

## **The New Role and Status of Intellectual Property Rights in Contemporary Capitalism**

**(Draft : this version March 2006)**

Fabienne Orsi, Benjamin Coriat  
CEPN-IIIDE, CNRS, Université Paris 13

Even if the thesis has opened to a series of debates and controversies it is now accepted that one of the key features of contemporary capitalism is the new role played by finance and financial actors in the accumulation process. It has often been argued that the breaking down of fordism has opened the way to new types of accumulation regimes often characterized as “finance driven”<sup>1</sup>. The aim of this article is to shed some lights on another series of institutional changes, typical of the new capitalism and to our view complementary to the ones related to finance. The new institutional arrangements we would like to focus on in this paper, are linked to the spread of the so called « knowledge based economy ». They consist in the new importance given to intellectual property rights (IPRS) systems in the regulations of to day capitalism. If these new institutional arrangements should deserve attention it is because at the same time i) they have modified the classical foundations of what used to be patentable vs. non patentable matters, extending the patentability domain to areas where it used to be excluded ; ii) they operate in the heart of the most powerful current technological waves (biotech and ITC) iii) they are deeply interconnected with some of the new financial regulations recently introduced, in such a way that they form new « institutional complementarities »<sup>2</sup> ; iv) last but not least, they vest (especially with the signing of the TRIPS in 1994) an international dimension.

In order to discuss the meaning of these changes, the article is organized as follows.

1. The first section is dedicated to the presentation of the traditional role played by the type of IP systems that prevailed in the after second world war, during the fordist era.
2. The importance of the mutations that have taken place in these fields in the last 25 years, are then underlined
3. The institutional complementarities established between IPR and some of the financial regulations introduced in the last two decades are then presented along with the role they have played in the surge of the so called “new economy”.

---

<sup>1</sup> For a restatement of the debate on this point, see Coriat B., Petit P., Schmeder G, 2006

<sup>2</sup> About this notion and its significance see below (section 3).

4. The international dimension of the new regime and its key features are described.
5. A short conclusion tries to give a theoretical interpretation of the changes.

### **1. IPR's in the age of fordism: the classical economic foundations of patent regimes**

During the period of the after second world war, which is too the period of the “thirty glorious” of the fordist accumulation regime, in the USA and in Europe prevailed a well defined type of IP regime<sup>3</sup> which demonstrated to be very favourable to innovation.

The economic foundations of this regime were posed at the occasion of a series of reflections and debates that have followed the publication of the Bush report (Bush, 1945) and the discussion it has raised on the crucial role of basic science and fundamental research in the process of economic growth (Nelson, 1959)

Insert Box 1  
Around here

To really understand the issues at stake, we think useful to start with Arrow's contributions on the role of basic science. Since his seminal article (Arrow, 1962), it has been recognised that an economy composed of private, decentralised agents in competition is constantly threatened with under-investment in research. This is due to the indivisible nature of the good "information", including the products of research. Granting inventors a patent, in other words a “temporary monopoly” to exploit their inventions, is intended to provide a sufficient incentive for private firms to invest in research activities, by making up for the shortcomings of the market<sup>4</sup>. Fundamentally, therefore, the purpose of patents is to compensate for so-called “market failures”, while at the same time curbing monopolies and restrictive or discriminatory practices<sup>5</sup>, which would deprive the public of the benefits of the inventions. So, the "optimal" patent must create the right balance between two opposing requirements: - the encouragement of innovation on the one hand, and its diffusion at a reasonable cost on the other.

According to this view (that, until recently, used be to the dominant one in economic theory and public policies), all patenting systems should be governed by considerations of social

---

<sup>3</sup> For a definition of the notion of IPR Regime, see Box 1.

<sup>4</sup> Let's recall that a patent is classically defined as the exclusive but temporary right to enjoy the proceeds of an invention – including the right to prevent from competitors from using it.

<sup>5</sup> What competition law formalizes as "abuses of a dominant position".

welfare. While guaranteeing the incentive to innovate, such systems must limit the social cost of the protection given to innovators by restricting the rights conferred on patentees<sup>6</sup>.

Another key principle at the heart of IP regimes concerns the definition of “patentable objects”, in other words the “frontier” which separates information and knowledge which can be patented from that which cannot. On a purely theoretical level, the search for this frontier has stimulated, particularly in the United States, certain observations of crucial importance concerning the status of basic research. Following on from the work of Nelson (1959), Arrow, setting out a principle that would be subsequently a key reference in the field, stressed the need to distinguish basic research from other research activities. He argued that because it occupies a very “upstream” position in the R&D process, the specific purpose of basic research is to provide *common knowledge bases*, in other words *multiple-use inputs* for other research activities. The results of basic research are characterised by the fact that they can only be used for future advances in research or for the development of new products. Consequently, as any private appropriation of the results of basic research would work against the fruitful development of innovation, by impeding their use, Arrow contended that all researchers should have free access to these results, in the interests of public welfare.

In this approach, long recognised as the authority in the matter, the patent is seen as *a constituent element of a frontier between “upstream” and “downstream” research activities*. Only patents on downstream research products are considered capable of playing a positive role in the encouragement of innovation. It is important to note that this frontier principle also explains why basic research is described as the product of an “open science” type of organisation (Dasgupta and David, 1994)<sup>7</sup> and should remain so.

Up until the 1980’s, the governance of patent right was in accordance with the economic principles described above. In congruence with the “frontier” principle, *only “inventions” - and not “discoveries”- were considered valid subjects of patenting*<sup>8</sup>. Formally, this distinction between “discoveries” and “inventions” is specific to European patent law. Nevertheless, in

---

<sup>6</sup> Note that all patenting systems demand something in return. The inventor must reveal the contents of his invention, so that society can benefit from the new knowledge and other players can develop it further or invent around it. In accordance with this principle, patenting systems have always required a written description of the invention as a condition for the granting of the patent.

<sup>7</sup> Publicly funded and governed by formal and informal rules (such as publication, “priority rules” for inventors/discoverers...), the “open science” principle contrasts with the rules governing the world of private innovation activities, also called the “kingdom of technology” (based on secrets, patents and rent-seeking).

<sup>8</sup> Provided, however, that they meet the traditional criteria of patentability. To be patentable, an invention must be new, entail an inventive activity and be open to industrial application.

the United States, where the distinction is formally absent or irrelevant, other legal considerations led to the same practical end result. In Anglo-Saxon law, the “frontier” principle was established by the fact that an object could only be patented if the “practical or commercial utility” of the invention had been proved. This excluded scientific discoveries from the field of patentability . As Rebecca Eisenberg pointed out, until recently, in the United States the doctrine of “utility” clearly established that *scientific discoveries cannot satisfy the criterion of utility because they are considered "basic tools" of science and technology and as such they are too far-removed from the "world of commerce"* (Eisenberg, 1997).

To conclude on this point, it should be noted that the principles of “open science” characterized by free access to basic knowledge and patents granted to the sole inventions which utility was clearly established, proved to be very conducive to the creation and diffusion of innovation, this during the whole period of the fordist regime. In the domain of pharmaceuticals for instance, this period is known as the one of “golden age” of the industry. It is during that period and under the regime of open science, that the larger number of new molecules and drugs were conceived and marketed. (Orsenigo, Dosi, Mazzucato, 2005)

## **2. The 1980's and the establishment of a new regime for intellectual property rights**

Beginning with the 1980's however, some dramatic changes took place. The changes were so rapid and deep, than in less than 25 years, a completely new regime of IPR was established (Coriat and Orsi, 2002). The new regime first appeared in the USA,. So it is on the changes that took place in that country that we must focus on. As we shall show it, the new regime was installed by the means of a number of institutional changes which origin is at the same time “political” (new laws emanating from the Congress of the USA) and jurisprudential. A number of key courts rulings, regarding IPR disputes were delivered, In a country marked by the tradition of the *Common Law*, these rulings of course played a key role for the enforcement of the new regime.

### *Legal changes*

A series of changes of a legal nature were first introduced to open up the area of patents (and more generally IPR) to new players. In practice, these were the universities and research laboratories, authorised by the new legislation to file patents on the products of their research, even—and this is the noteworthy point—when the research in question is publicly funded. This step was taken in 1980 with the passage of the Bayh-Dole Act, which introduced a series of complementary arrangements. On the one hand, it authorised the filing

of patents on the results of publicly funded research<sup>9</sup>. On the other, it opened the possibility of transferring these patents to private firms in the form of *exclusive licenses* or creating joint ventures with such firms in order to take advantage of the knowledge thus transferred. This created the opportunity for such joint ventures firms either to trade on it or to make use of it to arrive at marketable products. A massive increase in the number of patents registered by university labs followed (Jaffé, 2000).

A clear indicators of the involvement of universities in patenting activity is given by their spectacular increasing licensing revenue. According to a recent survey on this issue : “ Beginning in 1991, university licensing revenue chiefly from patents increased nearly three times, passing from \$200 millions to \$550 millions in less than a decade” (Merill et al, 2004). However closer examination reveals that the large majority of this revenue is concentrated in few biological inventions and is captured by a small number of institutions. “The top 10 universities patent holders accounted for 66 percent licensing revenue in 2000” (id).

Even more profoundly, the Bayh-Dole Act was to bring about a fundamental transformation in the practice of academic research with the creation of technology transfer offices (TTOs) in the major American universities. While “in 1980 24 universities reported having technology transfer offices, by 2000, nearly all research intuitions had them” (Merill et al 2004). These bodies soon came to play a decisive role in the very orientation of research insofar as their activity is aimed at promoting ongoing research likely to permit the rapid filing of patents. In many cases, they were also to push for delaying the publication of scientific results by requiring prior filing of patents on the subjects covered by the publication (Owen-Smith and Powell (2001). The transformation introduced by the Bayh-Dole Act was decisive. In fact, until this law was passed, the prevailing doctrine in the area of patents had a considerably different orientation which, consistent with the economics of research as analysed by Arrow and Nelson<sup>10</sup>, attempted to compensate for the market shortcomings resulting from the ‘public interest’ nature of scientific information. The Bayh-Dole Act broke with this practice and the doctrine underlying it. With the introduction of the possibility of attributing the results of publicly-funded research in the form of *exclusive licenses to private firms*, the very foundations of the incentive to innovate through public grants lost both its meaning and its bases in the theory of well-being.

---

<sup>9</sup> It has to be noticed that the practice of patenting results from publicly funded research did exist before the Bayh-Dole, but only in well defined and restrictive conditions. The passing of the Act opened the way to the generalization of such a practice.

<sup>10</sup> Presented in section 1 of this paper.

The effects of the the Bayh-Dole Act were all the more profound that they took place in a context of general and dramatic changes of doctrine regarding patents and IP protection, largely fuelled by a series of key new court rulings that have largely modified the prevailing jurisprudence.

### *New Court Rulings: software programs and living entities as patentable matters*

The changes introduced by the new court rulings covered numerous issues, but the essential change consisted of enlarging the scope of patentability to cover objects which had not previously been included or were explicitly excluded from it<sup>11</sup>.

Two main areas are concerned here: computer software and living organisms. In the first, this development was reflected by the authorisation to patent *algorithms corresponding to the simultaneous use of mathematical equations*. In other words, elements of 'generic' knowledge currently used by the community of software programmers and designers were now patentable. The 1990s were thus to see the patentability of the famous "business models" for sales methods or financial services.

As a consequence of these changes the granting of software and internet patents surged. « ... [from 1992 to 1997] ... the USPTO granted 750 internet patents » But it is mostly after 1998 that the granting of such patents soared. More than 4 000 patents were granted in 1999, and nearly 5 7000 in the year 2000, mainly to software developers and to ICT companies. Between 1995 and 2000 the rate of increase of internet was estimated at 1 515 % » (I. Liotard, 2004). It has to be noticed too, that during the same period many Internet companies were promoted on the basis of the financial markets' evaluations of their intangible assets, which took the form of patents and other IPR on computer methods.

But the change was most radical and heavy with implications in the *life-sciences* field. Here, the breach was first opened by the well-known Chakrabarty ruling allowing General Electric to patent a micro-organism and this decision was the first in a long series which ultimately led to the patentability of genes and partial gene sequences. In the United States today, more than fifty thousand patents on gene sequences or partial gene sequences have been granted or filed, thus *opening up the way to a veritable commodification of scientific knowledge* (Orsi 2002; Orsi and Moatti 2001). In numerous cases, moreover, the patents granted cover not inventions of recognised utility but a wide range of future applications. By granting patents on basic knowledge itself (the input of future inventions), the American courts have also

---

<sup>11</sup> For a detailed presentation of the modifications, see (Jaffé, 2000) and (Coriat and Orsi, 2002).

protected not only the inventions described and disclosed but all the potential and virtual ones which might be derived from the use of patented knowledge.<sup>12</sup>

The changes in the IP regime on living organisms offer an exemplary demonstration of the process leading to the elimination of the distinction between ‘discoveries’ and ‘inventions’. In the past, this border clearly separated two worlds: that of the production of knowledge, constituted as the world of “open science” (Dasgupta and David 1994) and that of the commercial exploitation of these discoveries (the world of innovation) where industrial firms confront each other. The diffusion of the new regime to the European Union, gives ample illustrations of the kind of contradictions arising from the establishing of the new rules. (See Box 2 presenting the case of the 1998 EU Directive regarding on living entities)

Insert Box 2  
around here.

Finally it can argued that we are witnessing something like a “displacement of borders” inaugurating the era of the privatisation of the scientific commons, which firms can now break up and appropriate for their own use (Orsi 2002). These firms sign agreements with research laboratories (most often public) which result in the creation of bilateral monopolies, whereas free access had been the rule in return for public funding. Today, this unprecedented situation is denounced by highly important and influential sectors of the scientific community but also by private-sector innovators.

A general and rather critical assessment of the new IPR regime has been recently achieved by the powerful National Research Council of the American National Academies. The conclusions published under the names of Merrill and al (2004) confirm on numerous points the anxieties expressed by the scientific community and the authors call up to a series of reforms aiming at sitting on more solid grounds the granting of patents. These conclusions so come to strengthen those of many very influential who plead for return towards more balanced forms of protection, leaving more space to the principles of the open science (Heller and Eisenberg, 1998; Rai, 2000; Rai and Eisenberg, 2003; Nelson, 2003).

---

<sup>12</sup> In this respect, American jurisprudence broke with prior doctrine, for the precise description of the invention concerned in order to demonstrate its practical utility had been an essential criterion of patentability. In 1997, however a court decision (*Regents of the Univ of Cal v Eli Lilly and Co*) has stated that simply describing a method for isolating a gene or other component of a sequence of DNA is not sufficient to show possession and the complete sequence or other identifying features must be disclosed to have a patent granted. It is however too soon to evaluate the practical effects of such a tentative to put limits to the granting on genes on so called research tools (more on this issue in Merrill et al 2004)

The fact remains, however—and this point should be noted—that the transformations of IP have occurred with particular force *in the two major areas where powerful waves of innovation are developing today*. It is as if, after American industry's extremely pronounced losses of competitiveness in the 1980s, a reaction were organised in the new technology fields in order to allow firms to gain privileged access to the basic knowledge provided by the American science system through a new IP law.<sup>13</sup>

Since the famous book by Dertouzos et al (1989) published under the title *Made in America* many analysts have pointed out the fact that most of the rival firms of the American corporations (especially the Japanese ones) by spending few resources in basic research and concentrating their investments in development, were much more innovative than the US firms. In this context, no doubt that, by displacing the frontier of patentability towards more “upstream research”, it was expected to complicate the task of the American firms' rivals. Moreover, it is clearly no coincidence that that the two areas under examination constitute new and “emerging” fields in which American academic research has possessed in the past, and still possesses a considerable relative advantage. Everything has happened as if the new IP regime intended to ensure that these research advantages could be *immediately* transformed into competitive advantages, with the actual research product being directly covered at a very “upstream” level by patents, thus guaranteeing the right to exclude rival firms. As the present paper suggests, there is nothing accidental about the public authorities' decision to help “close” access to a discovery in order to preserve it in a patented form. Nor is it accidental that these patents are granted through *exclusive licenses*.

As important as these mutations may be, the role they play in the new regulations could not be fully understood, without taking into account their connections with a set of some other intuitional changes that were introduced at the same time or so in the financial sphere. As we shall show it, the institutional complementarities thus established between finance and IPR, were at the origin of a new and powerful models of innovating firms.

### **3. New financial regulations and the establishment of new institutional complementarities IPR/ Finance**

Concerning the formation of this new complementarity between finance and IPR, the things can be presented as follows.

---

<sup>13</sup> For a discussion of this point, see (Coriat and Orsi, 2002) as well as (Coriat, 2002). For the specific case of living organisms, see (Orsi, 2002).

### *Constitution of new kinds of financial markets specialised in the commodification of IPR*

The conversion of knowledge into merchandise (in the form of marketable IPR guaranteeing future rents) previously described, created the necessary conditions for the entry of finance capital into the space of the production of knowledge. The key step occurred in 1984 with the NASD<sup>14</sup> regulation authorising the market entry and listing of firms operating at a deficit on the condition that they had considerable 'intangible' capital, which was composed precisely of IPR. Known as 'Alternative 2', this regulation permitted the promotion of such firms (in deficit but holding a stock of IPR), no longer on the OTC market, which, with its limited liquidity, is not attractive, but on the First Market of the Nasdaq National Market.<sup>15</sup>

Other legislative and regulatory changes in the financial domain followed. The 'prudent man' law on pension funds was modified so as to authorise them to invest part of their holdings in risky securities and stocks which had previously been prohibited (Lazonick and O'Sullivan, 2000). In this way, part of the enormous liquidities concentrated in the pension funds expanding rapidly during this period allowed the financial markets to promote hundreds of new firms which were in deficit but deemed "high potential" in view of their intangible assets (Coriat, Orsi, Weinstein, 2003)

### *New institutional complementarities and the rise of the "New Economy"*

This is how a particular 'institutional complementarity' between intellectual property law and financial market regulations was set up within the context of the American national innovation system. The notion of institutional complementarity, which is now used in numerous studies dealing with the economics of institutions (Amable, 2000 ; Hall and Soskice, 2001 ; Coriat and Weinstein, 2002) was first introduced and defined by Aoki (Aoki, 2001). Drawing on North's definition of the role of institutions as 'rules of the game', Aoki emphasises that these rules are never absolute, that they always open up a space of interpretation and discretion for the actors' game. In this approach, the key idea is that it is necessary to consider not the influence which each institution taken in isolation exerts on the agents but the interactions which may be established between them and the opportunities which give rise to complementarity between *institutional arrangements belonging to seemingly distinct domains*.

In the case which concerns us here, the parallel, complementary changes in intellectual property law and financial regulations offered unprecedented possibilities to the actors involved in innovation processes. What is important is the aspect of the *institution conceived*

---

<sup>14</sup> NASD = National Association of Security Dealers, the body responsible for overseeing the regulation and security of Nasdaq transactions under SEC supervision.

<sup>15</sup> For a detailed account, see (Orsi, 2001) and (Coriat, Orsi, Weinstein, 2003).

as a 'resource' to be mobilised by the agents in the service of their strategies (Coriat and Weinstein, 2001). The coexistence of the formation of a new intellectual property law regime and the creation of an Alternative 2 within Nasdaq regulations to allow the introduction on the market of non-profitable firms whose assets were composed of IPR has permitted the launching of a very special kind of companies following unprecedented business models. It must be recognised that these new types of business models initially produced remarkable effects. A number of firms which have now become world leaders in biotechnology (Genentech), computer software (Oracle) or Internet (Yahoo, Google) greatly benefited from the new institutional framework to ensure their rapid development. Indeed, a large share of the supposed 'New Economy' owes its origins and its strength to this phenomenon. However, the financial crisis and the burst of the financial bubble (especially on Nasdaq) and the long series of bankruptcies that resulted from this episode, clearly highlighted the limits of such a model of promoting innovative firms.

Before analysing the diffusion of the new regime worldwide, let's recall the main criticisms addressed to the new system as it has been enforced in the US, and to a certain extent in Japan and in many European Union countries.

*Will innovation be boosted by the new regime ?*

To try to answer to this question the first series of changes to be considered is the extension of the domain of patentable matters, an extension that was largely based on the new rulings allowing the patenting of basic and upstream research. If these new provisions have favored the birth of a series of new specialized in the commerce of basic research (through the selling of licenses), on the other hand that, by displacing the border between 'invention' and 'discovery', the new IPR regime has undermined the delicate equilibrium which prevailed until now, destroying the logic underlying the production of innovations. Once access to knowledge becomes costly and subject to market strategies of pricing, the firms ready to involve themselves in innovative activities may be discouraged from doing so. The dangers which this situation brings to bear on the progress of scientific knowledge have been denounced by numerous analysts and observers. Thus, in the case where the innovation depends on a large number of cumulative advances (typical of sectors such as computer software and programs), Shapiro exposes the risk of 'hold-ups' where innovative new entrants are taken hostage by the large firms which have stocks of patents on the commonly used algorithms (Shapiro, 2001). In the area of living organisms, the risk lies in the development of a veritable "anticommons tragedy" (Heller and Eisenberg, 1998): when the

scientific commons are fragmented and appropriated by private firms for their exclusive use, there is great risk that research will be obstructed (Nelson, 2003).

If we consider more specifically the case of the United States and of the new institutional complementarities between finance and IPR generated by the regulations introduced in the last two decades, one has to admit that this new complementarities were in this country, at the origin of a new and original model of promoting innovative firms.<sup>16</sup> However this model of promoting innovating firms, which has been showered with praise and cited everywhere as something that has to be imitated and replicated, is now subject to profound re-evaluation. The contradictions generated by the new configuration were quick to produce their effects, for the promotion of firms whose main assets are 'intangible' created considerable problems of evaluation.<sup>17</sup> How do we determine the 'value' of a firm whose assets are composed of a patent on a gene? Or in the case of firms on the Internet, one which has a 'virtual' number of customers? Added to the players' mimetic behaviour on the financial markets (Orléan, 1999) and the many deficiencies of financial regulations as revealed by the Enron affair, these difficulties led to considerable financial over-evaluations and ultimately to the formation and subsequent explosion of one of the most remarkable speculative bubbles in the history of capitalism.

Nevertheless and in spite of the numerous criticisms that the system generated, it quickly extended at the world level. Because of the growing importance it vests, the international dimension of the new regime is the last aspect of the new regime, we would like to focus on.

#### **4. The TRIPS and the international dimension of the new regime**

To better understand the meaning of the changes that took place at this level, one has to remember that, up until 1994 and the signing of the TRIPS which meant the adoption worldwide of a new IP regime, and to which we shall come back soon, international treaties, at that time under the authority of World Intellectual Property Organization (WTO) recognised the right of different countries to implement *different* systems of protection, *according to their level of economic development and according to the products concerned*.

---

<sup>16</sup> This dimension of the new model is more completely exposed in (Coriat and Orsi, 2002) and in (Coriat, Orsi, Weinstein, 2003).

<sup>17</sup> Concerning the thorny problems raised by the evaluation of start-ups whose assets are mainly intangible, see (Dubocage and Rivaud-Danset, 2003).

Thus, in most of developing countries (DCs) prevailed a situation of no or very loose patent systems<sup>18</sup>. This is not at all surprising. Many studies demonstrate the clear correlation between the level of economic development of a country and the strength of its patent system. And if it is in the interest of most developed countries to grant patents to their innovative firms (to provide their firms and other “national champions” with some institutional advantages), most DCs, on the other hand, having no such firms and very limited technological capabilities, have the opposite interest. To favour their economic development, their interest is to install very loose or no patent systems at all, so that they can learn by “copying”, in the same way than current Developed countries did in the past<sup>19</sup>. The US for example, during a long period refused to recognize the patent rights granted to British firms by the patenting British authorities, using their right to “learn by copying” as long as it was their interest to do so.

It should be underlined that, the possibility of implementing different IPR rules, according to the level of economic development and the products concerned – a situation that prevailed until 1994 - was accepted because international agreements were founded on priorities of welfare and equity. The existence of such a differential regime (between developing and developed countries) was based on principles of public interest (as in the case of access to health care or food), or the promotion of sectors of vital importance for the economic and technological development of the industrializing countries (Coriat and Orsi, 2003).

Nevertheless, at the same time that a regime that was “internal” (to American law) was being dramatically changed as aforementioned, the U.S. government was committing itself to an active policy involving an *international defence and promotion of the new regime*. The actions and initiatives taken by the US authorities were aiming three series of interrelated objectives : i) enforce out of the United States the type and level of patent protection granted to the American firms in their domestic market; ii) attract the larger number possible countries to converge towards the US norms and standards as regards IP matters; iii) modify the international treaties to substitute to the prevailing arrangements one single set of provisions, enforcing at global level an homogenous system of IPR.

---

<sup>18</sup> This is clearly the case in pharmaceuticals, a situation that prevailed until the mid 1990s (Remiche and Destrebecq, 1996). But in many other areas most of the DCs choose very softy patent systems.

<sup>19</sup> To take the case of pharmaceutical products, the local production of “similar” or “generic” drugs is the only possible means to reduce the cost of treatment. Thus Brazil, for example, dispensed with any form of IPR for drugs from 1971 to 1996 (the date of TRIPS implementation in this country). This made it possible to establish a large industry for the low-cost production of generic drugs, the only way to ensure access to treatment for the poorer segments of the population (Orsi et al., 2003).

The main instrument of this action was the adoption, under “Section 301”, of the 1984 *Trade Act*, of a set of specific stipulations intended to promote and ensure international compliance with the IPR awarded to American firms by U.S. national entities. These provisions are regrouped into a specific sub-section of “Section 301” called “301 Special”, and entirely devoted to IPR. They were reinforced by the 1988 *Omnibus Trade and Competitiveness Act*, which still comprises U.S. law in this area<sup>14</sup>.

These provisions, upon which the US Trade Representative heavily relied, were used by the US public authorities, putting a number of countries under the threat of trade retaliation, to finalize bi-lateral trade agreements incorporating, in the chapters relating to IP protection, most of the US standards and norms.

The whole process culminated at the end of Uruguay Round negotiations under the auspices of the WTO, with the signing of the TRIPS<sup>20</sup>.

With the signing of the TRIPS<sup>21</sup> in 1994, the international protection of IPR, until then organised exclusively under the aegis of the WIPO, moved into the sphere of competence of the WTO (Zhang, 1994). This adoption of IPR protection into the domain of the WTO was of considerable importance. It signified the enforcement, for and on behalf of the WTO, of a new international standard, largely based on the standards of the most advanced countries. Coming after the considerable reinforcement of IPR in the Northern countries, the signing of the TRIPS heralded the enforcement of this new, stricter law on a worldwide scale (Reicham and Lange, 2000; Rémiche and Desterbecq, 1996). From this moment, the adoption of common “minimum standards” regarding IP protection covering all fields of activity, became mandatory for all member countries of the WTO. The signing of the TRIPS thus represents a radical break with some of the foundations and rules which had hitherto shaped international IP protection.

Given this context, the advent of TRIPS could only result in major conflicts. The economic gap between developed and less developed countries has not evolved, over the last few

---

<sup>14</sup> A more detailed analysis of the form in which such stipulations feature in successive versions of U.S. Foreign Trade law (until the 1988 *Omnibus Trade and Competitiveness Act*, which is still in effect) is offered in our article Coriat (2000). On this topic, see also Zhang (1994).

<sup>20</sup> It has to be noticed however that this process has not ended with the signing of the TRIPS. A series of Bilateral Free Trade Agreements (FTAs) continue to be signed by the US and DCs. These FTAs include sections on IPR that are considered as “TRIPS Plus” agreements since they incorporate higher standards of IP protection than those defined in the TRIPS agreement. On this issue see Corr ea (2004)

<sup>21</sup> Agreement available at [www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm)

decades, in any way that could justify the type of homogenisation of international IPR rules<sup>22</sup>. We have witnessed. Since their ratification, the TRIPS agreements, which had already provoked serious antagonisms between developing and developed countries during the Uruguay round of negotiations (Zhang 1994), has been the constant source of important discussions, the leading subject of which being the issue of Public Health and access to drugs in developing countries.

The Southern countries were quick to bring the issue of the impact of the TRIPS on public health care to the forefront. Because the TRIPS obliges these countries to introduce drug patenting protection identical to that of industrialised countries, the debate has crystallised around the issue of access to a series of generic drugs, hitherto produced cheaply by many Southern countries. When these countries become TRIPS-compliant, all production of generic copies becomes impossible. Consequently, the debate has centred on the question of access to HIV/AIDS treatments. This debate has been fuelled by the dramatic contrast between AIDS victims in the industrialised countries and those in the Southern countries that has appeared since the introduction (in 1996) of Highly Active Antiretroviral combination Therapies (HAART),<sup>23</sup> which provide longer and improved conditions of life. While the great majority of people affected by the disease live in Southern countries, the high price of the treatments produced by patentee firms renders their purchase by these countries almost impossible. Before generic ARVs came into the market, the price of HAART was around ten to twelve thousand dollars per person per year. Obviously, this prohibited access to care for almost all AIDS sufferers in Southern countries, where no health insurance system, even where one does exist, can support such a cost for each patient<sup>24</sup>.

Even if the TRIPS agreements contain some exceptions to exclusive patent rights (TRIPS, 1994, Article 30) and makes provision for "Other Use Without Authorization of the Right Holder" (TRIPS, 1994, Article 31), mainly under the use of compulsory licenses<sup>25</sup>, the signing

---

<sup>22</sup> On this point, see the very complete report of the Commission on intellectual property rights set up by the UK government: "Integrating Intellectual Property Right and Development Policy", London, September, 2002, available at [www.iprcommission.org](http://www.iprcommission.org)

<sup>23</sup> This treatment is called "tritherapy", as it combines three different ARVs.

<sup>24</sup> In the year 2000, with the arrival of generic copies, this cost fell to around 300 dollars per person per year, and it has continued to fall ever since.

<sup>25</sup> This legal tool allows WTO members to authorize themselves or third parties to use the subject matter of a patent, for reasons of public policy, without the permission of the patent owner (Reichman and Hasenzahl, 2002). In other words, the patentee must tolerate the exploitation of his invention by a third person or by a government. In this case, As Reichman and Hasenzahl point out, "*the public interest in broader access to the patented invention is considered more important than the private interest of the right holder to fully exploit his exclusive right*" (op. cit. p. 4). The practice of compulsory licensing is long established and has been used on numerous occasions by industrialised countries, including the United States.

of the TRIPS marks a turning point. As regards IP regimes and systems, the signing of the TRIPS means the entry into a new juridical « global order ». An order where the right to « learn by copying » - abundantly exploited by to day developed countries as long as they needed it, is now denied to the new comers and pretenders. This, in a period when every agrees on the fact that more than ever, access to knowledge is a key condition and component of the process of economic development

## **5. To Conclude : the post TRIPS IPR Regime as a new International Regime**

To seize well the situation which we entered after 1994, and which according to us marks the birth of real IPR International Regime, it is necessary to remind, even briefly, some of the key features which prevailed before the signature of the TRIPS.

Before the signing of the TRIPS agreement in 1994, international relations in these matters were governed by very loose common rules. International relations in the field of IP protection were governed by only two important Treaties (Berne and Paris) which imposed few constraints on the signatory countries. If there was such a thing as an “international regime”, which is debatable, it would certainly have to be described as “weak”, in that the internationally recognised rules were both few and lax.

Signatory countries enjoyed great latitude to define their own “national IPR codes. The result was a wide heterogeneity of situations<sup>26</sup>.

At this light, there is no doubt that the signing of the TRIPS agreement heralded an unprecedented new stage in the status of IPR in international relations. Compared with the previous state of international relations in these fields, four series of changes should deserve attention.

- i) Firstly, IPR was established as a component and integral part of international trade. IPR agreements, now negotiated within the framework of the WTO, were a constituent part of trade treaties. The very name TRIPS (Trade Related Intellectual Property Rights) is quite explicit about the new status attributed to IPR in world trade agreements.

---

<sup>26</sup> So in the drugs sector, for example, as we have already pointed out, strong protection was granted to both processes and molecules in the US and most European countries, whereas Brazil hadn't recognised patents on either processes or molecules since 1970, and India recognised no patents on molecules, the copying of patented drugs being perfectly legal in both these countries.

- ii) Within this new framework and context, what were called “minimum” standards were imposed on all signatory countries: these affected the very essence of national IPR codes, and if they didn’t concern every subject, they covered the essential aspects<sup>27</sup>; they thus brought an end to the situation of heterogeneity that had prevailed before 1994 and to the large degree of autonomy and freedom which each country had hitherto enjoyed in the drafting of its national IPR law.
- iii) An IPR Council was established within the WTO, responsible for the development of common standards, the modification of existing rules and, if necessary, favouring the formation of new rules; it was this Council which issued the Decision of 30 August 2003 which, on several very important points, modified the state of rules negotiated in Marrakech on the import and export of generic drugs<sup>28</sup>.
- iv) Finally, the DSB (Dispute Settlement Body), competent to make rulings in trade disputes, was also given competence over IPR disputes. Thus the United States lodged several complaints against developing countries (Brazil, in particular), which the US accused of not meeting the new “standards” imposed by the TRIPS agreement.

By the standards of the now classic definition of an “International Regime” as “explicit or implicit sets of principles, norms, rules and negotiation procedures in terms of which actor expectations converge on a field of international relations and through which the individual behaviour of these actors can be coordinated”<sup>29</sup>, there is no doubt that the situation created by the TRIPS agreement in the field of IPR can be considered an international regime<sup>30</sup>.

Given the nature of the new rules of the game that are now enforced worldwide, it is no surprise to observe that the new International Regime has already caused major conflicts, notably but not only in public health affairs. Given that their effects on North-South trading, such as we can begin to assess and measure them (Aboites and Cimolli, 2002) seem to be totally incapable of dissipating trade-related inequalities (contrary to what proponents of this policy have purported), one can expect that in the future new conflicts will emerge and grow.

---

<sup>27</sup> Thus specifying, in the name of “minimum standards”, features such as the definition of patentable matters and the duration of protection (harmonised to the 20-year standard of the most developed countries), features which are essential components of national IPR codes and which, before the signing of the TRIPS agreement, were left largely to the discretion of each country’s legislation.

<sup>28</sup> On this issue see

<sup>29</sup> (Conference on International Regimes, Los Angeles 1980; cited in J. A. Finlayson and M. W. Zacher, “The GATT and the regulation of trade barriers: regime dynamics and functions”, *International Organization* 35/4 (1981), 563)

<sup>30</sup> More generally on the notion of International Regime see Krasner (1983), Keohane (1984) and (1993) and for a restatement : Keabadjian (1998).

More generally if the whole process is considered from a theoretical point of view, we must observe that, underlying the current malaise is the fact that in the new IP doctrine, the very reference to the theory of welfare is in upheaval. "Social" usefulness no longer seems to provide the foundation for patents and other IPRs. Instead, a chain has been set up with a view towards providing those firms that benefit from the new IPR with relative advantages that are developed institutionally, the implied argument being that what is good for them is necessarily good for the world economy.

If the world's economies have truly become more knowledge-intensive, cutting off access to knowledge (through an extension of patents, which are nothing but pure institutional barriers) is surely not the most suitable way to help developing countries to grow. If we expect that, in a not too long period, DC's could be able to make their own contribution to the overall growth and global welfare, very different provisions than the one recently introduced as regards the patent systems have to be enforced. If the goal is to go from a system that is constantly leading to confrontation to one that highlights co-operation, it is urgent that the rules relating to TRIPS be reviewed and redefined.

Envisaged from the point of view of the *Regulation Theory*, one has to admit that indeed, new regulations are taking place. And in a way, these new regulations are at odds with the transformations of the real world. A key feature of the new situation is that with the spread of the knowledge based economy we have witnessed a dramatic change in the patent systems, as if the rich countries wanted to take some institutional guarantees regarding the sharing of the actual and future rents to be extracted from the new technological waves. As we have pointed it already it is no surprise if the main changes in the IP regime have taken place on ITC and Biotech. Moreover, it is remarkable to observe that some of the new regulations have installed the dominance of finance and financial actors in the world of science and technology. The process of commoditization of basic research previously described is certainly of major importance for the future of our societies.

Obviously, the Fordism, with a type of production of knowledge organized around the principles of "open scene", is dead. What is succeeding however seems heavier of risks and threats than of positives promises.

## Box 1

### In what sense can we speak of an IPR *Regime*?

In this paper the concept of IPR regime is defined on the basis of a set of laws and/or juridical rules which codify the conditions under which agents (firms, organisations, individuals...) can assert their rights in terms of IP.

These rules (which fall within the domain of substantive law) constitute a veritable Code of IPR. They can be divided into three main categories.

- i) Those which define what can and cannot be patented (patentable matters); in continental law this concerns the frontier between “discoveries” and inventions”.
- ii) Those which define the conditions of patentability: (in practice, 3 sets of basic conditions are required, relating to novelty, non obviousness and utility.
- iii) Lastly, those which define the nature of the protection accorded to the patent holder: the duration and scope of the patent (i.e. the nature of the patent holder’s claims recognised).

In addition, a set of institutions are needed to enforce these rules; the main ones involved are the following:

- i) The Patent Office, which examines patent requests and grants rights of variable scope (on the basis of the claims submitted by the applicants).
- ii) Courts of justice (more or less specialised, depending on the country), which rule on conflicts in the interpretation of these claims or against alleged infringers upon request by patent holders
- iii) IP consultants and lawyers who patent applicants or holders.

For a long time, these rules, like the nature and relative power of these different institutions, varied considerably from one country to another, giving rise to IPR regimes of national or at best regional scope.

## Box 2

### The 1998 EU Directive and the extension of the new IPR Regime to Europe

On July 6 1998, the European Parliament and the European Council adopted directive 98/44/CE on the legal protection of biotechnological inventions (Directive 98/44/CE).

According to its supporters, the aim of the directive was to carry out a simple adaptation of the traditional regime of patentability to include the protection of biotechnological inventions, and to favour the standardisation of the legislation of different member countries by clarifying the interpretation of the law in the field of biological material. According to M. Rothley, MEP, rapporteur on the directive proposal for the legal committee of the European Parliament, the fundamental message of the directive was to specify that patent law also applies to living matter and all inventions concerning it provided that the traditional conditions of patentability are respected (Rothley, 1999). More generally, according to the European legislators, *"living matter is unquestionably patentable. This is not an invention of the directive, but the recognition of a situation in accordance with existing law"* (Directive 98 /44/CE, p 8381).

However, this interpretation of "existing law" has been fiercely contested by many players. One of the key arguments of opponents to the patentability of genes is that they should be excluded from patent law because they are incompatible with article 52a of the European Patents Convention (EPC) which excludes "discoveries" from the field of patentable matter.

Today, after various modifications, the Directive is presented as a *text of compromise* between the different institutions of the European Union. The essential "compromise" is expressed in the particularly convoluted text of Articles 5.1 and 5.2 of the Directive. Article 5.1 stipulates that: *"the human body, at the different stages of its constitution and development, as well as the simple discovery of one of its elements, including a gene sequence or partial gene sequence, cannot constitute patentable inventions"*. According to the legislators, the aim of this article is to respect the principle of the exclusion of discoveries from European patent law, while also meeting the ethical requirements of non-commercialisation of the human body. However, the legislators also specify that when elements of the human body are isolated or produced using technical processes, then these procedures can be recognised as patentable inventions. This is what article 5.2 stipulates: *"An element of the human body that is isolated or otherwise produced using a technical process, including a partial gene sequence, can constitute a patentable invention, even if the structure of this element is identical to that of a natural element"*.

Notwithstanding the ambiguity of these two articles and despite the legislators' affirmations that this directive does no more than adapt European patent law to a new domain without altering its specificities, it is clear that the principle of the frontier between "discoveries" and "inventions" – one of the explicit foundations of patentability in Europe – has been totally destroyed, in favour of an adaptation of the norm of gene patentability in force in the United States.

Intended for transposition into the national legislation of the members of the European Union on July 30 2000, the directive remains hotly contested to this day, and certain countries have still not incorporated it into their national law. It is noteworthy, however, that in spite of the controversies still provoked by this directive in certain members of the European Union, the granting of patents on human genes already constitutes an effective practice of the European Patent Office (EPO)<sup>(\*)</sup>

At a time when the sustainability of the American model is being fiercely contested, it is to be regretted that Europe has not been capable of launching a real debate on the economic grounds for the introduction of such a patentability regime. Today, such a debate, using the lessons to be drawn from the American experience, would provide an opportunity for serious reflection on an alternative European path that could guarantee progress in research and the production of innovations in the life sciences.

---

<sup>(\*)</sup> As demonstrated, for example, by the granting of three European patents on the BRCA1 gene and all the diagnostic and therapeutic methods connected with this gene to the American firm Myriad Genetics. However, it should be noted that these three patents are the subject of several appeal procedures at the EPO, principally on the grounds that they block the development of new genetic testing techniques and have pernicious effects on public health systems. The significance of this conflict is explored in details in Orsi, Coriat (2005).



## References

- Aboites J. et Cimolli (2002) « Intellectual Property Rights and National System of Innovation. Some Lessons from the Mexican experience » in *Revue d'Economie Industrielle*, n° 19,
- Amable, B. (2000), "Institutional Complementarity and Diversity of Social Systems of Innovation and Production", *Review of International Political Economy*, n°7 (4), pp.645 - 687.
- Aoki, M. (2000) *Information, Corporate Governance and Institutional Diversity*, Oxford University Press.
- Arrow, K., (1962), "Economic Welfare and allocation of resources for invention" in R. Nelson, ed, *The Rate and Direction of Inventive Activity*, Princeton University Press, Princeton.
- Bayard T. et Elliott K. (1994) *Reciprocity and Retaliation in US Trade Policy*, Institute for International Economics, Washington DC.
- Bhagwati J. (1991) *The World Trading System at Risk*, Princeton University Press.
- Bush, V. (1945), *Science: The Endless Frontier*, available at: <http://www1.umn.edu/scitech/assign/vb/VBush1945.html>
- Coriat, B., Orsi, F., Weinstein, O., (2003) "Does Biotech reflect a New Science-Based Innovation Regime ?", *Industry and Innovation*, Vol. 10, p.231-253.
- Coriat B., and Orsi F. (2002) "Establishing a new Intellectual Property Rights Regime in the United States. Origins, Content, Problems", *Research Policy*, forthcoming.
- Coriat, (2002) "The new regime of intellectual property rights and its imperial dimensions – Implications for North/south relations, commutation to the 25<sup>th</sup> anniversary of BNDS, Rio de Janeiro.
- Coriat, B. and Weinstein, O. (2002), "Organizations, Firms and Institutions in the Generation of Innovation", *Research Policy*, vol .2, p.
- Coriat, B., Petit, P., Schmeder, J. (2006) *The Hardship of Nations – Exploring the paths of modern capitalism* ; Edward Elgar, forthcoming
- Cooréa C. M, (2004) "Bilateralism in Intellectual Property: Defeating the WTO system for access to medicines", *Case Western Reserve Journal of International Law*, vol 36 n°1, Wintre
- Dasgupta, P. and David P.A., (1994), "Towards a New Economics of Science", *Research Policy*, vol. 23, 487-521.
- Dertouzos, M., Lester, R., Solow, R., 1989, *Made in America*, MIT Press.
- Directive 98/44/CE du parlement Européen et du Conseil du 6 juillet 1998 (1998), "Protection Juridique et Inventions Biotechnologiques", *JOCE*, N° L213, 30 juillet.
- Dubocage, E., and D. Rivaud-Danset (2003). "L'organisation des échanges sur le marché du capital-risque." *Revue d'économie industrielle* , Vol 101, p.
- Eisenberg, R. (1997), "Property Rights and the Norms of Science in Biotechnology Research", *Yale Law Journal*, vol.97, pp.177-231.
- Hall, P. and Soskice, D. (eds) (2001), *Varieties of capitalism*, Oxford University Press.
- Heller, M and Eisenberg, R. (1998), "Can Patent Deter Innovation ? The Anticommons Tragedy in Biomedical Research", *Science*, Vol, 280, pp.698-701.
- Jaffe, B. J., 2000, The US patent system in transition: policy innovation and the innovation process, *Research Policy* vol.29, pp.531-557.
- Kebabdjian G. (1998) La théorie de la Régulation face à la problématique des Régimes Internationaux", in *L'Année de la Régulation*, vol 2, pp. 101-127
- Keohane R. (1984) *After Hegemony, Cooperation and Discord in the World Political Economy*, Princeton University Press
- Keohane R. (1993) "International Theory and the realistic challenge After the Cold War", in Baldwin R. Neorealism and Neoliberalism : The contemporary debate, Columbia University Press
- Krasner S. D.(ed) (1983) *International Regimes*, Ithaca, Cornell University Press

- Liotard I. (2004) (2004) "Les brevets sur les méthodes commerciales : état de lieux et perspectives économiques », *Propriété Intellectuelle*, n°11
- Lazonick, W., O'Sullivan, M., 2000, "Maximising Shareholder Value: A new Ideology for Corporate Governance", *Economy and Society*
- Merrill S., Levin R., Myers B. (2004) *A patent System For The 21<sup>st</sup> Century*, The National Academies Press, Washington DC, www.nap.edu
- Nelson, R. (2003), "The market Economy and the Scientific commons" *Working Paper, International and Public Affairs*, Columbia University.
- Nelson, R.R. (1959), "The Simple Economics of Basic Scientific Research", *Journal of Political Economy*, vol.67(3), pp.297-306.
- Orléan, A. (1999). *Le pouvoir de la finance*. Paris: Odile Jacob.
- Orsi, F., Coriat, B. (2005), "Are "strong patents" beneficial to innovative activities? The case of genetic testing for breast cancer" *Industry and Corporate Change*, à paraître.
- Orsi, F. (2002), "La constitution d'un droit de propriété intellectuelle sur le vivant aux Etats-Unis : origine et signification économique d'un dépassement de frontière", *Revue d'Economie Industrielle*, Special issue on Intellectual Property Right, Vol. 99, pp65-86.
- Orsi, F. (2001), *Droits de propriété intellectuelle et marchés financiers dans les nouvelles relations science/industrie, le cas de la recherche sur le génome humain*, Phd Thesis, University Aix-Marseille II.
- Orsi, F., and J.-P. Moatti (2001). "D'un droit de propriété intellectuelle aux firmes de génomique : vers une marchandisation de la connaissance scientifique sur le génome humain." *Economie et Prévision*, Vol. 150-151, pp. 123-138.
- Orsi, F., Hasenclever, L., Fialho, B., Tigre, P., Coriat, B. (2003), 'Intellectual Property Rights, Anti-Aids Policy and Generic Drugs: Lesson from the Brazilian Public Health Program', in, J.P. Moatti, B. Coriat, Y. Souteyrand et al.(eds) *Economics of AIDS and Access to HIV Care in Developing Countries. Issues and Challenges*: ANRS editions. pp. 109-135.
- Orsi F., Coriat B. (2005)
- Owen-Smith, J. et Powell, W. (2001), "To patent or not : Faculty decision and Institutional success at Technology transfers", consultable sur site : jdos@stanford.edu.
- Rai, A. (2001), "Fostering Cumulative Innovation in The Biopharmaceutical Industry : The Role of Patents and Antitrust", *Berkeley Technology Law Journal*, vol 16, (2), p.813-853.
- Rai, A. et Eisenberg, R. (2003), "*Bayh-Dole Reform and the progress of biomedicine*", *Law and Contemporary Problems*, Vol.66, p.289-313.
- Reicham, J. and Lange, D. (2000): 'Bargaining around the Trips Agreement: The case for ongoing public-private initiatives to facilitate worldwide intellectual property transactions', *Ducke Journal of comparative & International Law*, vol.9 (11). pp. 11-68.
- Remiche, B. and Desterbecq, R. (1996), 'Les brevets pharmaceutiques dans les Accords du GATT: l'enjeu?', *Revue Internationale de Droit Economique*, vol. 1. pp. 7-68.
- Rothley, M.W (1999), "La difficile entrée des biotechnologies dans le domaine des brevets", dans *Les inventions biotechnologiques - Protection et exploitation*, Litec, p9-15.
- Shapiro, C. (2001), "Navigating the Patent Thicket :Cross Licenses, Patent Pools, and Standard-Setting", NBER Conference on "Innovation Policy and the Economy".
- United States Patent and Trademark Office (2001), "Utility Examination Guidelines", *Federal Register*, vol. 66, p.1092-1099.
- Zhang, S. (1994): *De l'OMPI au GATT - La protection internationale des droits de propriété intellectuelle*, Paris: ITEC.