the EPO is only competent in one area of intellectual property and "is naturally attempting to extend its own area of competence and sources of revenue".35 According to the ESC, the E.C.'s proposal was unsound as it incorporated the view of the EPO, which lacked an appreciation of the overarching complexity of intellectual property rights. A legislative proposal should ideally take advantage of greater flexibility and variety in the legal arrangements for new technologies, as well as entertain the possibility of multiple intellectual positions regarding key questions of patent ability. This is an approach that cannot emanate from a body with a relatively limited mandate such as the EPO.

"Stickiness" and convergence in legal interpretation

Patent statutes are the obvious centerpiece of the patent system, and choice of approach to legal interpretation often has unrecognized systemic consequences. Interpretative theories are often debated at a high level of abstraction and generality that allows for a number of different reasonable approaches. Institutional assessments of legal rules in contrast take note of external pressures on interpretation that affect how these statutes are read and applied. The indifference of major interpretive approaches to institutionalism and their resultant failing has only recently received greater attention.[36]

Patent offices apply an incremental and technologically specific approach to patent law. Formally patent law operates a "one size fits all" system. All inventions, irrespective of technological field, must satisfy the same patentability criteria and all applications have to fulfill the same requirements. But patent doctrine is rife with different industry-specific sub-cultures of interpretation. Instances of industry- and technology-specific interpretations of patent doctrine abound, even if they are not explicitly articulated thus. Such "technological exceptionalism"37 is really a way of using past experience to modify current doctrine and practice marginally to adapt the law to new technologies.

34 In 2002, the European Economic and Social Committee described the doctrinal premise of the European Patent Office's interpretation of Article 52(2) of the EPC as "the product of legal casuistry". See J. Pila, "Dispute Over the Meaning of 'Invention' in Article 52(2) EPC - The Patentability of Computer Implemented Inventions in Europe", *International Review of Industrial and Copyright Law* 36 (2005), pp. 173-191.

35 See ESC Opinion, COM (2002) 92 Final - 2002/0047 (COD) (September 19,2002) 5.4. This is noted by J. Pila, ibid., p. 191.

36 See C. Sunstein, A. Vermeule, "Interpretation and Institutions", *John M alin Law and Economics Working Paper* No. 156 (Harvard: The John M. Olin Center for Economics, Law and Business). The authors argue for an "institutional turn" in legal interpretation based on institutional capacities and dynamic effect.

37 The term itself was introduced at length by Dan Burk and Mark Lemley. For a critique see P. Wagner, "Of Patents and Path Dependency: A Comment on Burk and Lemley", *Berkeley Technology Law Journal* 18 (2004), p. 1341.

The classic case of such incremental development specific to a technology is the use of the patent offices' considerable experience with chemical compounds as an analogy to characterize biotechnological inventions which turned out to be problematic in many ways.38 More recently, when the EPO had to consider what the scope of the exclusion of "animal varieties" from patentability should be for the first time, it immediately referred to the familiar regime for protection of plant varieties. Plant varieties are protected by another form of industrial property right called plant variety rights[39] (PVR), as well as patent protection of limited scope. The existence of such additional protection for plant varieties and the lack of it for animal varieties led the EPO to interpret the exclusion narrowly to make up for the lack of parity in protection. This is an example of incremental adaptive change that characterizes vast tracts of the patent system.

Technologically specific interpretations may not be a problem except that factbased and case-based interpretations tend to get converted into long-term doctrinal rules. The technical terminology and approaches to interpretation make patent law an unusual branch of legal interpretation where technology-specific applications of the rules tends to "stick", often due to institutional dynamics, rather than substantive merit.[40] As per the reasoning in the US case *Re Deuel,41* a novel chemical is non obvious if there is no structurally similar compounds in the prior art. Proteins are not structurally similar to the DNA molecules. The fact that a person skilled in the art could have used known methods to isolate the DNA sequence from amino acid sequence was, according to the court, irrelevant to the enquiry of whether the DNA sequences themselves were non obvious.[42] This interpretation leaves the notional standard of "the person skilled in the art" contemplating the gap between scientific possibilities and legal improbabilities.

38 See S.A. Bent et aI., *Intellectual Property Rights in Biotechnology Worldwide* (New York: Stockton Press, 1987), pp. 6-12 for a detailed discussion.

39 See M. Llewellyn, "From Outmoded Impediment to Global Player: The Evolution of Plant Variety Rights", in R.C.D. Vaver, L. Bentley (eds), *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish* (Cambridge: Cambridge University Press, 2004).

40 Polk Wagner argues that technological specificity is not a problem because the patent system is not path dependent, so any "errors" in interpretation of application of the rules will be gradually set right by the system. However he ignores the "stickiness" in the patent system created by institutional dynamics. P. Wagner, "Of Patents and Path Dependency: A Comment on Burk and Lemley", p. 1341.

41 51 F 3d. 1552 (Fed. Cir., 1995).

42 "Unfortunately the reasoning in *Deuel* leaves a biotechnologist of ordinary skill in the art in an awkward position. On the one hand, based on prior art knowledge, the biotechnologist knows that sequencing around twenty amino acids is sufficient to obtain the cDNA sequence that codes for a particular protein, absent unforeseen difficulties. On the other hand, under current law, the expected product of this scientifically obvious manipulation is legally unobvious and thus patentable. Such a convoluted result is unsettling". A. Varma, D. Abraham, "DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market", *Harvard Journal of Law and Technology* 9(53) (1996), p. 78.

Remarkably, this interpretation has sustained in the 200 I Utility Examination Guidelines[43] despite the well-recognized rift in scientific and legal perception. The Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation of the U.S. National Research Council makes a telling observation on the institutional nurture of this outcome. "because it makes it easy for patent applicants to get past the non-obviousness hurdle, they have no incentive to challenge the rule, and after being repeatedly reversed on this point, the USPTO seems to have little interest in raising it again, even though advances in the art may culminate in a different result".44

In contrast to other bodies that make decisions involving scientific advancements, including courts, the patent office has no recourse to the judgment of contemporaneously active technological practitioners. This sort of disinterested input in the early stages of patent application examination could take the form of a "peer review" model. Such a step would, particularly for applications that herald new subject matter, help to avoid errors.[45] In the absence of any technical input, patent offices often mimic the practice of patent offices in other countries in particularly difficult areas. Such close associations can lead to proliferation of "similar" standards or convergence,46 even though this in itself does not guarantee accuracy or optimal standards of patentability. One may characterize such convergence in a number of ways - as a preoccupation with legitimacy or as an inevitable part of risk-averse human behavior on the part of patent examiners.

Convergence is a more contained phenomenon than harmonization[47] and recently has been engineered primarily by domestic patent offices including those in the U.S., Europe and Japan.[48] To illustrate, in direct response to concerns that overly broad patent scope in genetics threatened future innovation, the USPTO in 200 I issued new

43 66 Fed. Reg. at] 095 (Jan. 5, 200]). The Guidelines cite *In re Deuel* and state "As the non obviousness requirement has been interpreted by the US Court of Appeals for the Federal Circuit, whether a claimed DNA molecu]e would have been obvious depends on whether a molecule having the particular *structure* (emphasis added) of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made".

44 Committee on Intellectual Property Rights in Genomic and Protein Research Innovation, National Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health* (National Academies Press, 2006), p. 70. Interestingly, even this restrictive approach to structural obviousness in the Utility Examination Guidelines is likely to lead to rejections as more DNA sequences become available on public databases.

45 See R. Eisenberg, "Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA", *Berkeley Tech Law Journal]* 9(885) (2004).

46 Harmonization allows for a certain degree of competition within common standards, while convergence indicates movement towards identical standards. Some commentators use the terms interchangeably. See, for example, in J. Hughes, "Political Economies of Harmonisation: Database Protection and Information Patents", *Cardozo Law School Burns Institute for Advanced Legal Studies. Research Paper Series* No. 47 (2002).

47 The international harmonization of intellectual property standards is not new or restricted to a post TRIPs world. See Hughes, ibid., pp. 7-8.

48 See the "Trilateral Project" website, avai]able at http://www.uspto.gov/web/tws/sr-3b3b-ad.htm.

guidelines for the utility requirement.[49] The Guidelines represent the understanding of the USPTO and are important tools in planning patent applications and litigation of genetic patent cases. A year after the Guidelines were issued a decision by the EPO opposition division[50] adopted the standard used in the 2001 Utility Examination Guidelines of the USPTO, namely the "specific, credible and substantial" (SSC) standard.

The standard was adopted on the basis of implicit assumptions about similarities between interpretation of "utility" under U.S. patent law and the understanding of "industrial applicability" under the EPC. Although both criteria in the different legal systems incorporate an idea of "use" of the invention, it was commonly understood prior to this decision that the emphasis on "use" was in the U.S. and in Europe.[51] There are specific institutional reasons for such remarkable convergence including institutionalized "cooperation" between European, Japanese and U.S. patent offices to explicitly enhance the mutuality of standards of search and examination of biotechnology patents.[52] Such accelerated transformation of patentability standards can have unsettling systemic effects and should ideally be preceded by a thorough exploration of the implications.

Courts

Specialist courts

Patent courts more than others often have their own, sometimes unusual, trajectories of development because of the specialist nature of the subject matter and the increasing court space given to intellectual property litigation. The United States Court of Appeals for the Federal Circuit (CAFe), for example, occupies a unique role as an appellate body jurisdictionally demarcated by subject matter rather than by geography. The specialist nature of such courts has a number of implications for the general expansion in patent rights.

Many have noted and analyzed the "pro patent attitude" of the CAFC which, according to Landes and Posner, is to be expected as "a patent court is more likely to take the pro-patent side ... simply because a court that is focused on a particular government program, like an administrative agency (invariably specialized), is more likely than a generalist court to identify with the statutory scheme that it is charged

49 Utility Examination Guidelines, 66 Fed. Reg.]092 (Jan. 5, 2001).

50 ICaS/seven transmembrane receptor OJEPO 2002, 293. The patent was revoked in the proceedings on the grounds that the disclosure of a *predicted* function of a protein is not adequate disclosure of the function of the protein.

5] See M. Llewelyn, "Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States", *EIPR* 11(473) (1994), p. 474.

52 Such projects have resulted in a comparison of biotechnology patent application examination procedures. See M. Hewlett, A. Christie, "An Analysis of the Approach of the European, Japanese, and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)", *IIC* 34(6) (2003), pp. 581-710.

with administering",53 In the D.S., the creation of the court seems to have had a positive and significant impact on the number of patent applications, the number of patents issued, the success rate of patent applications and the amount of patent litigation, but all of these have not necessarily had a positive effect on technological progress. 54 They note that what has also increased is the demand for patent lawyer services. Given that the patent bar had pushed strongly for the creation of the court, the authors conclude that

> the creation of the court, whose specialized character and resulting 'mission' orientation enabled a prediction that it would favor patents more than generalist federal appellate courts, may thus have been a consequence largely of interest group politics. 55

So are specialist patent courts a boon or a burden? The basic premise behind establishing the appeals court distinct from the twelve regional circuits, each of which has a United States Court of Appeals, was that centralization of authority would lead to clearer, more predictable patent law. A recent study indicates, however, that whether or not the court is fulfilling its mandate is a question that remains remarkably open.[56] In this context it is worth comparing two decisions on the OncoMouse laboratory mouse (also known as the Harvard mouse), one given by the Technical Board of Appeal at the EPO,5? which may be regarded as a specialist court for, *inter alia*, its Article 99 EPC jurisdiction[58] and the decision given by the Supreme Court of Canada. 59

Although based on very different statutory wording, the EPO in its decision focused on a literal application of the law to evaluate whether the "invention" of genetically modified rodents was patentable. To evaluate whether the exploitation or publication of this invention "would be contrary to ordre public or morality",60 the EPO adopted a balancing test to see whether the animal suffering in this case was balanced by evidence of substantial medical benefit. The EPO cut down the scope of

53 W.M. Landes, R.A. Posner, "An Empirical Analysis of the Patent Court", 71 *University of Chicago Law Review* 111 (2004), p. 112.

54 See Landes, Posner, *The Political Economy of Intellectual Property Law* (Washington, 2004), pp. 26-27, available at *http://www.aei.brookings.org/adminlauthorpdfs/page.* php?id=985.

55 Landes, Posner, "An Empirical Analysis of the Patent Court", p. 27.

56 Wagner and Petherbridge do not suggest that the court is an unqualified success in bringing additional consistency, uniformity or predictability to patent law, although the results suggest that the institutional picture of the court is one of broad transition and movement in the right direction. P. Wagner, L. Petherbridge, "Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance", 152 *University af Pennsylvania Law Review* 1105, p. 1111.

57 T *0315/03* Transgenic animals/HARVARD (July 6,2004).

58 Article 99 of the EPC allows for "any person" to file an "Opposition" to any patent within nine months of its grant. Most of the ethically controversial biotechnology patents were subject to a number of "Oppositions" under this rule. If convinced, the EPO can revoke a patent it has already granted.

59 Harvard College v. *Canada (Commissioner of Patents),* [2002] 4 SCR 45. 60
Article 53(a), EPC.

the patent from transgenic rodents to transgenic mice, on the grounds that there was no correspondence between animal suffering for all rodents, including squirrels and porcupines that may be so genetically modified, and substantial medical benefit that was only established in the case of mice. In contrast to this formal and tunnel vision, the Supreme Court of Canada, a generalist appellate court, embarked on a broad and eventful exploration of "inherent patentability" concluding that higher animals cannot be classified as a "method of manufacture" or "composition of matter" although this may apply to micro-organisms. Calling on Parliament to intervene, the Court gave a decision that was purposive in its approach to the law. Although it would not be prudent to draw a conclusion about the merits and demerits of specialist courts based on this one example, the scope of the Canadian decision is illustrative of the standing of higher generalist courts.

There are other peculiarities that are relevant for an institutional appraisal of specialist courts. For example, the apparent uniformity of technological views in a difficult area like biotechnology may be illusory because of the small number of judges who decide these cases.[61] In the D.S., a single federal judge, Judge Lourie, authors most of the cases identified by commentators as relevant to the technological issues for biotechnology inventions in the U.S.[62] Patent matters in the U.K. High Court, much like in U.S. federal cases, are heard by a limited number of judges. Justice Laddie, until he stepped down in early 2005, Justice Pumfrey and more recently, Justice Kitchin[63] preside over patent matters. The association of patent matters with a limited number of senior judges at the court of appeals is very significant as the House of Lords rarely hears patent cases.[64]

Awareness of the strengths and limitations of specialist patent courts and the composition of generalist appellate courts with jurisdiction over patent matters is likely to be of increasing importance in the future, particularly internationally. For those who would like to see the spread of intellectual property legislation, *convergence* in judicial practice is as important, as is getting appropriate legislation drafted under the TRIPS agreement in place. The World Intellectual Property Organization (WIPO) and the EPO sponsor parties of judges, or about-to-be-judges, from various countries of the undeveloped or semi-developed world to go on tours to see how western countries' judicial systems operate, with a view to implementing

61 See P. Wagner "(Mostly) Against Exceptionalism", *Public Law Research Paper* No. 7 (Philadelphia: University of Pennsylvania Law School), p. 5.

62 Wagner, Petherbridge, "Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance", pp. 1117-1118.

63 The U.K. patent office often consults "patent judges" in the context of proposed legislative or procedural amendments; it is notable that only three judges, Justices Laddie, and Pumfrey and Lord Justice Jacob, appear to have responded. For example, see patent office consultation on "Should Patents be Granted for Computer Software or Ways of Doing Business?", *http://www.* patent.gov. uk/about/consul tations/responsesl comsoft/ *gtoml*

64 This is generally true, although in the two years three important appeals made their way to the House of Lords; *Kirin Amgen Inc and Others* v. *Hoechst Marion Roussel Ltd and Others,* [2004] UKHL 46, *SabafSpA* v. *MFl Furniture Centres Ltd and Others,* [2004] UKHL *45, Synthon BVv. Smithkline Beecham plc,* [2005] UKHL 59.

TRIPS in their own countries. This is part of the spate of initiatives on the part of WIPO to bring greater substantive harmonization between countries' patent laws.

Advocates of judicial convergence are supported by the idea of a "global patent system" which, as an idea, is underpinned by two main substantive arguments: first, that the sophistication of technological achievements make it impossible for small patent offices in developing countries to examine patent applications effectively,65 and second, that there is already a significant level of sharing of the results of substantive examination. In this context the tendency of the harmonization efforts is to gravitate towards the procedures and methodologies of the patent offices and courts in developed countries. This of course begs the question of whether such entities function in a manner that lends methodological, substantive and normative credibility to the patent system.[66] Reconsideration of the institutional design of the patent system anywhere in the world should incorporate a more sophisticated understanding of the unintended consequences of current specialist courts, and the advantages of the appellate authority of higher non-specialist courts.

Research funding bodies

Political and legislative opinion in Europe identifies the biotechnology sector as one of dynamic growth and potential for Europe.[67] Yet in Europe the industry lags behind the U.S. in significant ways.68 Many different variables make up a more supportive institutional arrangement in the U.S.[69] Since access to finance is crucial for innovation in biotechnology, what power if any, do public agencies that give grants for research and development have on patent protection TO It is submitted

65 Lord Justice Robin Jacob of the U.K. Court of Appeals questions the possibility of countries with limited scientific resources setting up an "effective" patents court, suggesting that if TRIPS is to be implemented, some sort of international resolution of patent litigation would have to be devised. R. Jacob, "Intellectual Property in the New Millennium", available at http://www.law.ed.ac.uk/scriptlnewscriptlnoframes/nfonline.htm.

66 See B. Dhar, "Will Global Patent Courts Work?", *Economic Times*, March 23, 2004. Available at http://economictimes. indiati mes.com/articleshow *1575999* .cms.

67 Opinion of the advocate general in *Kingdom of the Netherlands v. European Parliament and the Council of the European Union, C-377/98* (2001). Also see European Commission Green Paper COM (95) 688 Final, and the Recitals of the Directive for the Legal Protection of Biotechnological Inventions *98/44/EC* (hereafter Directive).

68 The turnover of the biotechnology industry in U.S. is double that of European industry (3 I ,808 million euros compared to 15,327): Emst and Young, *Beyond Borders: The Global Biotechnology Report, 2002.*

69 The greater availability of venture capital is noteworthy. Pisano, Mang, "Collaborative Product Development and the Market for Know How: Strategies and Structure in the Biotechnology Industry", in Burgelman, Rosenbloom (eds), *Research on Technological Innovation, Research and Policy* (Greenwich: JAI Press, 1993), pp. 109-120.

70 Public funding of research is particularly significant in the context of biotechnology due to the research-intensive nature of the industry. See Kroll et aI., "Tracing the Influence of Basic Scientific Research on Biotechnology Patents: A Case Study of Signal Transduction and Transcriptional Regulation (STTR)", *Patent World*, March 1998, pp. 38-46.

here that strong, centrally positioned research funding bodies have expanded the institutional cluster of the patent system and added to our repertoire of tools when dealing with patentability and patent exploitation in a manner that is significant for social optimality.

The NIH is part of the U.S. Department of Health and Human Services, and is the primary federal agency for conducting and supporting medical research. More than 80% of the NIH's annual $28 billion budget for medical research is awarded through almost 50,000 competitive grants to researchers at over 2,800 universities, medical schools and other research institutions in the U.S. and abroad.[71] NIH funding has doubled since 1992, a growth that excee s In atlOn.[72] In contrast, and as highlighted by the Lambert review, in 1981 the U.K.'s total spending on research and development as a proportion of its gross domestic product in 1999 was lagging behind Germany, the V.S., France and Japan and only just keeping pace with Canada.[73] In the U.K., public funding for basic research is channeled through seven different U.K.-wide research councils, in addition to the charity sector led by the Wellcome Trust. Generally, universities own intellectual property that arises out of public funding that is channeled through a peer review process.

A strong single research council that has some ability to specify how public money should be used in exploiting research results can modify patenting behavior among a large population of scientists. The presence of federal agencies like the National Institutes of Health (NIH) and National Science Foundation that fund research in American universities, and the absence of a corresponding central agency in the U.K. is therefore highly significant. Even in the European Union there is no entity with comparable clout to the NIH. Currently, the European Commission is in the process of setting up a European Research Council to manage a research fund for European universities and research institutes. This is expressly fuelled by concern that the funding for basic research in Europe is far from optima1.[74] Plans for this council include complementing or even replacing national funding mechanisms.[75] Whether it can evolve into a sophisticated "norm-setting" institution like the NIH remains to be seen.

71 http://www.nih.gov/aboutINIHoverview.htmI.

72 See presentation to the Association for Independent Research Institutions 2003 at *http://www.grants.nih.gov/grants/award/awardtr.htm.*

73 Lambert Review on Business-University collaboration, December 2003 (www. lambertreview.org.uk), p. 3 (hereafter Lambert Review) ..

74 As per the Lisbon Declaration of March 2000 and the Barcelona Summit of March 2002, that aim is for Europe to become the most competitive and dynamic knowledgebased economy by 2010. See http://europa.eu.intlcomm/research/press/2004/pr1803e.n.cfm. According to one leading scientist the possibility of meeting the 20 I 0 goal and surpassm~ ~he U.S. in research funding did not amount to "a snowball's chance in hell". R.M. May, "Ralsmg Europe's Game: How to Create a Research Council that is a Champion's League for Science", *Nature* 430 (2004), pp. 831-832.

75 European Research Council: A Cornerstone in the European Research Area. Final report of the European Research Council Expert Group, December 2003, Annex I, Explanatory Comments. Available at http://www.ercexpertgroup.org/finalrepo_rt_.a_s_p_.

Promoting the institutional goals of science

The economic structure of research has undoubtedly changed considerably in the U.S., owing significantly to the explicit U.S. policy of allowing grantees to seek patent rights in government-sponsored research results. The policy, codified during the 1980s with the passage of the Bayh Dole *Act1*[6] and the Stevenson Wydler Act,77 has made universities keen players in the patenting arena. Concern about this issue has also been expressed in the U.K., even in the absence of a specific policy similar to that of the U.S .. The Royal Society observed that, although patenting rarely delays publication significantly, it could encourage a climate of secrecy that does limit the free flow of ideas and information that are vital for successful science.[78] Both in the U.S. and the U.K., academic norms of sharing and building on each others' work has, according to many observers, been replaced with territorial behavior that threatens to deplete the common pool of knowledge essential for further innovations.[79]

Institutional economics prominently includes an analysis of formal and informal norms as part of the constraints that shape human behavior.[80] Norms are distinct from legal rules, the violation of which is typically punished by private actors.[81] The NIB's power to set formal and informal rules backed by law is, from this perspective, of critical importance to maintain and where necessary, reform norms of behavior

76 35 U.S.c. 200-212 (1994). The policy has a number of converging goals including saving federally funded research from "publication oblivion". See R. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research", *Virginia Law Review* 82(1663) (1996), pp. 1664-1665. See also P. Mikhail, *"Hopkins v. CellPro:* An Illustration that Patenting and Exclusive Licensing of Fundamental Science is not Always in the Public Interest", *Harvard Journal of Law and Technology* 13(375) (for a critique of the policy with specific reference to biology).

77 Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. 3701-3714.

78 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science,* April 2003. Also see *Annual Survey on University Technology Transfer Activities, Financial Year 2002* (Nottingham: Nottingham University Business School, 2003).

79 A. Kaur Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science", *North Western University Law Review* 94(77) (1999). Also see R.S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research", *Yale Law Journal* 97(177) (1987); R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use", *University of Chicago Law Review* 56(1017) (1989); but see S. Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science -A Response to Rai and Eisenberg", *Northwestern University Law Review* 95(691) (2000).

80 D.C. North, *Institutions, Institutional Change and Economic Performance (1990).*

81 The "law and norms" theory is part of legal scholarship where moral persuasion may be more effective than legal authority such as in international law and "cyber-governance". But in the final analysis Internet norms generally rely on supreme legal authority, initial property entitlements and contractual arrangements that govern the net. See M. Lemley, "The Law and Economics of Internet Norms", *Chicago-Kent Law Review* 73 (1989), pp. 1257-1294. Similarly, the NIH is a governmental body backed ultimately by the law.

within academic institutions.[82] The NIB's exercise of its institutional capacity by way of intramural regulations on access to research tools to ensure that the institutional goals of science are met is an interesting case in point.

Access to patented research tools is a significant problem resulting from the science-based nature ofbiotechnology.83 In the U.S., research tools developed using federal government funds present a unique problem. In 1997, the NIB convened a working group to study access to unique research platforms that concluded that access to research tools was severely constricted and suggested regulating NIH grant recipients.[84] The working group explored ways of including wide dissemination of research tools developed with federal money as preconditions of funding. From October 2004, the NIB requires grant applicants to include a specific plan for sharing of model organisms and other materials[85] that result from funded research. Applicants' track record of sharing will be taken into account when their grants are up for renewal. The application for funds, as per the new policy, should also include a sharing plan on how intellectual property rights will be exercised while making the research resources available to the broader scientific community.86

These guidelines hit squarely at the inherent tension between the NIH, which seeks to maximize the impact of the research it supports, and universities that are entitled to patent and profit from inventions made with government money. NIH policies clearly have the potential to modify behavior, including the post-grant enforcement of patent rights, as non-compliance may result in loss offunding.[87] Putting pressure on patent holders funded by the NIH to share the outcome of publicly funded research also has the potential to rectify the weakening of the experimental use exemption in U.S. patent doctrine.[88] This institutional picture is significant as it shows relocation

82 See Robert Merton's work in identifying the overriding institutional goals of science. R. Merton, "The Puritan Spur to Science" in *The Sociology of Science* (Chicago: University of Chicago Press, 1973), pp. 228-253, cited in R. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research", *Yale Law Journal97(* 177) (1987), pp 182-183.

83 For a succinct description of the problem see Cornish, Llewellyn (eds), *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (London: Sweet & Maxwell, 2003), pp. 842-843.

84 Report of the National Institutes of Health (NIH) Working Group on Research Tools (June 4, 1998), http://www.nih.gov/news/researchtools/.

85 Termed in general as "biomedical research resources". See NIH Policy on the Sharing of Model Organisms for Biomedical Research, May 7, 2004, available at http://grants.nih. gov/ grants/ guide/notice- fi lesINOT-O 0-04-042 .html.

86 The new policy was enforced by the NIH in making stem cells produced by the Wisconsin Alumni Research Foundation (WARF) using NIH funds available for academic research. For more information see http://www.nih.gov/news/stemcell/WicellMOU.pdf.

87 See C. Jennings, "Universities Unnerved by Revised Rules for Sharing NIH Research", *Nature* 430 (2004), p. 953. Realistically however it is likely to be a last resort. Ruiz Bravo of the NIH is quoted as saying "We don't want to use a hammer to swat flies". See also "Share Issues", *Nature* 430 (2004), p. 951.

88 A recent comprehensive paper by Mathew Rimmer uses a comparative approach to study the research use exemption and concludes that it is imperative that the narrow U.S. law does not become the international standard. M. Rimmer, *The Freedom to Tinker: Patent Law and Experimental Use,* Expert Opinion (London: Ashley Publication).

or sharing of responsibility to maintain the science base of technology between the courts (in the U.S., the research exemption is judge-determined)89 and the executive arm of the government.

Meeting public interest needs

The Bayh Dole Act also includes certain provisions to protect the public interest. One such, called "march in" rights, allows for mandatory licensing of patents under certain conditions.[90] Among other reasons, the NIH can exercise "march in" if the contractor or assignee has not taken, or is not expected to take within reasonable time, effective steps to achieve practical application of the subject invention. It can also be exercised to alleviate health and safety needs which are not reasonably satisfied by the contractor, assignee or their licensees.[91] This power is not used often. The following case illustrates the dynamic created by this power between courts, inventors and the NIH.

Cell Pro appealed to the NIH's "march in" power to obtain a mandatory license to practice stem cell separation technology that was invented by a researcher at Johns Hopkins University under a grant from the NIH.[92] CellPro failed to obtain a license from Johns Hopkins and its sublicensee, Baxter HeaIthcare Corporation, and was subsequently found by the CAFC to be in willful infringement of the patents.[93] However, Cellpro was not required to immediately cease marketing its device. The CAFC allowed it to make, use and sell the device as until such time as an alternative device was approved for therapeutic use in the United States.

Sometime before their appeal to the federal circuit, Cell Pro complained to the NIH that allowing Johns Hopkins and Baxter to enforce their full patent rights and exclude CellPro from making, using or selling its cancer treatment device would create a public health need.[94] After a fact-finding enquiry, the NIH decision was made a few days after the federal circuit court's determination. The NIH refused to exercise

89 Under U.S. law, the extremely narrow scope of the exemption was clarified in *Madey v. Duke University* 307 F. 3d 1351 (Fed. Cir., 2002) with the effect that the exception is confined to private study and may not include even un-sponsored university research. In the U.K. the statutory research exemption has a closed definition that on the one hand provides certainty to users but on the other hand can be too inflexible. It does not apply to the use of research tools as methods or subjects for further investigation, for example. *Monsanto v. StaufJer,* [1985] RPC 515. Furthermore the EPC in this context is interpreted differently in different countries. Cornish (1998), 29 IIC 735.

90 35 U.S.C., s. 203(I) authorizes a federal agency in limited circumstances to ensure that a federally funded invention is available to the public.

91 35 U.S.C., s. 203(1)(a)-(b)(1994).

92 The technology involved a method of purifying stem cells and had potential application in the treatment of cancer. Cell Pro had obtained regulatory approval to use a device incorporating an associated technique before John Hopkins or Baxter Healthcare.

93 Johns Hopkins Univ. v. CellPro, Inc., 931 F. Supp. 303 (D. Del. 1996).

94 H. Varmus, Office of the Director, *Determination in the Case of Petition of CellPro, Inc., Aug.* /, /997 (National Institutes of Health), available at http://www.nih.gov/news/pr/ aug97/nihb-0 l.htm.

"march in" rights as Hopkins and Baxter had already produced another device that was awaiting regulatory approval. The NIH in its determination concluded that "it would be inappropriate for the NIH, a public health agency, to exercise its authority under the Bayh-Dole Act to procure for Cell Pro more favorable commercial terms than it can otherwise obtain from the Court or from the patent owners. CellPro's commercial viability is best left to Cell Pro's management and the marketplace".95

In this case NIH's determination was directly complementary to the federal circuit court's decision to allow CellPro to continue to market its device. If the court had not filled the gap that would have been created by a full exercise of the Baxter patent, the NIH determination may well have gone the other way.96 Tempering the exclusive rights of the patent holder in the public interest is an equitable measure that can also be taken by the courts.[97] However, given the recent patent friendly posture of the Federal Circuit Court,98 NIH power to temper the exercise of patent rights over inventions made with public money is significant. Not unlike the specter of compulsory licensing, the real power of "march in" rights may reside in deterrence rather than actual use.[99] Additionally, under U.S. law, the patentee's absolute right to exclude is subject to the government's power of eminent domain that can be exercised by the NIH.[IOO]

95 Ibid., p. 8.

96 For a criticism of the NIH determination see P. Mikhail, *"Hopkins v. CellPro:* An Illustration that Patenting and Exclusive Licensing of Fundamental Science is not Always in the Public Interest". The author believes that the NIH feared the chilling effect of "march in" rights on future investment and erred on the side of caution.

97 In the U.S. there is dated precedent for not enforcing full patent rights when the public interest is at stake.

Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation, 146 F.2d 941 (9th Cir., 1944) (discussing suppression of patents against the public interest, in this case, in connection with a patent for irradiated margarine used to treat rickets); *City of Mi/waukee v. Activated Sludge,* 69 F.2d 577, 592-93 (7th Cir., 1934) (denying injunctive relief when the requested relief would have closed the city's sewage treatment plant thereby causing public health concerns). Also see B. Mcgarey, A. Levey, "Patents, Products and Public Health: An Analysis of the Cellpro March In Petition", *Berkeley Technology Law Journal* 14(I 095), p. 1107.

98 Studies have linked an upsurge in patenting in the U.S. to the so-called "Patent Friendly Court Hypothesis". See J.L. Turner, "In Defence of the Patent Friendly Court Hypothesis", available via http://ssrn.com/abstract=713601 (April 2005).

99 Article 31 of the TRIPS Agreement allows for compulsory licensing in certain specified circumstances.

100 28 USCA § 1498 (West Supp., 2001); and Exec order no. 10, 789, 3 CFR 426 (19541958 Comp). K. Murashige, "Patents and Research-An Uneasy *Alliance",Academic Medicine* 77(12) (2002), pp. 1329-1338, p. 1331 (arguing for a change to the patentees absolute power to exclude in the context of access to research tools). For an early case that applies the doctrine of eminent domain to patents in the U.S., see *Crozier v. Fried Krupp Aktiengesellschaft, 224* US 290 (1912).

Conclusion

Bioethical decision-making is a subset of the general method of change and transition in the patent system. Legal change in the patent system has been greatly compressed, and the conventional stages of transition by which new technologies are accommodated have in some cases been bypassed altogether.[lol] Hence it is even more important that we understand the institutional nature of the patent system and study the inertias, the competencies, and the dynamics within the system that thwart debate on the social optimality of patenting certain kinds of subject matter.

Complex institutional relationships within the patent system make it difficult to implement changes to patentability rules and doctrine that are not directly related to or adapted from past experience. There are at least three conclusions that can be drawn from the discussion here. Firstly, the present nature of patent offices and specialist courts clearly indicate an institutional trend towards expansive patent rights. Thus, successful objections to the social optimality of a certain class of inventions, including bioethical implications, will have to surmount the institutional dynamics in addition to the substantive and often formal legal requirements. Secondly, norm setting mechanisms backed by law can provide a more comprehensive intellectual position than what is currently possible among patent offices and courts. Thirdly, the incremental advance of the rules react uneasily to "policy overhaul" type of arguments[l02] that are often required when debating ethical implications of unprecedented subject matter as in the case of biological material in the early years of the biotechnology revolution. The long-term projection of this process of change is further complicated by institutional "stickiness" that can make it hard to reverse undesirable or simply inaccurate interpretations of the rules.

The virtual inevitability of incremental ism may come as a disappointment to some idealists. However the appeal of incremental ism in policy formulation in general and in the patent system in particular is high because "overhaul" type of reform introduces formidable legal and political risk. "Satisticing",103 rather than

I 0 I R. Merges, "One Hundred Years of Solicitude: Intellectual Property Law, 1900*2000"*, *California Law Review* 88(2187) (2000).

102 Often incrementalism or "muddling through" is portrayed as antithetical to the rational comprehensive model which might be an overly rigid of looking at it. Charles Lindbloom depicted the two as mutually exclusive. Regarding the rational comprehensive or "root" method he observed "starting from the fundamentals anew each time, building on the past only as experience is embodied in theory, and always prepared to start completely from the ground up". The branch in comparison "continually building out form the current situation, step by step in small degrees". C. Lindbloom, "The Science of Muddling Through", *Public Administration Review* 19 (1959), pp. 79-88.

103 "Satisficing" is the strategy of choosing the first reasonable option - this may not always be the best option, but it maybe the best strategy given that unlimited resources maybe required to search for the elusive "best" option. Overwhelmed by the complexity of the problems they confront, decision makers lean heavily on pre-existing policy frameworks, adjusting only at the margins to accommodate distinctive features of a new situation.

goal maximizing, is the preferred criterion and slight improvement compared to past performance is favored.[lo4]

Prof. Cornish notes that

> inevitably, patent systems have been shaped over time by the technologies for which their aid has been sought. In large measure this impact on the system has been interstitial, a matter of remark only to its specialists' .... Judges and patent offices have accepted a variety of stratagems, which only patent specialists comprehend; *they*, of course come soon enough to believe in the devices as necessary categories of thought. It is from these strange games that much of the new upset about biotechnology patents originates.[l05]

Incremental tweaks here and there conclusively shape the patent system, often leading to a case of the tail wagging the dog.

104 See W. Hayes, "Policy Formulation: An Introduction", The Public Policy Web http://www.geocities.com/-profwork/pp/formulate/.

105 W. Cornish, *Intellectual Property: Omnipresent, Distracting. Irrelevant*, Clarendon Law Lectures (Oxford: Oxford University Press, 2004), pp. 10-12.