European Intellectual Property Review

1999

Article

BIOTECHNOLOGY PATENTS, MARKETS AND MORALITY

Peter Drahos.

Subject: INTELLECTUAL PROPERTY. Other related subjects: Science

Keywords: Biotechnology; Ethics; Patentability

Abstract: Whether global expansion in scope of patentability, including biotechnology, has failed to address fundamental moral values and international cooperation will be necessary to redress balance.

*441 Law and morality are connected. There is no disagreement about this claim. As any student of legal philosophy knows, the problems arrive when one tries to explain the nature of the connection. Some areas of law invite adjudicators to draw on morality in the process of legal decision-making. Somewhat surprisingly, given its characterisation as a tool of economic regulation, patent law does just this. More accurately, some systems of patent law explicitly require decision-makers to consider moral standards as part of the process of deciding whether or not to grant a patent. Probably the best-known example of a patent system inviting morality into its domain is Article 53 (a) of the European Patent Convention (""EPC") 1973, which does not allow the grant of patents for ""inventions the publication or exploitation of which would be contrary to "ordre public' or morality". In the Australian Patents Act 1990 there is, in section 18 (2), an express prohibition on the patenting of human beings and biological processes for their generation.

The express connection between patent law and morality is hardly new. The U.K. Patents Act of 1883, for example, gave the comptroller a right to refuse the grant of a patent the use of which would be ""contrary to law or morality". [FN1] There is at least an argument that section 6 of the Statute of Monopolies of 1623 (still referred to in the definition of patentable invention in s. 18 (1) of the Australian Patents Act), includes moral standards within its ambit.

Even within those patent systems where moral standards are not explicitly referred to, it does not follow that such standards play no role in the patent system. When legislatures enact patent law, the moral standards of the community to which they belong are one factor that affects the content of those patent laws. Similarly, in one way or another morality usually enters the interpretive process involved in judicial decision-making on patent law. When the majority in Diamond v. Chakrabarty decided that it was for Congress to decide to exclude from patent protection genetically engineered organisms, they expressly endorsed a political morality that allocated matters of ""high policy" to Congress. [FN2]

Like it or not, the creation, operation and interpretation of the patent system is linked to moral standards. Patent law is located within and not outside a public ethic of community values and shared economic and social interests. There is nothing surprising about this. Patents are a species of property rights. Property is a key institution, perhaps the key institution, of social and political morality. Its definition affects resource distribution and takes one straight into issues of social justice. Similarly, the claim that patenting is an ""ethically neutral act" seems weak. [FN3] A system can be described as morally neutral if it does not affect A's interests or does not hinder or assist A's interests vis-à-vis the interests of B. Since the whole point of patenting is to exclude others from access to informational resources of the patent, it is hard to see how patenting can be described as ethically neutral. The act of exclusion will almost always affect someone's interests.

The remainder of the article argues that morality has been given short shrift by those who have interpretive custody of the patent system. These custodians are caught up in a structural predicament of global dimensions. The outcome of this predicament is that the scope of patentability is expanding while the role of moral standards in the operation of the patent system is being increasingly limited. Ironically, this is happening at a time when the moral debate over patentability, at least in the field of biotechnology, has never been greater. There are, this article suggests, no easy solutions to this structural predicament. The challenge is to think of regulatory processes of decision-making that will give citizen groups some influence over the direction of biotechnology, a technology that looks set to transform their social lives in ways much greater than in the past. Among other things, this requires international co-ordination and action. And this is not likely to be easy in a world where international business, the world's most single powerful global actor, is likely to oppose regulatory initiatives that give citizens a greater say in the content of regulation that affects the conduct of international business.

Before closing this section, the use of the term ""patent community" in this article needs to be clarified. It is used to refer to patent attorneys and lawyers, patent administrators, and other specialists who play a part in the exploitation, administration and enforcement of the patent system. They form a community by virtue of their technical expertise and general pro-patent values. Regular users of the patent system (like the pharmaceutical companies) might also be said to be part of this community, although in this article from time to time a distinction will be drawn between international business (of which the pharmaceutical industry is a part) and the patent community.

The patent community is also an interpretive community. It is the patent community working with a shared set of assumptions, understandings, conventions *442 and values that settles issues and problems of interpretation within the patent system. [FN4] By doing so, the patent community probably exercises more influence on the direction and content of patent policy than legislatures, which in any case rely on committees of specialists to advise them on matters of patent policy.

The Expanding Patent Universe

The patent system has undergone a process of regulatory globalisation and harmonisation. This simply means that more and more countries have adopted patent systems and that those patent systems have progressively become more like each other. Patent systems are not harmonised at the level of rules, but they share common principles. The degree of patent harmonisation is increasing rather than decreasing. For example, all states that are members of the World Trade Organization (""WTO") will have to recognise process patents and to comply with Article 34 of the Agreement on Trade-related Aspects of Intellectual Property Rights (""TRIPS") concerning the burden of proof in civil proceedings for the infringement of process patents.

Aside from the globalisation and harmonisation of patent law, the patent universe has been growing in another manner: the scope of what is regarded as patentable subject-matter has quietly expanded. This expansion has occurred in two ways. First, the scope of patentable subject-matter has been given an inclusive interpretation. Secondly, the restrictions on patentability have been narrowly interpreted. Each national patent system has its own detailed history of expansion. Legislative, judicial and administrative actors have had in this regard roles of differing importance in each national system. Tracing these national histories is well beyond the scope of this article, but some illustrations can be provided. Legislatures have sometimes extended patent protection, the passage in the United States of the Plant Patent Act of 1930 being one such instance. An obvious example of judicial activism on the issue of patentable subject-matter in the context of biotechnology is Diamond v. Chakrabarty. [FN5] Because this was a decision of the U.S. Supreme Court and because it affected patenting in the world's biggest market, the decision had an important influence on patent thinking and policy around the world. In Australia the High Court, having to decide on the validity of some process claims dealing with the use of known chemicals for weed control, entrenched a purposive and expansionary approach to the question of what constitutes a manner of new manufacture. [FN6] This decision was in turn drawn on by English courts considering the issue of the patentability of micro-organisms. [FN7] Within Germany, the decision by the Federal Supreme Court in the Red Dove case is generally regarded as a landmark in the augmentation of patent protection for biotechnological inventions. [FN8]

Courts and legislature have not been the only important actors in this history of expansion. Patent offices like the European Patent Office (""EPO") and the U.S. Patent and Trademark Office (""PTO") have also been key players. Patent offices are hybrid creatures, business bureaucracies which make their living from granting more rather than less patent registrations, from ensuring the repeat custom of their transnational clientele and

from going on proselytising missions in those developing states or new market economies which are in the middle of acquiring patent systems. Patent offices can, through their decisions, include more things in the scope of patentability or narrow the operation of restrictions on patentability. Moreover, if they are supranational entities, as in the case of the EPO, they can exercise a profound harmonising influence on national systems. English courts, for example, have pointed out that it is of the ""utmost importance" that the exclusions in section 1 of the U.K. Patents Act 1977 should have the same interpretation as the EPO gives to the exclusions contained in Article 52 of the EPC. [FN9] The EPO has been singularly successful in giving a narrow reading to the limits on invention and patentability contained in Articles 52 and 53 of the EPC. In interpreting the historical text that surrounds the creation of the EPC, of the EPO has suggested that the widest possible conception of patentability was a predominant conception. [FN10] This conclusion has led to another, one that serves as a foundational interpretive assumption for European patent law-- exceptions to patentability have to be narrowly construed. [FN11] Precisely the same assumption is coded into U.S. patent law. [FN12] The effect of the assumption is to make the restrictions on patentability function weakly, if at all.

So, for example, despite the fact that Article 52 (2) (c) contains a prohibition on the patenting of software, the EPO was able to report in 1994 that it had granted more than 11,000 patents for software-related inventions, and that the national patent offices of Germany, the Netherlands, Sweden and the United Kingdom had essentially adopted the EPO approach to the patentability of software-related inventions. [FN13] Similarly, the U.S. Patent Office has been criticised for using its guidelines to extend the scope of patentability of computer software in a way that is not justified by the case law. [FN14] The Onco-mouse decision reveals that the EPO is reading the morality criterion in Article 53 (a) in a narrow way. The restriction on the patentability of human treatment can be overcome by formulaic *443 means. [FN15] The exclusion of plant varieties under Article 53 (b) of the EPC continues to be revisited. Claims relating to a transgenic plant by Novartis which were refused by the Examining Division because they did not fulfil the requirements of Article 53 (b) have been referred to the Enlarged Board of Appeal. [FN16] It may also be that the Directive of the European Parliament and the Council on the legal protection of biotechnological inventions (1998) does not match the restriction on the patenting of plant varieties to be found in the EPC.

A crucial aspect to the expansion of the patenting in biotechnology has been the development of juridical arguments and theories that have enabled applicants for biotech patents to overcome existing bars. [FN17] One of the interesting things is that, while these arguments are often analytically weak, they have been readily accepted by the patent community in the name of adapting the patent system to changing circumstances of technology and innovation. There is nothing wrong in adapting systems of law to changing circumstances. The crucial thing is that such adaptations must be governed by the public purposes that are embedded in patent law and the broader public ethic rather than private purposes. In the case of the adaptation of the patent system it is not at all clear that this has been the case. An example of where patent law has been engineered to suit the needs of biotechnology patentees relates to the discovery/invention distinction. Most patent law systems recognise a distinction between invention and discovery, and prohibit the patenting of discoveries. In the case of biotechnology patents, a bar to patenting a discovery is a serious problem from the point of view of obtaining patents, since much of biotechnology involves the discovery of the genetic basis of various biological functions, the discovery of organisms with interesting attributes and so on. Mother Nature's handiwork is never too far away in the case of biotechnological inventions. One way in which the potential problems of the invention/discovery distinction have been overcome is to embark on a re-characterisation strategy. What seem like discoveries on closer analysis are, it is argued, really inventions. Genes that have been discovered in nature when isolated and purified can no longer be said to exist in nature and may therefore be regarded as inventions. One suspects that, if Mother Nature had a patent on a particular naturally occurring gene sequence, she would almost always win a patent suit brought against the alleged inventor, since typically all that happens in nonnatural gene sequences is the removal of redundant codons. In essence the sequences are the same. To most people outside the patent community this kind of argument seems like a triumph of form over substance. How many people would think that the rock they pick up in the park becomes an invention of theirs after they have washed and polished it?

More important, however, is the fact that this kind of legal artifice ignores the purpose for having the distinction in the first place. The prohibition on the patenting of discoveries stems from the fact that the patent system is meant to promote the innovation of products and processes rather than abstractions. The purpose of the distinction is to drive the discoverer into the realm of practical application and workmanship. The distinction itself hooks up nicely with the requirement of non-obviousness or inventiveness. By imposing that requirement, the patent system seeks to encourage creative standards of practical application. The problem with corrupting

the distinction is that it creates problems of rent-seeking. Inventors may devote too many resources to the search for abstractions the use of which they can license to others, and too few resources to the development of products and processes.

Another example of a weak analytical argument that is to be found within patent law is the claim that a patent does not confer on its holder a right of exploitation. [FN18] It is merely a negative right to exclude others. This is hardly very persuasive. The right of liberty, most would agree, is a fundamental right. Can one exercise the right by walking down the street? The answer is yes, unless there happens to have been an accident and the police have temporarily blocked off the street. Like a patent right it is a negative right--a right not to be interfered with. Negative rights create zones of non-interference. They correlate with negative duties. The holder of the right can, as a result of this zone, exercise the right, unless for some contingent reason a restriction is placed on the exercise of the right. The claim that the holder of the patent right does not have the right to exploit it is misleading. The effect of the patent right is to create a zone of non-interference in which the patent holder may exercise the right by undertaking activities of commercial exploitation. Rights carry with them the right to exercise the right. There would be very little point in having them otherwise. Just as the right to liberty allows one to walk down the street, so a patent right allows one to exploit the patent commercially unless for some contingent reason one cannot exercise the right. Why it is that arguments like these have been regarded as persuasive by the patent community will become clearer from the section of this article entitled ""The Structural Problem".

To summarise this section, three things can be said to be happening in the patent universe. First, the patent system is globalising. Secondly, it is becoming increasingly harmonised. Thirdly, the scope of patentability is increasing.

The Shrinking Moral Universe

The patent system has for a long time been formally connected to morality. Despite this linkage the patent community has taken the view that morality has little to do with issues of patent grant or, if it does, the patent *444 system is the wrong place in which to consider such issues. The result of this patent community consensus has been that the connection between morality and the patent system has received little exploration as a matter of law, at least until recently. Patenting within biotechnology has changed the quiet life of the patent system. Largely as a result of opposition proceedings taken by activist NGOs such as Greenpeace, which have become worried by the prospect of ""patents on life", courts and patent administrations particularly in Europe have been forced into making pronouncements on the relationship of patents and morality. [FN19]

Patent systems remain territorial and national systems. Each patent jurisdiction has had to work out its own legal answers to the questions surrounding patenting in biotechnology and the role of morality. Broadly speaking, there are two international trends that can be identified. The first is that patent decision-makers have narrowed the role of morality as a criterion of excludability for patents. At the same time, they have devised juridical theories that have removed many of the serious legal hurdles to patenting in the field of biotechnology. Biotechnology law is no longer, in the words of one expert, arcane or anarchic. [FN20] This has largely been achieved by the patent community functioning as an interpretive community. Patent offices around the world have granted many thousands of patents in the biotechnology field including patents on genes, transgenic plants and animals. [FN21]

Within the United States, the courts have not had to wrestle with the kind of specific statutory exclusions on patentability that one finds in the EPC. Issues of patentability in the biotechnology field are decided under those standards of patentability to be found in all patent law systems; patentable subject-matter, utility, novelty and non-obviousness. [FN22] The Chakrabarty decision handed the moral difficulties of patents on organisms over to Congress. Congressional hearings have produced the view that ""patent law is not the place to exercise moral judgements about scientific activity". [FN23] This, of course, raises the question of where is the right place? From time to time Bills that have sought to place limits on patenting in the biotechnological field have been introduced in Congress, but they have failed to pass. [FN24]

The legal consideration of the morality of biotechnology patents in Europe has hinged on an interpretation of Article 53 (a). [FN25] The EPO has signalled a narrow approach to Article 53 (a) in its guidelines, pointing out that it would be likely to be invoked in only ""rare and extreme cases". [FN26] The cases themselves also entrench a narrow reading of the role of Article 53 (a). Article 53 (a), it was pointed out in the Relaxin case, is an exception to patentability and ""Boards of Appeal have repeatedly found that such exceptions are to be

narrowly construed". [FN27] The tests which have emerged concerning the application of the morality criterion are likely to be applied by the EPO in a way that sees very few patents endangered on the grounds that their exploitation would be contrary to morality. Tests of morality that depend on the patent being ""abhorrent to the overwhelming majority of the public, [FN28] a contravention of the ""totality of the accepted norms" [FN29] or a ""weighing up" [FN30] of advantages and disadvantages provide a patent office minded to do so with plenty of scope to narrow the scope of operation of the morality criterion. This is especially true if the relevant decision-maker downplays the probative value of survey evidence relating to patents and morality, as did the Technical Board of Appeal in the Plant Genetic Systems case. [FN31] The effect of such a move is to rob the morality test of any empirical content, while at the same time strengthening the effect of the foundational interpretive assumption that exceptions to patentability are to be ""narrowly construed". [FN32] The Onco-mouse case itself reveals a formalistic treatment of the morality criterion that did not really engage with the matters of principle that the opponents in that case were raising. [FN33]

Despite the different legal provisions in Europe and the United States the moral and legal outcome in the Onco-mouse case was precisely the same--the patent was granted. Given that both patent communities in the United States and Europe come to their interpretive tasks with the same set of pro-patent attitudes and assumptions, there is nothing surprising about this.

*445 The Structural Problem

It has already been seen that broadly speaking the scope of patentability is increasing. At the same time the bars to patentability are in various ways being lowered. This outcome has been largely fostered by the patent community working as an interpretive community. But why has the patent community retained its strong pro-patent attitudes in constructing the relationship between morality and patenting in the context of biotechnology patents? There is evidence of the disquiet of mass publics about patent practice in this field. [FN34] This disquiet seems to have done nothing to stop the trends that have been described.

The answer to the question concerning the strength of pro-patenting attitudes lies in understanding the structural situation in which the patent community exists. This structural situation places strong limits on the capacity of the patent community to develop the links between patent law and the broader public ethic within which the patent system operates.

For the purpose of understanding this structural problem, it is necessary to divide the patent community along territorial lines. The division that matters for present purposes is between Europe, Japan and the United States. They are the three most important patent jurisdictions in the world, so much so that they have a programme of trilateral co-operation. Each of these state actors has a patent office (for present purposes this article will treat Europe as a state actor and the EPO as its patent office). The goal of the patent system in each of these states is essentially the same, that of encouraging the development of science and technology. The development of science and technology is itself bound up with the belief that the patent system, by adding to dynamic efficiency, also contributes to economic growth and ultimately progress. Importantly, each of these patent offices is chartered to administer the patent system to promote national welfare and not global welfare.

Over the years nation states have used the patent system as part of a strategy of defending or expanding national industries. Patent mercantilism was around for a long time before there was talk about the links between intellectual property and non-tariff trade barriers. The United Kingdom, for example, in its 1919 Patent Act did not extend patent protection to chemical products unless they were made by a new process because it feared the market power of German chemical companies. [FN35] All states, one might note, could play the game of patent mercantilism because international treaties in the patent law area placed very few restrictions on their sovereign capacity to do so. Patent law harmonisation and globalisation are slowly restricting this capacity. Whether one looks to history or economic modelling, the conclusions concerning the policy preferences of states regarding trade and intellectual property protection are the same. Technology importers have tended to favour low-level, discriminatory regimes, while technology exporters have favoured high-level, non-discriminatory regimes. [FN36]

The structural problem that this article is about to outline does not, however, relate to the division between technology-exporting states and the technology-importing ones. Rather it relates to the United States, Europe and Japan. These three states are technology exporters. They favour a globalised high-level, non-discriminatory patent system. The patent provisions of TRIPs very much reflect this policy agenda. There are at least two reasons why a technology exporter would favour a high level, non-discriminatory patent system. The first is that

such a system means that a patented technology has the potential to be protected worldwide. As a net exporter of such technologies one experiences export growth, a favourable trade balance and so on. The second reason has to do with investment. In order for the dynamic efficiencies based on technological innovation to continue, investment in innovation has to continue. Domestic producers have to be encouraged to invest in research and the patent system is one established means by which to do this. The belief in most Western policy circles is that investment activity can be increased by means of a stronger intellectual property regime. There is no doubt that investment is ""the critical determinant of long-run economic performance". [FN37] The relationship between investment and intellectual property, however, is part of a very complex web of cause and effect.

The investment issue is further complicated by the fact that these days capital flows are highly mobile. They are also of fundamental importance to the economies of states. Investment has become the driving force of the international economy. In 1993 stocks of foreign direct investment (""FDI") were U.S.$1,650 billion. In the early 1990s, roughly 75 per cent of the total accumulated stock and 60 per cent of the flow of FDI were to be found between the United States, Japan and Europe. [FN38] Similarly, the United Nations Conference on Trade and Development points out in its latest investment report that developed countries have two-thirds of inward FDI and 90 per cent of outward stock. [FN39] The United States, Japan and Europe remain principal players. Demand for FDI also outstrips supply. [FN40] FDI flows increased by 19 per cent in 1997 and climbed for the seventh year in a row. [FN41] For these three states, which now see their comparative advantage lying in the production of intellectual property, not disturbing or *446 increasing their share of investment flows (whether domestic or foreign) is crucial. Economies that have become dependent on technological innovation for their economic growth cannot afford to make even marginal disruptions to investment activity. For the patent offices of these three states, all this leads to a practical truth. None of these offices can be seen to be weakening the patent system in any way. To do so would be to imperil investment flows in the territory for which the patent office has responsibility. Similarly, when one of the patent jurisdictions strengthens patent protection, the others take the view that they have no real choice but to follow. Again, the reason relates to investment. Under the principle of national treatment a state which raises its standards of patent protection also confers a benefit on foreign patentees. The foreign patentee gets the benefit of the increased protection. But in the case of competition between two high-technology economies where one state moves to a higher standard, the other cannot simply remain content to allow its citizens to acquire the benefit of that standard under national treatment. In other words, it cannot use the free-rider strategy. It too must move towards the higher standard. Why so? The risk it runs of not moving is that the first state will get the benefit of greater investment flows, with the strong possibility that more of the crucial R&D will be done in that state. Playing the free-rider strategy may not make a lot of sense in this situation. Among other things, lower levels of research may reduce the second state's capability in copying the technology coming out of the first state. The danger for a technology exporter of not matching the patent standards of another technology exporter is a reduced share of R&D capital and longer run loss of high-technology capability. It should also be added that one of the main uses of patents by companies is as a signalling device to stock markets that they have control of vital or fundamental technologies. How this valuation of a company's intangible capital takes place is poorly understood, but there is no doubt that it occurs. The patent system (along with other intellectual property rights) is progressively becoming more and more enmeshed in processes of market valuation. [FN42] For patent offices this creates further pressures to adopt a liberal attitude towards the grant of patents.

One important thing to understand about this argument is that it does not matter if some of the causal connections between investment and patents do not hold. The connections between FDI and intellectual property are, for the time being, only imperfectly understood. [FN43] It is enough if policy makers and patent administrators believe them to be true.

It is also clear from the preceding discussion that it is a comparatively easy matter for any one of the states to increase patent protection in an area like biotechnology, but a comparatively hard matter to decrease it or call a halt. Essentially, what happens is that when the U.S. biotech industry believes that European patent rules confer an advantage that U.S. patent rules do not, it pressures the U.S. PTO for reform. An example of successful lobbying by the biotech industry in the United States was over the rules relating to enablement and operability in section 112 of the Patents Act. [FN44] The European biotech industry behaves in a similar fashion. Under this set of conditions, a lead patent jurisdiction can only continue to drive up standards of patent protection. There is nothing in TRIPs that prevents a state from moving to raise standards of patent protection. The morality criterion in all this simply becomes a gently floating irrelevance.

No Easy Solutions

There are no easy solutions to the structural problem that has been described in the previous section. Essentially the three leader states in this field have accepted that increasing the strength of the patent system is a means of engineering competitive advantage through regulation. Even if patent administrators privately hold doubts about this, the industry is always there to remind them of the argument. In any case, an individual patent office is unlikely to move in ways that sees the size of its patent empire, as measured by number of applications and fees paid, reduced. Because the three lead patent states accept this view there exists, in effect, a global regulatory ratchet for strengthening the patent system as it relates to biotechnology.

What the public receives on the topic of patents and life can largely be described as symbolic regulation. [FN45] Within the United States, the patenting of life is said to be an important issue, but not one that is appropriate to decide in the context of the patent system itself. This means that the issue is deflected into the complex and fragmented forms of regulation that exist in relation to biotechnology and medical issues generally. [FN46] Here the patent issue has to compete with a multitude of other regulatory issues such as cloning, in vitro fertilisation, embryo experimentation, eugenic sterilisation, euthanasia, access to genetic information and lesbian parenthood, to name but a few. Symbolic regulation comes in the form of expert commissions such as the National Bioethics Advisory Commission. These commissions often work with few resources, uncertain funding futures and difficult deadlines. Thus in 1997 President Bill Clinton asked the National Bioethics Advisory Commission to report within 90 days on the issues raised by developments in cloning technology.

In Europe, as has been seen, the morality criterion is embedded in the European Patent Convention, but for *447 the reasons given earlier this has received the narrowest of interpretations. One suspects that this fate awaits the recent Directive on the Legal Protection of Biotechnological Inventions. [FN47] As in the case of the U.S. patent system, the argument is heard that the patent system is not the right place to be considering the issues raised by biotechnology patents. And Europe, just like the United States, has symbolic regulation, in the form of expert commissions.

If the global regulatory ratchet described in the previous section remains in place, one would expect the number of biotechnology patents to grow, even in controversial areas such as cloning. [FN48] The fundamental problem with this outcome of the patent system is that it is the product of a regulatory ratchet being worked by the patent community without the meaningful input of the citizens on whom biotechnologies have such a fundamental impact.

Towards Regulatory Naturalism

This final section of the article considers two issues. The first relates to the question of how one might improve the decision-making processes of the patent system in a way that is consistent with the ideal of citizen participation. The second issue relates to the question of what to do about the structural problem. Failure to address this problem will mean that suggestions for reform of the patent system motivated by the ideal of citizen participation will probably fail to achieve their goal.

Before discussing these two issues one needs to dispose of the argument that the patent system is not the right place in which to be considering the ethical issues raised by biotechnology patents. The main problem with this argument is that it ignores the complex causal role of the patent system within the broader social system. Increasingly, work within economic history suggests that efficiently defined property rights were crucial to the economic growth of Western states. Property rights were part of that crucial infrastructure of organisation that enabled Western states to achieve economic take-off and stability. [FN49] Efficient property rights themselves are strongly associated with democratic traditions and a strong civic culture. It is this kind of cultural and political background that is most likely to produce efficient property rights. Property rights, in other words, pattern economic growth and in turn are themselves patterned by culture. Property rights throughout history become both cause and effect. In some deep way, when we invent and define property rights we also create a social trajectory for ourselves. It is precisely because the patent system has this important causal role to play in the evolution of biotechnology that the moral debates about the creation and definition of efficient property rights in such technologies must be had within the patent system. Attempting to close off the patent system from this kind of debate is to ignore its causality, as well as to hand over the design of the property right to elites who may be more interested in maximising the monopoly rather than efficiency and morality aspects of patent rights.

The first issue that was raised at the beginning of this section related to the question of how to implement the ideal of public participation in the decision-making processes of the patent system. Clearly, it is better to have a morality criterion formally entrenched in the patent system in the way that it is in the EPC. This makes it

harder for patent decision-makers to dismiss the claim that the patent system is connected to morality in fundamental ways. Once entrenched, the issue becomes how to secure a process of interpretation that respects a moral conception of patent law. [FN50] In part this means overcoming the structural problem that has already been described, something this article will come to in a moment.

But even if the structural problem could be overcome this still leaves the question of how those who administer the patent system are to make decisions using the morality criterion. Patent examiners, after all, are not ethicists. The temptation is to say that at base the application of the morality criterion is a kind of subjective guessing game. Philosophically speaking, this is a rather uninstructed view of moral theory. Even those philosophers who defend moral subjectivism do not argue that moral argument is irrational or incapable of producing correct decisions. [FN51] But it is probably small comfort to patent examiners to be told, for instance, that non-cognitivist accounts of morality do not collapse into irrationality. They, after all, have to produce a regulatory decision. How are they to do this in some way that does not seem arbitrary?

One way forward is to consider ways in which something like the morality criterion might be given an identifiable empirical content. What one has in mind here is not a naturalistic ethic (facts leading to moral values), but rather what might be termed ""regulatory naturalism" in which one tries to discovery the values and facts that relate to the regulatory issue in hand and uses those in the legal process itself. Sociologists have for a long time drawn a distinction between values and attitudes. John Braithwaite, drawing on the work of Rokeach, formulates the distinction by saying that an attitude is

> a set of beliefs about a specific object or situation (such as an attitude toward slavery). A value, in contrast, is a single belief of a specified kind. It lifts us above attitudes about specific objects and situations, to more ultimate *448 goals that affect how we should judge a wide sweep of objects and situations. [FN52]

One important aspect to this distinction is that the empirical work on values tends to show that there is a high consensus within communities on values. It also shows that community values can be identified. Moreover, they do provide a stable basis for moral reasoning, for they do not come and go in the way that attitudes can. All this suggests that the values that relate to biotechnology and the patent system can be mapped. Of course, there are other problems to be faced. Identifying community values is one matter, reasoning with them another. There is also the issue of who is to do the reasoning. Ultimately one will have to look to independent judicial fora to decide the crucial issues of patent law and morality. These fora should be equipped with data about community values instead of being left to hazard guesses as to what these might be, or perhaps mistakenly to draw on attitudes or technocratic premises. The Technical Board of Appeal in the Plant Genetic Systems case rejected the probative value of surveys and opinion polls on the basis that these did not ""necessarily reflect "ordre public' concerns or moral norms" and that the results of such surveys and polls ""can fluctuate in an unforeseeable manner". [FN53] This is an argument against survey evidence that relates to attitudes, but it is not an argument against the kind of empirical work that social scientists can deliver when it comes to identifying community values. The Technical Board of Appeal correctly linked the morality criterion to ""deeply rooted" values. The case in this respect makes an important first step. Other steps involve identifying those values that relate to biotechnological patents and devising a regulatory procedure that draws on those values. The patent community, ethicists, NGOs and biotech companies should all be part of a vigorous contest and dialogue in these important cases, but the duty of judgment should fall to a court that is independent of the patent system. This line of argument accords with Beyleveld and Brownsword's suggestion that the final say on moral issues in the European patent system should rest with the European Court of Human Rights. [FN54] The Opposition Division in the Relaxin case itself observed that ""the EPO is not the right institution to decide on fundamental ethical questions". [FN55] The EPO is not the right place in which final decisions on fundamental ethical matters are to be taken, but it is one place in which such matters are to be contested. One possibility is that the EPO constitute a special Ethics Board with a plural membership to hear matters in which Article 53 is being argued. Ethics committees with a diverse membership are nowadays a routine part of the decision-making processes that govern medical experimentation. Following Beyleveld and Brownsword's suggestion, an appeal should lie from a decision of such an Ethics Board to the European Court of Human Rights. One objection to this might be that it will add to patent litigation. But this seems very unlikely. Regular users of the patent system are unlikely to take each other to the European Court of Human Rights for fear of obtaining the wrong precedents. NGOs are more likely to appeal to the Court, but they will have to keep a weather eye on the number of cases they bring before it. The Court is likely to become impatient with litigants who claim that all patents somehow raise issues of fundamental human rights. Finally, it might be noted that the morality criterion in the EPC has not spawned a lot of litigation.

The second and closing issue is what should be done about the structural problem that enables international business and the patent community to ratchet up patent protection in a process that tramples on citizen

sovereignty. There is, as the last section made plain, no easy answer to this problem. Clearly, overcoming the structural problem requires that the three lead states co-ordinate on the issue of the morality criterion. Scientific knowledge, like capital, is highly mobile. It was this truth that President Jacques Chirac was implicitly drawing attention to when in 1997 he pointed out that there would be little point in France alone implementing a ban on human cloning. [FN56] On a realistic assessment, there is no prospect of either the international business community or the United States, Europe and Japan agreeing to an international initiative that would seek to globalise a moral conception of patent law. For the time being, at least, the world's most powerful actors remain united on an agenda of stronger patent protection, including protection of biotechnology. There is little that citizen groups or weaker states can do in the world system to overcome a coalition of this kind.

In a recent study of globalisation, Braithwaite and Drahos conclude by identifying and analysing five strategies for intervening in global webs of regulation in order to secure better regulatory outcomes for citizens. [FN57] One of those strategies, that of creating framework conventions, is worth considering here. Such framework agreements have begun to emerge in the context of biotechnology generally. [FN58] Injecting a morality principle into such conventions with respect to patentability would at least create the potential for the evolution of more concrete obligations further down the track, a contracting space for further action. In their study Braithwaite and Drahos also point out that, in the past, global regulatory change has had its beginnings in a disaster of some kind, a disaster that has seen alarmed mass publics demanding regulation. Radio regulation at sea was importantly influenced this century by the sinking of the Titanic, financial regulation by major stock market crashes, nuclear power regulation by Three Mile Island, environmental regulation by many environmental disasters, and airline safety regulation by major crashes. Every major technology this century can point *449 to its disasters, its mass publics, government action and the eventual globalisation of that regulation. Biotechnology too will have its disasters. The anxious mass public of states will demand answers and action. Clever NGO strategists will implicate the patent system in these disasters. Co-ordinated international action, which for the time being looks an impossibility, will start to take shape, its nature profoundly shaped by those strategists that represent frightened mass publics and who have the ear of governments keen to be seen resolving a crisis. The patent community will also learn a truth that other regulatory communities already have--that technology makes us a community of shared fate, with the result that no regulatory system connected with technology can remain aloof from moral debate and the responsibility of control.

FN1. s. 86, Patents, Designs and Trade Marks Act, 1883.

FN2. 206 U.S.P.Q. 193, 200 (1980).

FN3. The claim that the act of patenting is ethically neutral is made by Crespi, among others. See R. Stephen Crespi, ""Debate" in Biotechnology, Patents and Morality (Sigrid Sterckx ed., 1997), pp. 219, 220.

FN4. The idea of interpretive community made a strong appearance in the jurisprudential debates of the 1980s. The idea was used by theorists to explain how the open-ended nature of language comes to have a specific meaning assigned to it. See Stanley Fish, Doing What Comes Naturally: Change, Rhetoric and the Practice of Theory in Literary and Legal Studies (1989).

FN5. n. 2 above.

FN6. National Research Development Corporation v. Commissioner of Patents (1959) 102 C.L.R. 252.

FN7. See, for example, American Cyanamid v. Berk Pharmaceuticals [1976] R.P.C. 231.

FN8. For a survey of the important liberalisation decisions, see Annex C of F.K. Beier, R.S. Crespi, J. Straus, Biotechnology and Patent Protection (1985).

FN9. Gale's Application [1991] R.P.C. 30.

FN10. PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors [1995] E.P.O.R. 357 at 367.

FN11. ibid., at 372; LUBRIZOL/Hybrid plants [1990] E.P.O.R. 173 at 177.

FN12. Diamond v. Chakrabarty n. 2 above, at 196-197.

FN13. European Patent Office, Annual Report (1994), pp. 12, 14.

FN14. Allen B. Wagner, "Patenting Computer Science: Are Computer Instruction Writings Patentable?' 27 (1998) The John Marshall Journal of Computer & Information Law 34-35.

FN15. For instance, a claim for a treatment of asthma using X would run into problems under Art. 52 (4), while a claim for the use of X as a medicine in treatment of asthma would probably survive.

FN16. Transgenic plant/NOVARTIS, O.J. EPO 1998, 511.

FN17. For an excellent account see Gerd Winter, ""Patent Law Policy In Biotechnology" (1992) 4 Journal of Environmental Law 167-187.

FN18. PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, n. 10 above, at 373. See also the discussion of this argument by Sigrid Sterckx, ""European patent law and biotechnological inventions" in Biotechnology, Patents and Morality, n. 3 above, pp. 1, 8-11.

FN19. Examples of European cases are HARVARD/Onco-mouse [1990] E.P.O.R. 501; PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, n. 10 above; Hormone Relaxin O.J. EPO 6/1995, 388. The patentability of medical treatment has also led courts into discussions of patents and ethics. See, for example, Eli Lilly 7 Company's Application [1975] R.P.C. 438 (United Kingdom, Patents Appeal Tribunal), Wellcome Foundation v. Plantex Ltd and Pharmap Lantex Ltd [1974] R.P.C. 514 (Israel, Supreme Court); Commissioner of Patents v. Wellcome Foundation [1979] 2 N.Z.L.R. (New Zealand, Supreme Court); Anaesthetic Supplies v. Rescare (1994) 28 I.P.R. 383 (Australia, Federal Court).

FN20. Philippe Georges Ducor, Patenting the Recombinant Products of Biotechnology (1998) p. 1.

FN21. For example, at a conference in 1996 a representative of the EPO observed that the EPO had granted about 12,500 patents in the field of biotechnology, with 2,400 relating to genetic engineering, 500 to transgenic plants and 200 to transgenic animals. See Larissa Gruszow, ""Types of invention in the field of genetic engineering, arising in the practice of the European Patent Office" in Biotechnology, Patents and Morality, n. 3 above, pp. 149-158, 149.

FN22. See ss. 101 and 102 of the Patent Act 1952, U.S.C. Title 35.

FN23. Ronald Schapira, ""Biotechnology patents in the United States" in Biotechnology, Patents and Morality, n. 3 above, pp. 171, 172.

FN24. See Sigrid Sterckx, n. 18 above, pp. 1, 18-19.

FN25. HARVARD/Onco-mouse, n. 19 above; PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, n. 10 above; Hormone Relaxin, n. 19 above. For a discussion see Joseph Straus, ""Patenting Human Genes in Europe--Past Developments and Prospects for the Future", (1995) 26 International Review of Industrial Property and Copyright Law, 920-950.

FN26. EPO Guidelines C-IV, 3.1.

FN27. Hormone Relaxin, n. 19 above, at 398.

FN28. ibid., at 399.

FN29. PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, n. 10 above, at 366.

FN30. HARVARD/Onco-mouse, n. 19 above, at 513.

FN31. See PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, n. 10 above, at 368-369.

FN32. HARVARD/Onco-mouse n. 19 above, at 510.

FN33. Amanda Warren, ""A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by ""Dolly" [1998] E.I.P.R. 445 at 447.

FN34. See the discussions in Part 2 of Sigrid Sterckx (ed.), Biotechnology, Patents and Morality, n. 3 above.

FN35. This restriction was removed in 1949. See Neil Davenport, The United Kingdom Patent System: A Brief History (1979), p. 26.

FN36. Arvind Subramanian, ""The International Economics of Intellectual Property Right Protection: A Welfare-Theoretic Trade Policy Analysis" (1991) 19 World Development 945-956.

FN37. Stephen Bond and Tim Jenkinson, ""The Assessment: Investment Performance and Policy" (1996) 12/2 Oxford Review of Economic Policy 1-29 at 1.

FN38. P. Hirst and G. Thompson, ""Globalization, foreign direct investment and international economic governance" (1994) 1 Organization 277 at 290. See also Ray Barrell and Nigel Pain, ""Foreign Direct Investment, Technological Change, And Economic Growth Within Europe" (1997) 107 The Economic Journal 1170-1786 (pointing out that the bulk of global FDI has been between developed countries, especially OECD countries).

FN39. World Investment Report 1998: Trends and Determinants, UNCTAD, Geneva, August, 1998, at 7.

FN40. See Sajal Lahiri and Yoshiyasu Ono, ""Foreign Direct Investment, Local Content Requirement, and Profit Taxation" (1998) 108 The Economic Journal, 444- 457 at 444.

FN41. World Investment Report 1998, n. 39 above, at 1.

FN42. See Keith Bradley, ""Intellectual Capital and the New Wealth of Nations II" (1997) 8/4 Business Strategy Review 33-44; Annie Brooking, (1996) Intellectual Capital chap. 12.

FN43. At best, intellectual property protection is one factor that influences FDI flows. Much depends on the particular sector in question. Most studies have looked at this issue in the context of developing country economies. See E. Mansfield, Intellectual Property Protection, Foreign Direct Investment and Technology Transfer, Discussion Paper no. 79, World Bank, Washington D.C. (1994); J.Y. Lee and E. Mansfield, ""Intellectual property protection and US foreign direct investment" (1996) 78 Review of Economics and Statistics 181- 186; C. Correa, ""Intellectual property rights and foreign direct investment" (1995) 10 International Journal of Technology Management 173-199.

FN44. See Harriet M. Strimpel, ""Comment on the proceedings of the conference on biotechnology, patents and morality' in Biotechnology, Patents and Morality, n. 3 above, pp. 283, 286-287.

FN45. For the theory of symbolic regulation see Murray Edelman, The Symbolic Uses Of Politics (1964).

FN46. For a description see Roger B. Dworkin, Limits: The Role of the Law in Bioethical Decision Making (1996).

FN47. Directive 98/44 of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions.

FN48. Again the limitations that the Directive on the Legal Protection of Biotechnological Inventions imposes is a matter of interpretation. For a discussion see Amanda Warren, n. 33 above, at 450. It is also worth noting that only some jurisdictions expressly ban cloning. For a survey see Annex E of Cloning Issues in Reproduction, Science and Medicine, a report from the Human Genetics Advisory Commission and The Human Fertilisation and Embryology Authority (December 1998). Those

jurisdictions that impose a ban generally only ban the use of the technique for human reproductive cloning. This would permit, among other things, the use of the technique for the development of human spare parts. There is a very high demand for organs for the purposes of transplantation within Western economies.

FN49. See Douglass, C., North, Institutions, Institutional Change and Economic Performance (1990).

FN50. See Deryck Beyleveld and Roger Brownsword, Mice, Morality and Patents, Common Law Institute of Intellectual Property (1993), chap. 2.

FN51. For an example of a subjectivist who defends the rationality of moral argument see John Mackie, Ethics (1977).

FN52. John Braithwaite, ""Community Values and Australian Jurisprudence" (1995) 17 Sydney Law Review, 351-372 at 354.

FN53. PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors, n. 10 above, at 369.

FN54. See Beyleveld and Brownsword, n. 50 above, p. 90.

FN55. Hormone Relaxin, n. 19 above, at 388, 403.

FN56. See ""Chirac to Push for World Ban on Cloning", http://www.foxnews.com/scitech/042997/cloning.sml.

FN57. John Braithwaite and Peter Drahos, Global Business Regulation, chap. 26 (forthcoming Cambridge University Press, 2000).

FN58. See, for example, the UNESCO Declaration on the Human Genome and Human Rights adopted on November 11, 1997; the Council of Europe Convention on Human Rights and Biomedicine, 1997.

END OF DOCUMENT