Patent Fever in Developed Countries and Its Fallout on the Developing World

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Summary

This paper examines the relationship between innovation and intellectual property rights. Over the past 25 years, the traditional balance between patent legislation and knowledge as public good has started to shift in favour of the former. The global, uniform, but flawed approach to patenting systems, driven by the United States and reflected in the TRIPS agreement, will cause negative externalities for developing countries. The paper suggests that these effects might be mitigated through appropriate instruments and prudent transposition of the TRIPS agreement into national legislations. It argues that the legal and economic foundations that have underpinned traditional intellectual property rights remain valid. Recent trends in approaches to intellectual property rights, including patent proliferation and geographical spread, are critically examined against the background of US-sponsored linkage of patent protection with free trade agreements. Examples from the life sciences and biotechnology illustrate the problems of unwarranted patents and excessive patent breadth, reinforcing doubts about the current uniformization of intellectual property rights protection, and highlighting the risk to innovation and development policy. In the final section, the paper explains how two developing countries have invoked the remedial measures embedded in the TRIPS agreement. These mechanisms include interpretative freedom, opposition procedures and compulsory licences. The paper concludes that from a Schumpeterian viewpoint, "open source" makes the main factors governing innovation more compatible than patent-based protection.

1. Introduction

Intellectual property rights, patents in particular, are meant to boost innovation. However, they also constitute a barrier against the free use of recently[1] accumulated knowledge – a public good.[2] For a long time a balance was kept between these two forces. Since 1980, however, that balance has been tilted more and more against the free flow of knowledge. Even the incentive to innovate that patents offer has been diluted: it is not uncommon for a party other than the actual inventor or discoverer to be granted the intellectual property rights under the form of one or several patents. Even when patents are properly assigned, their scope[3] tends to be significantly greater than what is considered reasonable according to the basic principles of law and the results of microeconomic analysis. These trends are especially prevalent in two fields of great importance for future economic growth and social well-being: information and life sciences, and their related technologies.

This approach to patenting, prevalent in the developed world, has to a large extent been imposed on developing countries over the last ten years within the framework of the World Trade Organization (WTO). Hence, the individual patenting systems of developing countries are being funnelled into a single uniform system[4] – a system riddled with defects. The first consequences of the TRIPS[5] Agreement are likely to create havoc in the public health systems of the developing world and to generate heavy financial transfers[6] from the poorest to the richest countries.

These negative effects might to a certain extent be mitigated, however, by the fact that the TRIPS Agreement is left open to interpretation (for example, in exempting not-for-profit research, research dealing with living organisms or parts of organisms, and with software and business methods,…). Another way to soften the effects of the TRIPS Agreement is to make the most of three instruments, which may become more and more central to rebalancing the approaches to protecting intellectual property: opposition procedures (in the spirit of what is done in Europe), compulsory licences, and open-source mechanisms of cooperation between innovators. This mitigation, of course, presupposes that developing countries, when transposing the TRIPS Agreement into their respective bodies of law, do not give up the right to use these very instruments.

2. Innovation and intellectual property rights: legal and economic foundations

There are basic legal principles that have traditionally limited the domain of applicability of patents. These principles may be summarized as follows. To be patentable, an innovation should be new, that is, it should not merely reproduce something that is already known. It should be sufficiently new that it entails an actual "inventive step". It should have practical uses. A discovery is not an invention[7] and thus is not patentable according to this legal tradition. The rights conferred by a patent should be properly adjusted to the claims that the inventor can legitimately lay. In other words, the breadth of a patent must correspond to the actual scope of the invention.

The fact that these principles are well established does not imply that they cannot be modified or updated. The question that must be asked is: are these principles relevant to today's technical and economic circumstances? Let us turn to economic analysis to find some answers to this question.

First, endogenous growth theory provides solid foundations for investigating the economic factors conducive to innovation. Indeed, as Aghion and Howitt put it, "Economic growth involves a two-way interaction between technology and economic life: technological progress transforms the very economic system that creates it".[8]

In this framework, it has been shown, both theoretically and empirically, that there are four main factors conducive to innovation.

1) Competition for realizing inventions: in its extreme form, this is Schumpeter's "creative destruction".
2) *Ex ante* competition on product markets: firms try to escape "neck-and-neck" competition by innovating, hence transforming to their own advantage a quasi-homogeneous market into a differentiated one.[9]
3) Diffusion, as large as possible, of knowledge created by previous innovations. As Isaac Newton put it, "If I have seen far, it is by standing on the shoulders of giants".[10] Knowledge is a public good and, as such, should ideally be freely available.
4) Limitations on *ex post* competition on markets for the products derived from the innovative effort: the prospect of a protected market is more attractive for the innovator than the prospect of a competitive one.

After one round of innovation, *ex post* competition becomes *ex-ante* competition before the next round of innovation occurs; factors (2) and (4) are thus colliding. Although this is not directly the case between (1) and (3) on one side, and (4) on the other side, it indirectly becomes the case as soon as the limitation in (4) is implemented through patents. Joseph Schumpeter was very much in favour of setting limits on *ex post* competition, to the point of recommending monopoly powers in favour of the innovators. What he meant, however, was monopoly powers on products emanating from new knowledge (private goods), not monopoly powers on knowledge itself (a public good). With that in mind, along with the fact that any monopoly reduces the immediate consumers' surplus, it appears that granting patents to innovators is a very imperfect way (not even a second-best way) of creating incentives for innovation, and of financing the necessary investments. It should thus be used only under the condition of carefully balancing its benefits and its costs, and of taking into account other possible incentives and sources of finance.[11]

In particular, making knowledge available as largely and as freely as possible is of the utmost importance. As Paul David argues, "Legal and other institutional arrangements may be imposing high costs on research intensive firms, and society more generally, by restricting access to some elements in the streams of creative thought, and thereby making it less likely that the elements will be rapidly rearranged and recombined in new and fruitful ways".[12] It is not possible to determine in advance who will have the creative vision to "rearrange and recombine" elements of knowledge in the most fruitful ways, hence the paramount value of a level playing field.

The results of the economic analysis above largely vindicate the traditional legal principles mentioned earlier. There is no point in creating incentives to reinvent something that already exists. On the contrary, when a patent is granted, there is very possibly a high cost in terms of privatized knowledge and the burden of all the transactions necessary to access that knowledge.[13] Even when an invention is new – but only insignificantly so – the cost still surpasses the benefit. In contrast, why should a discovery not be patentable? Here, economic analysis does not provide a direct answer. In the course of research or an inventive process, it is often more difficult to bypass the results of a discovery than the content of an invention. This leads us to appeal, when appropriate, to the "essential facility" argument, which will be discussed later in this section, along with results on the appropriate breadth of a patent.

The extent of the monopoly power embedded in a patent depends on its length and breadth. A length of 20 years is becoming increasingly uniform around the world. For products subject to long regulatory delays, such as pharmaceuticals, it may be up to 25 years. These are legal lengths. The actual

lengths are often shorter, as new competing products are developed that do not infringe existing patents. That leaves the breadth as the only effective instrument for defining the force of a patent. A patent's breadth can often be characterized by the minimum degree of differentiation that a new product must entail with respect to the product covered by the patent, in order to avoid infringing the patent. There is thus a protection zone that competitors must respect in their efforts to innovate in their turn. They might be helped in these efforts by the information that must be disclosed when a patent is granted, information that would not be available if, in the absence of patents, innovations were kept secret.

If its breadth is excessive, however, a patent will act more as a roadblock than as a stepping stone to further innovation. In such a case, the benefits are superseded by the losses in terms of factors (1), (2) and (3), and in terms of the direct consumers' surplus. The losses in terms of (3) – that is, the lost opportunities of the free use of knowledge as a public good – may be particularly significant, as Merges and Nelson, two distinguished scholars of law and of economics respectively, recall, "When a broad patent is granted, its scope diminishes incentives for others to stay in the invention game, compared with a patent whose claims are trimmed more closely to the inventor's actual results".[14] In this way, economic analysis supports the traditional legal principle pertaining to the appropriate adjustment of a patent's breadth to the actual achievements of the inventor. Economists have produced more precise results on the subject, however, by specifically investigating what they have called the "optimal" breadth of a patent.

Many contributions[15] in the economic literature specialized in the subject provide some elements of the answer to this problem. From these elements, the following results emerge. A patent on an invention or a discovery[16] should be all the narrower:

1) the fewer close substitutes there are for the products developed from the invention, or the more difficult it is to bypass the invention or the discovery in subsequent research;
2) the lower the cost of completing the invention;
3) the higher the non-monetary incentives (for example, "academic rewards") available to motivate the inventor.

There are deeply rooted imperfections in using patents as instruments to further innovation, the adverse effects of which must be minimized; conditions (2) and (3) above reflect this. Condition (1) implies that it is not appropriate to grant a broad patent to an invention or a discovery that in turn commands access to lines of research that cannot be pursued without the results covered by the

patent. Under such circumstances, the invention or discovery is an "essential facility", that is, it is essential for working on further research. This is where the Economics of the Protection of Intellectual Property and the Economics of the Protection of Competition (including the competition for innovation and the access to knowledge) reach a junction, as argued by Tom and Newberg in *US Enforcement Approaches to the Antitrust-Intellectual Property Interface*. Both members of the US Federal Trade Commission, Tom and Newberg state, "If market power in an antitrust sense is not to be presumed, then, as with any other form of property, the existence of such power must be determined by evaluating the availability of close substitutes".[17]

Consider, for example, elements in the body like genes and proteins. This is an extreme case of the situation discussed above, because there are no substitutes. Regarding such elements, which incidentally are discovered and not invented, even the caution urged by Merges and Nelson might not be sufficient; from the viewpoint of economic efficiency, it might be necessary to reduce a patent's breadth below what would coincide with "the inventor's actual results". In antitrust terms, genes and proteins are "essential facilities". Moreover, they are no longer costly to isolate, sequence and characterize. For all these reasons – and the essential facility characteristic is paramount – no broad patent should be granted on a gene, and possibly no patent should be granted at all.

3. Recent trends in the approach to intellectual property rights

In 1982, in an atmosphere of pessimism concerning the technical capabilities and the relative productivity of the US economy, Congress created the Court of Appeals for the Federal Circuit (CAFC) within the framework of the Federal Courts Improvement Act. This federal court is specialized in intellectual property matters, and it is the only court appointed to deal with appeals on such matters. The objective was to ensure greater consistency in dealing with appeals. It was also done to support an approach systematically sympathetic to the defence and the promotion of intellectual property. The judges chosen to sit on the CAFC were indeed selected according to their supposed willingness to further this latter objective. The statistics on decisions made by the CAFC since its inception – including a lavish increase in the number of rulings on patent infringements in favour of patent holders as well as skyrocketing damages granted by the judges to the latter – reveal a pro-patent bias that is certainly not disappointing the founders of the CAFC.[18]

As legislator, it thus appears that Congress consciously promoted easier access to patenting. It

appears to have done so unconsciously as well in its function as controller of public receipts and expenses: by starving the US Patent and Trademark Office (USPTO) of adequate funds, it created a situation where overloaded and underpaid examiners were not able to properly assess the submissions they had to deal with. Within a system of incentives geared towards granting patents, it is only natural that examiners tended to grant patents easily on the basis of generally superficial investigations.

The result has been a remarkable increase in the number of patent requests submitted – and of applications accepted. The scientific and technical breakthroughs that occurred during the 1980s and the 1990s of course contributed to that increase. Most of it, however, can be attributed to a de facto reversion of the patenting system to what it was at its origin in the nineteenth century – simply a registration system.

Consequently, patents are routinely granted to submissions devoid of novelty, or with only insignificant original contributions. Patents are granted to parties that are not the real contributors to the innovations involved. Overlapping patents are granted, which is a sure way to ignite conflict. Breadths are systematically inflated. New "subject matters" are annexed, not on the basis of rational balanced assessments, but as lava spreads on the slopes of a volcano. This can be illustrated in several branches of knowledge and economic activity. For this text, I have chosen examples from the life sciences and biotechnology (see Section 4).

Tinkering with patents, in or out of court, uses up no less effort or money than working on genuine innovations. As Robert Barr[19] put it at a Federal Trade Commission Roundtable in 2002:

> An innovator asks two questions:
> Can I get a patent?
> Do I infringe the patents of others?
> The answer to the first is usually too easy: yes.
> The answer to the second is much more difficult
> and, as a practical matter, impossible.

He could have added: if the innovator acts on the basis of a "yes" to the second question, it may indeed be very costly in time and money to disentangle the web of dependences on existing patents. If, on the other hand, the innovator acts on the basis of a "no", it may be even more costly in legal battles and defeats. Small and medium-sized firms tend to act on the basis of a "yes" to the second

question, as they do not have enough resources to stand a legal battle against large firms. In the current system, the small and medium-sized firms that could be particularly innovative are deterred from fulfilling their potential. Not only is free access to knowledge marginalized in such a state of affairs, the very function of patents – to act as incentives to innovation – is stifled by the proliferation of bad patents.

The excessive approach to patenting has also spread geographically. To understand the United States' forceful push in this direction, it is again useful to remember the atmosphere of technical and economic pessimism of the 1970s: there was a general feeling in the United States that the absence of a proper system of protection of intellectual property rights in many countries was seriously distorting competition to the detriment of the United States. The idea emerged that the best remedy would be to introduce compulsory rules on the protection of intellectual property into the mechanisms regulating free trade among nations. That would make it an item on the broad agenda of the at-the-time ongoing Uruguay Round[20] under the General Agreement on Tariffs and Trade (GATT), within which a broad range of bargains was possible. Moreover, the idea of extending to intellectual property the arbitrage and sanction mechanisms applied to trade conflicts was also attractive.

Thus it was that a small group of lawyers and of chief executives of large firms, active mainly in electronics and life sciences, elaborated a doctrine and a strategy of action. They recruited more firms and convinced key legislators, the Department of Commerce and the US Trade Representative to insert into the Uruguay Round mechanisms for protecting intellectual property. Making the most of their connections with European and Japanese business associations, they were able to secure the backing, albeit somewhat reluctant, of Japan and the main European countries.

The attitude towards emergent countries has been less gentlemanly. Many among them resisted the idea of a global, uniform system for protecting intellectual property. These countries had to be pressured into compliance. The whip was provided by Congress in 1984 under the form of an amendment to Section 301 of the US Trade Act. It allowed the US Trade Representative to impose trade restrictions on countries that were deemed lacking a proper system of protection of intellectual property, a lack that allegedly made them unfair competitors for the United States. The threat of Section 301 was swiftly exercised on a sample of countries, among them Brazil, Korea and Thailand, to help create a climate conducive to accepting the United States' position at the GATT negotiations. As a result, an Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) was part of the positive conclusion of the Uruguay Round in 1994. The creation of the World Trade Organization (WTO), granting it specific arbitrage and sanctioning powers, was also decided on that occasion.

4. Undue patents and patents with excessive breadth: examples from the life sciences and biotechnology

4.1. Protein CCR5 and new medicines for combating AIDS

In 1995, a US biotechnology firm, Human Genome Sciences (HGS), filed for a patent on a gene coding for a protein – CCR5 – that, according to HGS, might be involved in inflammatory disorders. In fact, no precise function was claimed to justify the requested patent. While USPTO was examining the claim, scientists at the National Institutes of Health (NIH, the large US network of public laboratories working in life sciences) and at the Free University of Brussels (whose joint work did not depend in any respect on HGS's claims) discovered that CCR5, when on the surface of a cell, might function as a gate for the HIV virus to enter into the cell. On that basis, new drugs were developed that essentially shut the gate.

As if ignoring this independent discovery, USPTO granted HGS a patent that asserted rights over the gene that codes for CCR5, hence over all functions of that gene and over all the applications derived from those functions. As a result, therapies for AIDS derived from the role played by CCR5 could not be marketed without licenses granted by HGS, even though their development did not scientifically rely on anything HGS had done. HGS agreed to several licenses, for a significant portion of the profits made from the new medicines.

This is an emblematic case that also illustrates the oddity of patenting a gene as if it were merely a "material compound", that is, as if it were a synthetic chemical molecule, for which broad patents are traditionally granted.

4.2. Taxol against cancer

Taxol is a major drug used to fight cancers of the ovaries, breast and lungs. It was first derived from the bark of the Pacific yew tree. The curative properties of this natural material were discovered and then firmly proved in the course of research conducted at the NIH,[21] and at laboratories supported by the NIH, from 1960 to 1990. Also supported by the NIH, scientists at Florida State University in 1994 succeeded in synthesizing Taxol. This was a decisive step towards meeting a large demand for the drug.

At this point, Florida State University licensed its method to the pharmaceutical firm Bristol-Myers-Squibb. On the basis of the 1986 Federal Technology Transfer Act, the federal authorities[22] granted Bristol-Myers-Squibb five years of exclusive marketing rights. During this period, the firm made between US$1 and US$2 billion a year from Taxol; it paid Florida State University a few tens of million US dollars a year, and the NIH almost nothing.

The stories of CCR5 and Taxol are neither exceptional nor non-representative cases. For more than half the really innovative drugs put on the US market during the last ten years, similar stories abound. This has made it possible for the "Big Pharma", as the set of large pharmaceutical firms is nicknamed, to spend more than twice as much on marketing and corruption operations as on research.[23]

4.3. Genes $BRCA_1$ and $BRCA_2$ as indicators of the susceptibility to breast cancer

This case involves the biotechnology firm Myriad Genetics (Salt Lake City, Utah, USA), which has owned since 1977 the rights attached to patents granted by the US Patent and Trademark Office (USPTO) on genes $BRCA_1$ and $BRCA_2$. These genes indicate susceptibility to breast cancer, that is, mutations of these genes reveal a greater risk of developing breast cancer. The patents also cover diagnostic tests for detecting mutations. On this basis, Myriad Genetics claims the rights to all diagnostic tests involving the BRCA genes. This is in line with the broad scope that the USPTO and the US courts generally grant to patents on genes.

In order to enforce its patenting rights, Myriad Genetics notified all laboratories engaged in independent research or clinical trials of diagnostic tests involving the two BRCA genes, that they should cease these activities. Among the most concerned laboratories was the service of clinical genetics at the University of Pennsylvania. They had become rather advanced in testing for susceptibility to breast cancer, and had a significant number of persons at risk under observation. Nevertheless, the lawyers advising the University recommended they cease all activity for fear of litigation by Myriad Genetics for infringement of its patents. In Canada, on the contrary, the Public Health Service (PHS) has been more reluctant to comply with the requests from Myriad Genetics (it has also been much less exposed to judicial action). Canada's PHS was not prepared to pay Myriad Genetics US$2800 per test, while the cost in Canada was only US$300.

In Europe, the European Patent Office (EPO), following the lead of the USPTO, has also granted broad

patents to Myriad Genetics. However, within a certain period after it has been granted by the EPO, a patent may be opposed by any person or organization that has reason to think that the patent has been inappropriately granted (this is called an opposition procedure). In the case of Myriad Genetics' patents, the Institut Curie in France, along with other Belgian, Danish and French medical institutions, filed an opposition. The outcome of the procedure, conducted by a kind of appellate body within the EPO, was awaited with great interest. On the basis of the evidence provided by the opposing parties, the result of the opposition procedure was that the scope of Myriad Genetics' patents was considerably reduced (for Europe, at least), to the point of no longer being a concern for the Institut Curie and its partners. The procedure is not over, however, as Myriad Genetics has appealed the ruling.

4.4. Gene coding for growth factors

What does it mean when it is said that a gene codes for a growth factor? It means that the gene controls the production of a protein, the function of which is to bind with a receptor situated on the surface of a cell, and then to stimulate cell division. This effect may contribute to the repair or replacement of damaged or diseased tissues. The growth factor is the protein, but to be effective, it needs to bind with a receptor on the surface of a cell, which is consequently stimulated to reproduce itself.

What is at stake in the lawsuit considered here are the rights over the gene coding for heparin-binding growth factors (HBGFs), heparin being a receptor on the surface of many cells. Thomas Deuel (Harvard Medical School) purified and sequenced some HBGFs among these genes, and on that basis petitioned for patents. In November 1993, the appellate body of the USPTO backed the decision made by the examiners of the Office to reject Deuel's petition on the grounds of "obviousness" (in other words, his work was not sufficiently innovative), taking into account the scientific and technical knowledge available at the time.

Deuel lodged an appeal with the Court of Appeals for the Federal Circuit (that is, the federal court that is specialized in intellectual property disputes), and in 1995, it reversed the decision made by the USPTO. The Court accepted that the scientific and technical literature, to which Deuel had access at the time his work was in progress, suggested how to proceed, and offered an application to another line of molecules. That was not a sufficient reason, however, to deny Deuel a patent. This is not an unreasonable conclusion, as long as it is recognized that Deuel's results are neither pioneering nor broad enough to be worthy of a broad patent. The Court, however, refused to recognize this limita-

tion and granted a broad patent anyway, not only over the genes that Deuel had purified and sequenced, but also over all genes that code for HBGFs. How many of those genes there are, nobody knows, but it is clear that the number is high. The Court's decision is all the more paradoxical when explained in their "discussion": "claims 4 and 6 are thus tantamount to the general idea of all genes encoding the protein, all solutions to the problem".[24]

This example illustrates a characteristic drift of treating marginal inventions as if they were pioneering, when, in truth, they are only closely related to discoveries or inventions of much greater significance, and which were and remain freely available. The marginal invention that gets a broad patent positions itself on the border between what D. Foray (2003) respectively calls "IPR science"[25] and "open science". Deuel sought the protection of IPR science, and the Court of Appeals for the Federal Circuit granted him protection so broad that it is as if he deserved all the credit for the open science on which he relied.

5. How to make use of the flexibilities in the TRIPS Agreement

While patent protection provides an incentive for R&D, the patenting of intermediate technologies (particularly gene-based ones) required in the research process may actually create disincentives for researchers in terms of accessing, or unwittingly infringing patents on technologies they need. This is an area where patent practices in the developed world can impinge directly on what research is done for people in the developing world, and there are implications for the type of patent regimes that developing countries adopt.[26]

John Barton and the Commission he chaired, on behalf of the UK Department for International Development, were looking for means of *integrating intellectual property rights and development policy*. What they are saying here, in carefully chosen words, is that such integration is made all the more difficult by the disease of the patent system, which started and developed in the United States and then reached Europe. This *disease* is characterized by unwarranted patents, unduly broad patents, less than rigorous examinations by patent offices, excessive pro-patent zeal of the courts specialized in intellectual property disputes, an explosion of transaction and litigation costs – to the point of hindering rather than promoting research and innovation.

If this is the system that the WTO, by implementing the TRIPS Agreement, is meant to spread all over

the planet, the doubts that one might already have concerning the uniformization of intellectual property protection are seriously reinforced. The difficulties of integrating intellectual property rights and development policy are increased. However, in part due to arguments introduced into the negotiations by the European parties and in part due to residual resistance from some emergent countries, the TRIPS Agreement is not the exact image of the US system of protection of intellectual property, to the disappointment of many among its US promoters.[27] Members of the WTO are in principle entitled to interpret TRIPS in ways that, for example, make room for exempting not-for-profit research,[28] for dealing in specific ways with living organisms or parts of organisms, for keeping mathematical algorithms, certain kinds of software, and business methods out of the reach of patents, and so on. This is precisely what Russia did when it recently reformed its law on intellectual property rights to make itself just eligible for a possible adhesion to the WTO.

The TRIPS Agreement is also compatible with two mechanisms that might prove extremely useful in containing the excesses committed under the auspices of the protection of intellectual property: these mechanisms are opposition procedures and compulsory licences. Last but not least, the TRIPS agreement, if cautiously implemented, need not preclude open-source cooperation between innovators, be they firms or individuals. These possibilities depend crucially, however, on the precise ways in which the TRIPS Agreement is implemented in a country.

The European Patent Office (EPO) has an opposition procedure that seems more accessible and more efficient than elsewhere: when a patent is granted, parties that are unhappy with the decision, and that think they have robust arguments to prove it is unwarranted, may require that an opposition procedure be got under way before an appellate body within the EPO. Such a procedure is somewhat quicker and much less costly than going to court. Above all, it considers all significant evidence that is submitted. The opposition procedure functions as a device that puts under examination relevant information that the opposing parties have, and have a clear interest to communicate. This is particularly important in a situation where the quality of direct information gathering by the examiners in patent offices has seriously deteriorated. This function of the opposition procedures is so important that economist Jean Tirole suggests that they might be the main step of the whole process of assessing patent submissions.[29] The EPO opposition procedure has recently proved how valuable it may be in cases like the European cancer research institutes vs. Myriad Genetics (see Section 4).

When patents come across essential facilities, it might raise problems, as mentioned in Section 2. This is not necessarily the case, however. Such problems do not emerge when patents play their basic role as supports for efficient transactions in knowledge. That has been the case with the Boyer-Cohen

patent that covers a basic technique in genetic engineering:[30] it has been the support of a large number of non-exclusive licenses sold at reasonable prices. Moreover, free use of the technique for non-profit research has always been possible.[31] More often, however, in order to maximize their profits, patent holders either want to exploit their patents themselves (like Myriad Genetics) or sell exclusive licenses. It may even happen that, in order to protect existing production techniques, they block the use of the patents they own.[32] Thus, there are many circumstances in which licenses are not offered to everyone needing them and prepared to pay reasonable prices.

Public utilities (electricity, rail, telecommunications,…) depend on essential infrastructures (grid, track, local networks, …). Without access to these natural monopolies at fair prices, firms are excluded from the corresponding businesses. Regulating access, and the price of access, by specialized public authorities (the regulators) is now the almost universal approach to the problem.[33]

Genes, proteins, and other elements of the body, constitute an example of essential infrastructure of critical importance for public health and for furtherance of research. If owners of patents do not offer licenses at reasonable prices, when some research or public health imperative would require it, then it is no less economically justified to regulate them than it is to regulate the owners of electricity, rail or telecommunications networks. Compulsory licenses may be used as a regulation tool in such cases. Canada and the United States have a long experience with compulsory licenses. Canada uses them for dealing mainly with health requirements. The United States uses them as antitrust remedies;[34] there they have also been used in defence procurement to overcome deadlocks between private firms (in aeronautics, and in electronics) deemed detrimental to the national interest.

There are familiar objections against compulsory licenses. They weaken the incentives to innovation brought by the corresponding patents.[35] In network utilities, the parallel concern is that capped prices for the access to essential infrastructures lead to underinvestment in these infrastructures. More generally, the asymmetry of information between regulator and regulated firms would make it impossible for the regulator to set appropriate access conditions (to essential patents here, to essential infrastructures there). These problems are serious, and deserve serious consideration, which is precisely what they get in the regulation of network utilities. In particular, both academic research and regulators' learning-by-doing have produced converging procedures, which have made it possible to set reasonable access conditions. This has been done in such a way that information useful to the regulator is revealed during the course of the procedure, thanks to built-in incentive devices.[36] What has been possible for network utilities regulation does not seem unattainable for intellectual property regulation.

Brazil has illustrated how to play the threat of compulsory licensing to good effect in public health.[37] Pressured by the United States into reforming its system of protection of intellectual property (that was basically a system of protection of production processes), Brazil accepted to implement the TRIPS Agreement as early as 1995. On the basis of the delays obtained by the developing countries at the end of the negotiations in the Uruguay Round in 1994, Brazil was entitled to wait until 2005. It happened that, at the same time Brazil accepted patents on new drugs, it launched a public health programme aiming at distributing the most efficient drugs against HIV to all Brazilians in need (between 100 000 and 150 000). The contradiction between the two moves was overcome by a strategic use of the legal possibility (that Brazil had retained and that was not encumbered with legal or bureaucratic restrictions) to issue compulsory licenses, and of the capacity of Brazilian private firms and public laboratories to produce at short notice generics of any new drug. Thus, Brazil was able to extract from the international pharmaceutical companies price concessions on their drugs as they were introduced onto the market. These price concessions were not as attractive as the prices that the Indian manufacturers were able to offer (India has delayed till 2005 the implementation of the TRIPS Agreement), but they were at least compatible with the financial constraints of the Brazilian programme against AIDS.

From the Brazilian case, one should not draw conclusions that are too optimistic. It is highly dependent on a conjunction of favourable factors, among them the availability of sizeable and efficient public laboratories. On the contrary, the latest information from India rings an alarm bell. The Indian Parliament recently voted a law meant to transpose the TRIPS Agreement into national law. It appears that, under the pressure of "multinational and Indian pharmaceutical companies that are eager to sell high-priced drugs to India's middle class, which is larger than the population of the United States",[38] the text introduces such cumbersome provisions for issuing compulsory licenses that it renders the mechanism almost useless. This will severely impair "India's ability to provide generic versions of essential medicines". The perversion characterizing the patent system around the world is so pervasive that the checks and balances in the TRIPS Agreement are in great danger of being distorted. As a consequence, people enjoying only modest incomes, in India or in countries depending on India for essential medicines, will from now on be denied access to such medicines, in particular to state-of-the-art drugs against HIV.

Open-source mechanisms of cooperation between innovators (be they firms or individuals) are gaining importance in certain developed countries and are penetrating an increasing number of technical and economic sectors (not merely software).[39] This is well-documented in E. Von Hippel (2005) and in P. Aigrain (2005). Open-source mechanisms can also be of great value in developing coun-

tries as soon as minimal scientific and technical resources, material and above all human, are available; they in particular might contribute to improvements in living conditions. They are not incompatible with a reasonably functioning system of intellectual property rights. For example, the inventors of a significantly new technique for introducing foreign genes into a living organism might like to grant free use of the technique, provided any later improvement to it is also freely available.[40] However, specific inventions that make use of the technique might be patented, as long as the technique itself and its improvements are not. Here, we are back to the initial and limited concept of protection that Schumpeter had in mind. This leads to thinking of "open source" in terms of Schumpeterian analysis. It also shows that "open source" makes the main factors governing innovation more compatible than patent-based protection (see Section 2).

References

Aghion, P., C. Harris, P. Howitt and J. Vickers (2001), "Competition, imitation and growth with step-by-step innovation", *The Review of Economic Studies*, 68(3), pp. 467-492.

Aghion, P. and P. Howitt (1998), *Endogenous growth theory*, Cambridge, MA: MIT Press.

Aghion, P. (2003), "Empirical estimates of the relationship between product market competition and innovation", in J.-P. Touffut (ed.), *Institutions, Innovation and Growth*, Cheltenham, UK and Northampton, MA, US: Edward Elgar.

Aigrain, P. (2005), *Cause commune*, Paris: Editions Fayard.

Angell, M. (2004), *The truth about the drug companies – How they deceive us and what to do about it*, New York: Random House.

Armstrong, M., S. Cowan and J. Vickers (1994), *Regulation reform: Economic analysis and British experience*, Cambridge, MA: MIT Press.

Arrow, K.J. (1962), "Economic welfare and the allocation of resources for inventions", in R.R. Nelson (ed.), *The rate and direction of inventive activity*, Princeton: Princeton University Press, pp. 609-625.

Barton, J.H. (1995), *Patent breadth and antitrust: a rethinking*, Paper presented at the Federal Trade Commission hearings on Global and Innovation-Based Competition, Washington, D.C.

Broothaerts, W., *et al.* (2005), "Gene transfer to plants by diverse species of bacteria", *Nature*, 433 (10 February 2005) pp. 629-631.

Chang, H.F. (1995), "Patent scope, antitrust policy, and cumulative innovation", *Rand Journal of Economics*, 26(1), pp. 34-57.

Commission on Intellectual Property Rights, chaired by J.H. Barton (2002), *Integrating intellectual property rights and development policy*, UK Department for International Development, London.

Coriat, B. and F. Orsi (2003), "Brevets pharmaceutiques, génériques et santé publique. Le cas de l'accès aux traitements antirétroviraux", *Revue d'Economie Publique*, 12, pp. 153-177.

David, P. (1993), "Intellectual property institutions and the panda's thumb: patents, copyrights and trade secrets in economic theory and history", in M.B. Wallerstein, *et al.* (eds), *Global dimensions of intellectual property rights in science and technology*, Washington, D.C.: National Academy Press, pp. 19-61.

Denicoló, V. (2002), "Two-stage patent race and patent policy", *Rand Journal of Economics*, 31(3), pp. 488-501.

Duttfield, G. (2003), *Intellectual property rights and the life science industries*, Aldershot, Hampshire, UK: Ashgate Publishing.

Foray, D. (2004), *The economics of innovation*, Cambridge, MA: MIT Press.

Federal Trade Commission (2003), *To promote innovation: the proper balance of competition and patent law and policy*, Report by the Federal Trade Commission, Washington D.C.

Gallini, N. and S. Scotchmer (2002), "Intellectual property: when is it the best incentive system?", in A. Jaffe, J. Lerner and S. Stem (eds), *Innovation policy and the economy*, Cambridge, MA: MIT Press.

Henry, C. and M. Matheu, (2001), "New regulations for public services in competition", in C. Henry, M. Matheu and A. Jeunemaître (eds), *Regulation of network utilities: the European expeience*, Oxford: Oxford University Press, pp. 1-35.

Jaffe, A. and J. Lerner (2004), *Innovation and its discontents*, Princeton: Princeton University Press.

Katz, M.L. and J.A. Ordover (1990), "R&D cooperation and competition", *Brookings Papers on Economic Activity*, Special Issue, pp. 137-191.

Kaul, I., "Public goods: a positive analysis", in B. Gazier and J.-P. Touffut (eds), *Public goods!*, Edward Elgar Publishing, forthcoming.

Merges, R.P. (1997), *Patent law and policy* (second edition), Charlottesville, VA: The Michie Company.

Merges, R.P. and R.R. Nelson (1990), "On the complex economics of patent scope", *Columbia Law Review*, 90(4), pp. 839-916.

Nickell, S. (1996), "Competition and corporate performance", *Journal of Political Economy*, 104, pp. 724-746.

Nuffield Council on Bioethics (2002), *The ethics of patenting DNA, a discussion paper*, The Nuffield Foundation, London.

Sagara, C.O. (2005), "L'expérience des C3LD est confrontée à la menace des brevets de logiciel", in V. Peugeot (ed.), *Le développement face aux biens communs de l'information et à la propriété intellectuelle*, Caen: C&F éditions.

Scherer, F.M. (1998), "Comments on intellectual property, technology diffusion, and growth", in R.D. Anderson and N.T. Gallini (eds), *Competition policy and intellectual property rights in the knowledge-based economy*, Calgary, Alberta, Canada: University of Calgary Press, pp. 104-108.

Scotchmer, S. (1991), "Standing on the shoulders of giants: cumulative research and the patent law", *Journal of economic perspectives*, 5(1), pp. 29-41.

Scotchmer, S. (1999), *Cumulative innovation in theory and practice*, discussion paper, Goldman School of Public Policy, University of California at Berkeley.

Shapiro, C. (2000), "Navigating the patent thicket: cross licenses, patent pools, and standard-setting", in A. Jaffe and J. Lerner (eds), *Innovation policy and the economy*, Cambridge, MA: MIT Press, pp. 119-150.

Tirole, J., C. Henry and L. Tubiana (2003), *Protection de la propriété intellectuelle: une introduction et quelques pistes de réflexion*, Rapport du Conseil d'Analyse Economique, Premier Ministre, Paris: Documentation française.

Tom, W.K. and J.A. Newberg, (1998), "US enforcement approaches to the antitrust - intellectual property interface", in R.D. Anderson and N.T. Gallini (eds), *Competition policy and intellectual property rights in the knowledge-based economy*, Calgary, Alberta, Canada: University of Calgary Press, pp. 343-393.

Von Hippel, E. (2005), *Democratizing innovation*, Cambridge, MA: MIT Press.

World Bank (2001), *Global economic prospects and the developing countries: making trade work for the world poor*, The World Bank, Washington D.C.

Endnotes

[1] The great majority of patents have a legal duration of 20 years.

[2] According to the standard definition, "...public goods have two main properties: nonrivalrousness in consumption and nonexcludability of benefits. These properties, it is commonly argued, entail that the goods are public in consumption, that is, available for all" (see Inge Kaul, "Public Goods: A Positive Analysis" in B. Gazier and J.-P. Touffut (eds) *Public Goods!*, Edward Elgar Publishing, forthcoming in 2005). For example, a coat is a *private good*: only one person can use it at a time; simultaneous use is impossible. Knowledge, on the other hand, is a *public good*: any number of persons can simultaneously use the same piece of knowledge in, say, electronics to repair their respective television sets. Although a piece of knowledge is nonrivalrous and nonexclusive, access to this knowledge might be artificially and willingly restricted, thereby damaging its quality of public good.

[3] That is, the extension of the scientific and technical domain that is granted to the patentee; it is also called breadth.

[4] In comparison, the present-day developed countries were able, in their developing days, to allow their intellectual property systems to evolve in rhythm with their respective pace of development.

[5] Trade-Related Aspects of Intellectual Property Rights; it is the official name of the Agreement on intellectual property rights implemented by the WTO.

[6] For preliminary evaluations of the amounts at stake, see World Bank (2001).

[7] To distinguish between the two, innovations are manmade, and discoveries are structured observations of natural phenomena.

[8] Aghion and Howitt (1998), p.1.

[9] The effects of "neck-and-neck" competition on innovation are considered in S. Nickell (1996); in P. Aghion, C. Harris, P. Howitt and J. Vickers (2001); and in P. Aghion (2003).

[10] Or, "The invention makes it possible for other researchers to begin working on the next innovations" (Aghion, P. and P. Howitt, 1998, p. 54). See also the review paper by S. Scotchmer in the *Journal of Economic Perspectives* (1991), for which she has chosen the title, "Standing on the shoulders of giants: cumulative research and the patent law".

[11] Academic competition, and the partly symbolic retributions it entails, provide powerful incentives to discover and invent, but it requires public or charitable funds for its financing. In a world of perfect information, that would not create distortions; in a world where imperfect information prevails, however, it does, leaving us again with an imperfect instrument. In *Intellectual Property: When Is It the Best Incentive System?*, N. Gallini and S. Scotchmer (2002) assess the merits and the imperfections of various systems of creating incentives to and providing finance for innovation. In *R&D Cooperation and Competition*, M.L. Katz and J.A. Ordover (1990) note for the United States rates of more than 40 per cent for public subsidizing of private research (universities not included).

[12] P. David (1993), p. 29.

[13] As is shown in C. Shapiro (2000), who considers how to "navigate the patent thicket".

[14] R.P. Merges and R.R. Nelson (1990), pp. 916.

[15] Among the most significant ones are: R.P. Merges and R.R. Nelson (1990); H.F. Chang (1995); S. Scotchmer (1999); N. Gallini and S. Scotchmer (2002); V. Denicolo (2002).

16 According to traditional principles, a discovery is not patentable; only an invention is. Nevertheless, for about the last 20 years, the distinction has been ignored by the main patent offices and by the courts.

17 W.K. Tom and J.A. Newberg, 1998, p. 346. That "market power is not to be presumed" means that not all patents automatically create problems from the point of view of competition protection; however, problems, possibly serious ones, derive from the absence of close substitutes, and thus need remedies. See also J.H. Barton (1995). For a recent and extremely well-documented report on the relationships between competition policy and the protection of intellectual property rights, see Federal Trade Commission (2003).

18 See A. Jaffe and J. Lerner (2004), pp. 104-107.

19 R. Barr, Vice President, Worldwide Patent Counsel, Cisco Systems Inc.

20 The Uruguay Round started in 1982 and was not concluded until 1994.

21 Precisely at the specialized National Cancer Institute (NCI).

22 In this case, the Food and Drug Administration (FDA).

23 After having been editor in chief of the *New England Journal of Medicine*, Marcia Angell, now at Harvard Medical School, wrote a well-documented book on these matters; see M. Angell (2004).

24 Claims 4 and 6 are the claims with the broadest reach made by Deuel. The complete "discussion" presented by the Court is reproduced in R.P. Merges (1997), pp. 595-598.

25 IPR for "Intellectual Property Rights".

26 Commission on Intellectual Property Rights (2002), p. 34.

27 Hence, the pressure put on many countries to enter into bilateral agreements to "improve" TRIPS; the resulting agreements are dubbed TRIPS+.

28 Now very much in doubt in the United States, following the CAFC Duke University vs. Madey decision in 2003.

29 See the first chapter of J. Tirole, C. Henry and L. Tubiana (2003).

30 Herbert Boyer (University of California at San Francisco) and Stanley Cohen (Stanford University) are the first scientists to devise a method for inserting into a bacterium a DNA fragment from a different organism, in such a way that the bacterium becomes able to produce proteins normally produced by the organism involved (human insulin for example).

31 Other major discoveries or inventions in biology and biochemistry were not patented at all, and their use is completely free. The Kohler-Milstein method for the in vitro production of monoclonal antibodies is a case in point. Their work was entirely funded by the Laboratory of Molecular Biology, Cambridge (U.K.) and was not patented (to the disgruntlement of then Prime Minister Margaret Thatcher). G. Kohler and C. Milstein were subsequently granted the Nobel prize in medicine.

32 This is known as the *Arrow effect*, introduced in K. Arrow (1962).

33 See C. Henry and M. Matheu (2001).

34 See J.H. Barton (1995), and F.M. Scherer (1998).

35 Interestingly, from the large set of data he has gathered, F. M. Scherer concludes that, statistically, to impose compulsory licenses on the firms considered had no effect on their subsequent propensity to innovate.

36 See C. Henry and M. Matheu (2001), and M. Armstrong, S. Cowan and J. Vickers (1994).

Here is a simple example. British Telecom (BT) was privatized in 1983. At the same time, a second operator called

Mercury was created from scratch, in order to introduce a measure of competition on the market for public telecommunications. This new operator quickly built, using brand new technology, new long-distance lines on links with high expected traffic (like London-Birmingham). It was, however, obviously impossible for Mercury to duplicate BT local networks. Hence, Mercury had to rely on the local networks (essential facilities) of the firm with which it had to compete (BT) for its long-distance services.

The regulator, also put in place in 1983, had to sort out the consequences of that awkward situation. The law had it that he should first try to mediate between the two firms. This led nowhere, due to the asymmetry of information in favour of BT: according to BT, the interconnection between its own local networks and Mercury's long-distance lines was technically very difficult; Mercury would therefore have to pay interconnection charges that were so high that its business would not be profitable. However, BT did not provide any precise figures on its costs, and without that information the regulator could not have an accurate idea of BT's interconnection costs. He and his staff of engineers and economists could, however, estimate a lower and an upper bound for these costs. BT pretended that its costs were above the upper bound; that, the regulator knew was not true, but he was not able to provide proof acceptable to the judges in case they would be involved in the conflict.

The regulator, still acting according to the law, then published a "draft determination", that is, he proposed a level for the interconnection charges. He deliberately chose a level near the lower bound. In so doing, he radically changed the conditions of the exchange of information with BT: henceforth, it was in BT's best interest to provide cost figures based on credible data in order to obtain somewhat better interconnection charges than those set in the draft determination. Thus, in the matter of the exchange of information, the regulator had reversed the situation.

[37] See B. Coriat and F. Orsi (2003).

[38] *AIDS drugs threatened,* front-page article in the *International Herald Tribune,* March 7, 2005. An opposition mechanism is created by the same law; however less convenient than the European one, its implementation is less constrained than in the case of compulsory licences.

[39] Software is presently the flagship of the open-source movement, but, as such, it is seriously threatened by the use of patenting: generalizing the patentability of software would place the open-source programmers under the permanent threat of infringement. This contributes to explain the opposition, among members of the European Parliament in particular, against the directive project promoted by the European Commission. Similar threats are looming in Africa, as shown in C.O. Sagara (2005).

[40] This is not science fiction. Indeed, in a Letter to *Nature* (February 10, 2005), W. Broothaerts and his co-authors report how they have been able to transfer into plants genes from bacteria other than *Agro bacterium tumefaciens*. The latter has been used and patented by Monsanto, in order to create the various genetically modified plants this firm sells: a foreign gene of interest, providing for example salinity resistance, is introduced in the bacterium (according to the Boyer-Cohen technique), and then transferred by the bacterium to the plant. Performing these operations while dispensing with *Agro bacterium* makes it possible to create genetically modified plants without infringing Monsanto's patents.