

IPR, Innovation and Public Interest.

Is the new IPR regime enforced worldwide by the TRIPS sustainable?

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Abstract: This paper discusses about the implications of the emergence of a new IPR regime in three dimensions: (1) the basic an upstream research; (2) the North-South trade-related inequalities and conflicts; and, (3) the social usefulness of patent grants. The article pays major attention on IPR over healthcare and alive organisms and its threathment in TRIPS agreement.

Key words: intellectual property rights, TRIPS agreement, patent systems, Development.

JEL: O19, O33,O34.

1. Introdução

The aim of this position paper is to question the content and some of the practical implications of the new intellectual property rights (IPR) regime that is being enforced at world level. The new regime in facts consist in a series of key new institutional arrangements regarding the IP protection granted to innovative firms.

If these new provisions should deserve attention it is because at the same time i) they operate (and to tell the truth were implemented first) in the heart of the current new technological waves (biotech and ITC), ii) they have modified the foundations of what used to be patentable vs.

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non patentable matters, extending the patentability domain to areas where it used to be excluded; iii) last but not least, they vest (especially with the signing of the TRIPS in 1994) an international dimension, introducing in DC's and LDS's a type a patent regime that was designed in (and for) the most developed countries. It is worth noting that even in these countries (the most developed ones) some of the key provisions introduced by new regime are under serious critique, many observers being questioning wither the enforcement of the new regime is indeed favorable to innovation.

In order to discuss the changes introduced by the new regime, especially from the point of view of developing countries, the article is organized as follows. 1) The first section is dedicated to the presentation of the economic foundations of IP systems that prevailed in the after second world war, up until the end of the 1970's. 2) The importance of the mutations that have taken place in these fields in the last 25 years are then underlined. 3) The international dimension of the new regime is recalled. 4) Taking the case of the new status provided by the TRIPS to pharmaceutical patents, an illustration is given of the serious problems generated by the enforcement of the new IP regime in DC's.

2. IPR and Innovation: economic foundations of patent regimes

Up until the 1970's in the USA and in Europe prevailed a well defined type of IP regime 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, after the 2WW, 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)

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”. 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 market allocations.¹ 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,² which would deprive the public of the benefits of the inventions. So, a well designed patent system must find the right balance between two opposing requirements: – incentives to invest in R&D activities and 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, at the end, be governed by considerations of social 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 patentees³ thus protecting the public interest.

Another key principle at the heart of IP regimes concerns the definition of “patentable objects”, in other words the “frontier” which separates the type of 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 be adopted and developed by other authors,⁴ 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).⁵

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.⁶ Formally, this distinction between “discoveries” and “inventions” is specific to European patent law. Nevertheless, in 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, were at the heart of patent systems, all over the world. It is noteworthy too, that such systems, enforced, after the 2WW and up to the 1970 proved to be very conducive to the creation and diffusion of innovation. In the domain of pharmaceuticals for instance (to which we shall come back⁷), 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, 2006).

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

Beginning with the 1970'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 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.

The passing of Bayh-Dole Act and its meaning

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 new and often complementary arrangements. On the one hand, it authorised the filing of patents on the results of publicly funded research.⁸ On the other hand, 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).

Even more profoundly, the Bayh-Dole Act was to bring about some fundamental transformations in the practice of academic research with the creation of technology transfer offices (TTO) in most of the major

American universities. 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.

The transformation introduced by the Bayh-Dole Act was decisive. 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. Thus the Bayh-Dole broke with this the classical doctrine underlying the granting of patents.

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

During the same period, as a result of court decisions, following a ‘jurisprudential’ path coherent with the American tradition of common law, intellectual property law itself was modified. These modifications 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.⁹

Two main areas are concerned here: computer software and living organisms. For computer software this development was first achieved by the authorisation given 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. A second stage was reached with, during the patentability of the famous “business models” for sales methods or financial services (more on this in Coriat and Orsi 2002 and 2003).

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 and protect 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 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.¹⁰ 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.

We have now witnessed a clear “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.

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. In the years preceding the establishing of the new regime, many analysts had 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 (see for example the famous book by Dertouzos et al, 1989). 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 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, their impact cannot be correctly envisaged if the changes introduced at the international level are not taken into account.

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 to which we shall come back soon, international treaties (at that time under the authority of World Intellectual Property Organization – WIPO) 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.

Thus, in most of developing countries (DCs) prevailed a situation of no or very loose patent system.¹¹ 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.¹² 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.

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 inter-related 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.

The main instrument of this action was the adoption, under “Section 301”, of the 1984 Trade Act, 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 en-

tirely devoted to IPR. They were reinforced by the 1988 Omnibus Trade and Competitiveness Act, which continues still comprises U.S. law in this area.¹³ 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 and retorsion, 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.

With the signing of the TRIPS¹⁴ 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 WIPO, 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 the same IPR regime, 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 IPR protection. It is noteworthy that the end of the “differentiated regime” that prevailed until then, clearly put “the world trade system at risk” (Baghwati, 1991).

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 decades, in any way that could justify the homogenisation of international IPR rules.¹⁵ Since its ratification, the TRIPS agreement, which had already provoked serious antagonisms between developing and industrialised countries during the Uruguay round of negotiations (Zhang 1994), has been the constant source of important discussions, the leading subject of which has been the issue of access to drugs in developing countries.

In the last section of this paper, we focus on this issue.

5. An illustration: pharmaceutical patents and public health under the TRIPS agreements

In the field of pharmacy and access to health care, the TRIPS agreement provoked dramatic changes. To appreciate the full impact of these changes some background knowledge of the status of drugs in the legal framework of patents and IPR is needed. We shall therefore start with a short description of the status of drug patenting.

A brief survey of drug patenting

The creation of new drugs (i.e. the design of new molecules with proven therapeutic properties) is highly R&D intensive, and the “productivity” (i.e. the number of molecules discovered as a ratio of the money invested) is relatively low.

For these reasons, the granting of patents to the originators of new drugs is one of the ways found to favor the private investment in this field. However as we have already noticed it, theoretical arguments underlying the granting of patents, also affirm that the protection (and the monopoly of exploitation) thus granted should not have too high a cost in welfare terms.

It should be pointed out that in the case of pharmaceuticals, such welfare considerations are even stronger, given that access to drugs and treatments is regarded as a “basic need”. Furthermore, complex insurance systems (either private or public) are required to make the demand affordable and to guarantee public access to medicines.

These are the reasons why, even in most developed countries, no patent system on molecules was introduced until the 60’s, or even (in the case of Switzerland) the 70’s¹⁶ (Sherer 1993). Nevertheless, during the same period, the pharmaceutical industry made spectacular progress. By the use of intense reciprocal reverse engineering, copying and “inventing around” the molecules, the large Western firms were able to build enormous technological capabilities, whilst at the same time efficiently serving the public interest. It is worth noting that the pharmaceutical industry thrived during that period. One explanation for this is that firms

can use a number of methods other than patents (secrecy, lead-time, etc.) to ensure they benefit from their innovations. In addition, the cost of entry into R&D-intensive industries is so high that it generally creates huge “barriers to entry”, under the protection of which innovative firms can enjoy the benefits of their innovations. Moreover, “brand” names for established pharmaceutical firms provide a huge competitive advantage. Established firms, by segmenting the markets and raising the price of branded products, are generally able to maintain their profit levels, even after patent expiry and the entry of generic products.

The *TRIPS* Agreement and the rise of public health controversies in Global fora

With the signing of the TRIPS 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). From this moment, the adoption of the same IPR regime, covering all fields of activity, became mandatory for all member countries of the WTO. The signing of the TRIPS¹⁷ thus represents a radical break with some of the foundations and rules which had hitherto shaped international IPR protection.

We must underline the fact that before this agreement was signed, international treaties had 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. Among these products, essential drugs, considered “basic necessities”, were ranked of the highest importance. Thus, before the signing of the TRIPS, many countries dispensed with any form of IPR for drugs. This made it possible for some of them (Brazil, Thailand, India among others) 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 (for a detailed analysis of the Brazilian case see Orsi et al., 2003).

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 decades, in any way that could justify the homogenisation of international IPR rules.¹⁸ Since its ratification, the TRIPS agreement, which had already provoked serious antagonisms between developing and industrialised countries during the Uruguay round of negotiations (Zhang 1994), has been the constant source of important discussions, the leading subject of which has been the issue of 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 legislation identical to that of industrialised countries, the debate has crystallised around the issue of access to certain generic drugs, hitherto produced cheaply by certain Southern countries. When these countries become TRIPS-compliant (2005 being the deadline for the compliance of most of the DC's), all production of generic copies becomes impossible.

Because of the dramatic dimension taken by the AIDS pandemic, the debate has centered 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),¹⁹ 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.²⁰

The TRIPS agreement contains certain 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). One example is compulsory licensing. 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.

It should be noted that the TRIPS does not define the grounds on which the issue of compulsory licences can be justified. It only recognises such grounds as “anti-competitive practices” “national emergency or other circumstances of extreme urgency” or “public non-commercial use” (TRIPS, 1994, Article 31b). Nevertheless, article 31 of the TRIPS stipulates the conditions governing the issue of compulsory licensing, including “case-by-case authorisations, adequate remuneration based on the economic value of the license, prior negotiations with rights holders”.

However, another condition, specified in article 31.f, is of particular importance to us in this chapter. According to this article, compulsory licenses should be granted “predominantly” to supply the domestic market. This means that the use of compulsory licensing for export to countries without sufficient manufacturing capacity is very limited. Consequently, although the TRIPS agreement does not prevent members from using compulsory licences for import purposes, in practice this use is highly limited by the restrictions on exporting goods produced under compulsory license. It is thus practically impossible for countries lacking technological capabilities to use compulsory licensing effectively, and this fact lies at the origin of the vast debate on the relationship between TRIPS and access to drugs. Initiated in 2001 by the Africa Group of the TRIPS Council this debate aims explicitly to clarify the interpretation and application of TRIPS provisions in the context of public health. The move by Southern countries to provoke this debate within the TRIPS Council was motivated by a number of recent events illustrating the effects of TRIPS on public health policies. Among these, the most significant was clearly the lawsuit brought by the Pharmaceutical Industry Association and thirty-nine of its affiliate pharmaceutical companies against the Govern-

ment of South Africa, alleging that its Medicines and Related Substances Control Amendment Act violated the TRIPS agreement. Although the pharmaceutical industry finally withdrew its complaint, under the strong pressure of national and international public opinion, this lawsuit indicated the urgency with which Southern countries had to “initiate discussions on the interpretation and application of the relevant provisions of the TRIPS Agreement, with a view to clarifying the flexibilities to which Members are entitled and, in particular, to establish the relationship between intellectual property rights and access to medicines” (TRIPS Council Report, 2001).

In June 2001, the TRIPS Council held its first session devoted to TRIPS and access to drugs and in November 2001, the fourth Ministerial Conference of the WTO in Doha adopted a Declaration on TRIPS and Public Health²¹ (the Doha Declaration).

The Doha Declaration of 2001

In this chapter, we shall not go back over the negotiations that preceded the Doha Declaration. We simply observe that this declaration constitutes a “compromise” text: – the result of grim negotiations, most often pitting the Southern countries against certain industrialised countries who proposed that exceptions should be limited to cases of health crisis and not applied to health in general, arguing that exceptions made for the protection of public health would be inconsistent with TRIPS.

It should also be noted that this declaration has no legal status. However, many observers agree that it is of great importance, above all because, while accepting that protection of intellectual property remains a highly incentive measure for the development of new drugs, the Declaration explicitly acknowledges that IPR can damage public health through their effect on the price of drugs. It is on these grounds that the Declaration affirms the right of countries to interpret and apply the TRIPS in the best way to protect public health. The primary aim of the Doha Declaration is to reaffirm the possibility of recourse to the exceptions provided for in the TRIPS by clarifying the way in which these exceptions can be used by WTO members. In this spirit the Declaration states in its 1st paragraph that

“We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (The Doha Declaration, 2001, Article 1).

Thus the Declaration specifies notably that: “Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted” (The Doha Declaration, Article 5b); “Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency” (The Doha Declaration, Article 5c).

In addition to the clarification of existing rules, the Doha Declaration set two specific new tasks. Among them it mandates the Council to find to provide a solution to the problem posed by Article 31 (f) for countries with little or no drug manufacturing capacity. This is set out in the famous paragraph 6 of the Declaration: “We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002” (The Doha Declaration, Article 6).

For many observers, the Doha Declaration represented an important clarification of the issue and appeared to herald the relaxation of restrictions weighing on the least developed countries. But these observers were to be heavily disappointed. The declaration should have been incorporated into WTO rules by December 2002 at the latest. It never was. The negotiations held for this purpose in Geneva at the end of 2002 came to nothing. The United States vetoed a compromise which had been accepted by all the 123 other countries taking part in the negotiations. It was only in August 2003, after bitter negotiations, that a text specify-

ing the conditions for the implementation of paragraph 6 of the Doha Declaration was approved by the TRIPS Council.²² This text, criticised by the major nongovernmental organisations (NGO) operating in this field (including Médecins Sans Frontières and Oxfam), set out, under very precisely defined and restrictive conditions, the possibilities for least developed countries to import generic ARVs. (Box 1 provides some arguments regarding the limits of this “Decision”).

For all these reasons there is still a consensual awareness about the need for further improvements in the legislation in order to open more room and to enlarge the “flexibilities” already embed in the TRIPS agreements.

In effect the prices of the new patented anti-retroviral medicines to be incorporated in the Therapeutic Consensus charged by the patent owners, mostly multinational pharmaceutical companies, are not compatible to the limited resources of the vast majority of DC’s and LDCs. In the case of Brazil, presently, 4 antiretrovirals under patent and imported by the Ministry of Health, account for 63% of the federal budget for ARV procurement. More generally, and because no generic competitor is allowed to enter into the production of the new generation of ARVS, there is a huge difference in the cost of 1st vs. 2nd line treatments. The Table 1 below gives a clear appreciation of the challenges posed by the growing need of 2nd line therapies.

Table 1 – Costs of 1st and 2nd lines treatments in Western and Developing Countries

	lamivudine/stavudine/ nevirapine (1st line)	tenofovir/didanosine/ lopinavir/r (2nd line)	2nd line vs. 1st line
Western Countries (a)	US\$ 8773/year	US\$ 13551/year	1.5 times more expensive
Developing Countries	US\$ 154/year Cipla Triomunc (b)	US\$3950/year Originator product	26 times more expensive
Reduction	- 98 %	- 70 %	

(a) Australian EXW prices: “Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners, May 2004. Exchange rate used for conversion (1 Australian \$=0.72213 US\$, May 1, 2004).

(b) Clinton Foundation price (FOB) + 10 % due to transportation and importation taxes

Source : E. t’Hoen (2005)

Given the constant need for updating the HIV/AIDS treatment, by the inclusion of 2nd and 3rd line therapies, “expeditious solutions” still have to be achieved as to assure the sustainability of the treatments needed by a rapidly growing number of patients.

Threats posed by the post-2005 scenario

2005 was a critical year to many developing countries, which were committed in the fight against the pandemic. This is the deadline for a number of developing countries, starting with China and India (largest world suppliers of APIs and generic ARVs) to comply with the provisions of TRIPS within their legal systems. As a result, the dispositions to be internalized will severely hinder the offer of antiretrovirals and active pharmaceutical ingredients (APIs) at low prices. These two countries, which represent the largest international suppliers of APIs (in the case of China) and generic ARVs (in the case of India), have strongly contributed to the procurement of medicines at reduced and affordable prices. One has to remember that it is thanks to the offer of generic versions of antiretrovirals, some of the first line H.A.A.R.T therapies are now available at prices between US\$ 200 et 300 per person/year (against US\$ 10 000 to 12 000 per person/year, provided by the patent owners, before the offer of generic versions in the international market).

Notwithstanding, the regular offer of generic medicines in the international market at affordable prices is now at risk. After the passing of the Indian Amended Patent law (voted in march 2005), the Indian generic drugs manufacturers, which were allowed by the domestic patent law to freely make copies of branded medicines, will now have to be forbidden to do so. In practice, this means that no generic versions of any new molecule or formulation under patent might be produced by generic manufacturers, as they used to do before the compliance of India and other developing countries' manufacturers to TRIPS. Dramatic effects will result from these changes in as much as the conception and the offer of generic equivalents to branded medicines used to be the driving force for market competition and price reduction. Already, this means that those ARV employed in 2nd and 3rd line treatments and which use

is growing due to resistance to first line treatments, won't be available as generic equivalents.

Finally, the last reason for concern relates to the so called "Trips Plus" agreements established bilaterally between developing countries and the United States in the field of Public Health. Regardless the joined efforts of developing countries and the international community to establish grounds for fair management of Intellectual Property Rights in the context of Public Health, the signing of such bilateral free trade agreements that imposes more restrictive provisions on IPR management whilst jeopardizing the conditions for access to treatment and care in these countries, puts the multi-lateral arrangements under suspicion.

**Box 1 Exportation of Drugs under Compulsory Licenses:
The August 30th WTO Decision on Implementation
of Paragraph 6 of the Doha Declaration on the TRIPS
Agreement and Public Health**

On August 30, 2003 the World Trade Organization's General Council issued an important decision entitled "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" (the Decision).

The Decision fulfilled an express mandate given to the Council for TRIPS in paragraph 6 of the Doha Ministerial Conference's "Declaration on the TRIPS Agreement and Public Health": to find "an expeditious solution" to the problems that could be faced by WTO members "with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing under the TRIPS Agreement."

Recognizing explicitly that for pharmaceutical products exceptional circumstances exist to justify the implementation of special means, the Decision sets up a system that both the exporting country and the importing country need to follow in order to implement these waivers.

(a) the importing country must be an “eligible importing Member”, which means that it must be a least-developed country⁸, or any other member country that has notified the Council for TRIPS that it intends to use the system as an importer

(b) the eligible importing Member must provide a notification to the Council for TRIPS which contains: (i) the name and expected quantity of the product (or products) needed; (ii) confirmation that it has established (in one of the ways set out in the annex to the Decision) that it has no or insufficient manufacturing capacity for the product in question – but least-developed countries are exempt from this requirement; and (iii) confirmation that the country has granted or will grant a compulsory license in accordance with Article 31 of the TRIPS Agreement if the pharmaceutical product is on-patent in its territory;

(c) the exporting country must notify the Council for TRIPS of the grant of the compulsory license, including the conditions attached to it (see below), and providing information about the licensee, the product(s) and the quantity for which the license was granted, the country of destination, the duration of the license; and the website that provides specified information about the license (see below); and

(d) the compulsory license must be subject to the following conditions: (i) only the amount of product necessary in the eligible importing country may be produced under the license and all that production must be exported to that country; (ii) all products so produced must be clearly identified under the system set up under this Decision through specific labeling or marking—the products should be distinguished through special packaging and/or special coloring or shaping of the products themselves, provided the distinction is feasible and has no significant impact on the price; and (iii) prior to shipment, the licensee must post on a website (which may be a WTO website to be set up for the purpose) the quantities being supplied to each destination and the distinguishing features of the product.

As should be readily apparent from the above description of the new system, it is detailed and relatively complex. And in the shadows of complexity, opportunities for misapplication abound. It is difficult to say that the system represents an “expeditious solution”, as envisaged in the Doha Declaration. It also contains a number of measures that raise transaction costs.

6. To Conclude: Is the new regime sustainable?

The purpose of this paper was to highlight three of the novelties associated to the emergence of a new IPR regime. To conclude, we wish come back to the significance of these novelties and to question, from a long term perspective the sustainability of the new regime.

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 start ups, it has to be noticed on the other hand that, by displacing the border between ‘inven-

tion' and 'discovery', the new IP 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 now consider the international dimension given to the new regime by the signing of the TRIPS, it is no surprise to discover that their application has already caused major conflicts, notably 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), what we have witnessed in many areas is the spectacle of major conflicts.

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.

Notes

- ¹ 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.
- ² What competition law formalizes as “abuse of a dominant position”.
- ³ 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.
- ⁴ Here, we refer to current work by “Law and Economics” specialists, such as (Heller and Eisenberg, 1998; Rai, 2001; Rai and Eisenberg, 2003). See also (Nelson, 2003).
- ⁵ 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).
- ⁶ 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.
- ⁷ See section 3 of this paper.
- ⁸ In fact this practice existed even before the Bayh-Dole Act, but it was confined to special circumstances. The Bayh-Dole opened the way to a generalisation of this practice.
- ⁹ For a detailed presentation of the modifications, see (Jaffé, 2000) and (Coriat and Orsi, 2002).
- ¹⁰ 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.

- ¹¹ This is clearly the case in pharmaceuticals, a situation that prevailed until the mid 1990s (Remiche and Desterbecq, 1996). But in many other areas most of the DCs choose very softy patent systems.
- ¹² 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).
- ¹³ 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 Zhang (1994).
- ¹⁴ Agreement available at www.wto.org/english/docs_e/legal_e/legal_e.htm.
- ¹⁵ 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.
- ¹⁶ Although patents on production processes are long established in the pharmaceutical industry (as in other sectors), the adoption of patents *on molecules* is a recent development in most countries.
- ¹⁷ Agreement available at www.wto.org/english/docs_e/legal_e/legal_e.htm.
- ¹⁸ 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
- ¹⁹ This treatment is called “tritherapy”, as it combines three different ARVs.
- ²⁰ 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.
- ²¹ WTO document number: WT/MIN(01)/DEC/2 available at www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
- ²² WTO document number: WT/L/540 available at www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

DPI, inovação e interesse público. Está o novo regime de DPI reforçado no mundo pela manutenção do TRIPS?

Resumo: Este artigo discute as implicações do surgimento de um novo regime de DPI em três dimensões: (1) sobre a pesquisa básica; (2) sobre as desigualdades e conflitos comerciais nas relações Norte-Sur; e, (3) sobre a utilidade social das

patentes. O artigo dá uma maior ênfase aos DPI sobre cuidados da Saúde e organismos vivos, assim como seu tratamento no acordo TRIPS.

Palavras-chave: Direitos de propriedade intelectual, acordo TRIP, sistemas de patentes, desenvolvimento.

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