current problems in physics, science and technology

intellectual property

ethics and law of
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. 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, patent systems in Europe and the United States 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 of bioethics.

Bioethical decision-making in the patent system is a subset of the normal process of change, transition and reform. Unearthing the dynamics of the general 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. See S. Thambisetty, "Understanding Morality as a Ground for Exclusion from Patentability under European Law", Eubios J Asian and Int'l Bioethics, March 12, 2002, pp. 48-53.
2 In the U.S. there is no equivalent statutory exclusion for patentability on ethical grounds. 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 concerns over which moral questions are raised by the research on biological material and the application of that research impinge 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) the controversy has been "settled" with little purposeful 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/Relacín, [1995] EPOR 541.
7 See T 0315/03 Transgenic animals/HARVARD (July 6, 2004) and Harvard College v. Canada (Commissioner of Patents), [2002] 4 SCR 45 (see discussion below).
9 Harvard College v. Canada (Commissioner of Patents), [2002] 4 SCR 45 (see discussion below).

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.10 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 1991.11

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 "Institutionalism" 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/AboutUs/AboutUs.html.

transformed from inward-looking and isolated entities 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 indefensible. It is being eroded by a self-funded, revenue-raising model. 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. The life of a patent is the patented invention'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 of time. 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 inventions will be encouraged to renew their patents. Reducing renewal fees also increases the inventors' expectation of profits that can then be appropriated through initial high application fees. 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, 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 sets the goal of accelerated processing times through "more focused examination." 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 means that an examiner is more likely to be rewarded for getting quantity rather than quality correct.

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." 18 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 (USPTO) 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

---

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.
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.
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.


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).


30 As per s. 91 (1) 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.


The Institutional Nature of the Patent System

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. 39 Plant varieties are protected by another form of industrial property right called plant variety rights (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 fact-based 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 impossibilities.

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. This is noted by J. Pila, ibid., p. 191.


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.


40 P. 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 unsatisfactory". 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 2001 Utility Examination Guidelines 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'.

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. 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, 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 and recently has been engineered primarily by domestic patent offices including those in the U.S., Europe and Japan. To illustrate, in direct response to concerns that overly broad patent scope in genetics threatened future innovation, the USPTO in 2001 issued new guidelines for the utility requirement. 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 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. 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. 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 (CAFC), 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

50 EPO Decision T1252, OJ EPO 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.
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.

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. 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,57 which may be regarded as a specialist court for, inter alia, its Article 99 EPC jurisdiction58 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 order 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 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 Kitchin63 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 world. They hear patent cases.


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 of 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.
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, 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.65 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.bsw.ed.ac.uk/scrupium/scrupium2/frame01.htm.


68 The turnover of the biotechnology industry in U.S. is double that of European industry (3.1 vs. 1.4 billion euros compared to 15.027). Ernst and Young, Beyond Borders: The Global Biotechnology Report, 2002.


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 Act and the Stevenson Wydler Act, 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. 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.

Institutional economics prominently includes an analysis of formal and informal norms as part of the constraints that shape human behavior. Norms are distinct from legal rules, the violation of which is typically punished by private actors. The NIH'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.

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.

The Institutional Nature of the Patent System

within academic institutions. The NIH'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 of biotechnology.83 In the U.S., research tools developed using federal government funds present a unique problem. In 1997, the NIH convened a working group to study access to unique research platforms that concluded that access to research tools was severely constrained 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 NIH requires grant applicants to include a specific plan for sharing of model organisms and other materials 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 of funding.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.

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/virmcel/WarrMOU.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) 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. 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. 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. CellPro failed to obtain a license from Johns Hopkins and its sublicensee, Baxter Healthcare Corporation, and was subsequently found by the CAFC to be in willful infringement of the patents. However, Celpro 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. After a fact-finding enquiry, the NIH decided 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 exemption 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. Stagnler, [1985] RPC 515. Furthermore the EPC in this context is interpreted differently in different countries. Cornish (1998), 29 DC 735.

90 35 U.S.C., s. 203(1) authorizes a federal agency in limited circumstances to ensure that a federally funded invention is available to the public.


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.


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.

Vitamins 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 Milwaukee 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. Mcgeary, A. Levey, "Patents, Products and Public Health: An Analysis of the Cellpro March In Petition", Berkeley Technology Law Journal 14(1), 1999, p. 1107.


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. Murakishige, "Patents and Research-An Unequal Alliance".Academic Medicine 77(12) (2002), pp. 1328-1338, 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. 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 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 incrementalism may come as a disappointment to some idealists. However the appeal of incrementalism 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. "Satisficing",103 rather than goal maximizing, is the preferred criterion and slight improvement compared to past performance is favored.104

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.105

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

---

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 Lindblom 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 from 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 may be the best strategy given that unlimited resources may be 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.