Patent Political Economy

Indian Lessons on Pharmaceutical Patent

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Summary

Abstract

The Intellectual Property Rights (IPR) regime adopted by any country is essentially a tool that strives to ensure both the growth of the domestic pharmaceutical industry and people's access to medicines. But, contrary to the very easily advanced theory, there is no paradox between the two. From this perspective, the Indian experience has shown that it is precisely the relaxation of its national IPR regime that promoted the growth of its domestic industry, thereby ensuring a better patient access to medicines. However, the globalisation process does not overlook any sector, which means that medicines too are submitted to the new legal framework established within the WTO. To understand better the stakes involved in the ratification of the TRIPS agreement in India, this paper addresses several issues. It begins by establishing that opting for the intellectual property regime is not without consequences. It determines the extent of progress achieved in the industrial and health sectors both in the developed as well as developing countries. Then, it analyses how the TRIPS agreement establishes a strong IPR system that aims to reconcile protection of innovation and public health promotion by providing for "exceptions" at the global level. Finally, after having dealt in detail with Indian reticence and tardiness in making its legislation TRIPS compatible, the paper presents the prospects available presently for India.

1. Introduction

The rationale behind patenting of an invention can be traced to the community of interests between the society and the inventor. For the society, it means that an individual can be guaranteed access to new therapies that are safe and effective and obtain disclosures of an invention to promote innovation. For the inventor, he gets the benefits in the form of a monopoly on the use of the patented product or process. Certainly, patents are an incentive for innovation in a sector where processes and products are the fruit of expensive research and development (R&D) programmes, which often expose companies to problems of appropriation (Arrow, 1962, Demsetz, 1967)[3]. Thus, interests albeit not conflicting but nevertheless divergent in nature are brought into play. The society as a whole and more particularly the consumers would prefer that patents be issued for a limited period and monopoly granted in proportion to the benefit brought by the inventor. On the other hand, the inventors would prefer patents granting a wide-ranging and long lasting monopoly that would provide them with a profit that far exceeds the investment in R&D (Scherer, 1998, Grabowsky, 2002, Sterckx, 2004).

This compromise between diverging interests was always at the heart of changes made in patent protection in the developed countries. Initially, these countries granted patents on processes alone in order to ensure the innovation's diffusion, a necessary condition for the growth of a competitive pharmaceutical industry. Later, from the fifties onwards, they ratified product patents (Remiche & Desterbecq, 1996, Mfuka, 2002)[4]. Finally, bowing to constant pressure from the pharmaceutical industry, the term of a patent was extended to twenty years in developed countries. As of the same period, we witness in the history of patents a new phase of extending patenting on a global level, especially to the developing countries (Braga, 1989).

In fact, the round of negotiation launched in 1986 at Punta del Este sought to extend the GATT trade regime to new sectors such as trade in services and intellectual property. This round lasted eight years. It culminated in the establishment of the World Trade Organisation (WTO) and the ratification of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at Marrakech in April 1994[5]. Beginning 1st January 1996, the developed countries are to amend their national legislation to comply with TRIPS. However, a moratorium is to be provided for the rest of the world: twenty years for the least advanced countries and ten years for developing countries and countries transiting towards a market economy.

Since then, there has been sharp questioning and criticism. While it has been constantly reminded that the agreement is not inconsistent with the legitimate aims of industrial development and public health, especially of the developing countries, there have been

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[3] In fact, companies experienced great difficulties in obtaining maximum benefit of their R&D activities and seemed unable to recover the considerable sum invested in the development of new treatment. They were under the constant threat of their competitors copying their products. So, it appears that in the absence of a suitable "institutional arrangement" (Arrow, 1962) the companies were evidently not inclined to allocate funds for their R&D, which resulted in the lowering of general welfare, as access to the latest innovations was being compromised.

[4] To cite a few examples, the United Kingdom introduced a patent on medicines in 1949, France in 1959 and Switzerland in 1977.

[5] The framework of international negotiations on intellectual property rights had thus shifted from the World Intellectual Property Organisation (WIPO), a specialised technical organisation, to the WTO vested with a larger mandate, but literally and definitely driven by trade considerations.

expressions of acute fear and sharp protests from Brazil, India and even the "African group" within the WTO. The flexibility provided for in the agreement fail to reassure the developing countries. The main aim of this article is precisely to shed light on the ins and outs of the extension of IPR to the developing countries. We will especially deal with Indian fears: step by step (and with delay), India is currently amending the patent law to comply with TRIPS.

To understand better the stakes involved in the ratification of the TRIPS agreement in India, we will begin by establishing that opting for the intellectual property regime is not without consequences. It determines the extent of progress achieved in the industrial and health sectors both in the developed as well as developing countries (§2). Then, we shall see how the TRIPS agreement establishes a strong IPR system that aims to reconcile protection of innovation and public health promotion by providing for "exceptions" at the global level (§3)[6]. Finally, after having dealt in detail with Indian reticence and tardiness in making its legislation TRIPS compatible (§4), we will analyse the prospects available presently for India (§5).

2. Industrial development and betterment of public health: the importance of the IPR regime

In one century, India has been a witness to two IPR systems. The passage from one to the other has markedly changed its industrial path as regards domestic pharmaceutical production. From a strong IPR system (process and product patents), in which the local industry was only at the fledgling stage, the country changed course to a weak IPR system (process patents) that allowed the dynamic pharmaceutical industry to grow. After all, the country's self sufficiency in healthcare vastly improved.

2.1. First, a strong IPR regime

Historically the growth of Indian pharmaceutical industry started during the colonial period (Felker & alii, 1997, Smith, 2000) with the founding of the Bengal Chemical and Pharmaceutical Works in 1901, the King Institute of Preventive Medicine (tropical diseases research centre) in 1904 and the Pasteur Institute in 1907. From the Second World War onwards, India started producing conventional medicines (serums and vaccines). The country also commenced manufacturing synthetic products to treat dysentery and leprosy. Later several government production units were established: Hindustan Antibiotics in 1954 with technical assistance from the WHO and UNICEF as well as Indian Drugs and Pharmaceuticals with technical support from the erstwhile USSR (Felker & alii, 1997, Smith, 2000, Dubey, 2003). Despite these forays following India's independence, the local pharmaceutical industry was still nascent and the country was heavily dependant on external supplies.

Faced with continuing dependence, experts found fault with the IPR regime inherited from the colonial days. In fact, patent policy dated back to 1856. The Indian Patent Act (IPA) amended in 1911 authorised issuing of both process and product patents. These patents were valid for a period of sixteen years and could be extended for another period of ten years if the patent holder believed that he had not been adequately defrayed for his innovation (Lalitha, 2002a). As of 1948-1950, the Patent Enquiry Committee specified that *"*the Indian patent system has failed in its main purpose, namely to stimulate inventions among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to

[6]The reinforcement of the IPR regime in the world is taking place at a time when the World Health Organisation (WHO), another international institution, has launched a programme promoting people's access to essential drugs, as these medicines go a long way in treating diseases that are the most prevalent in developing countries.

secure the benefits thereof to the largest section of the public*"* (Government of India, 1949, cited by Ramanna, 2002).

At the end of the sixties, a second committee confirmed this finding: the IPR regime was a tool in the hands of the multinational companies (MNCs) of the developed world to keep the Indian market exclusively for themselves. They held between 80 to 90% of the patents. Having cornered monopolistic positions, they indulged in prohibitive prices, which were among the highest in the world (Mittal, 1993, Keayla, 1995, Watal, 2001, Ramanna, 2002). Based on the findings of an enquiry on the price of 18 essential drugs, this committee pointed out that most often the same products were cheaper abroad. Therefore, it recommended the amendment of the existing IPR regime and the establishment of a new *"*institutional arrangement" (Arrow, 1962) that was more flexible and permitted a "fair-selling price". All these institutional modifications were supposed to encourage the development of a high-performance domestic industry capable of making the country's self-sufficient in healthcare and reduce the price of medicines.

2.2. Followed by a relaxation of the IPR regime with positive effects

In 1970, the patent law was relaxed. The 1970 IPA stipulated that patents would be granted only for processes for a period of seven years as regards the pharmaceutical industry[7]. Furthermore, a company would only be able to enjoy one patent for one manufacturing process (Lalitha, 2002a). From then on medicines were exempted from the scope of patentability[8].

Besides, only local production would validate the effective use of a patent. Contrary to the earlier practice, the import of pharmaceutical products no longer allowed the patent's effective use to be validated. As a result, the patent holder was given three years to exercise his right in the form of local production.

The IPA also provided for assignment of rights. If, at the end of the three-years period, a medicine was not available or at a reasonable price, the Indian government could construe that the public need had not been met and could issue a compulsory license (CL). It could thus allow a local company to manufacture the medicine and market it at a lower price. *A fortiori*, if two years after the issue of the CL, the medicine was still not available, the government could simply revoke the patent due to lack of satisfactory usage.

Along with industrial policy measures, the public authorities instituted price control in the same year. The Drug Price Control Orders (DPCO) was established in 1970 in order to enhance people's access to drugs (Singh, 1985, Felker & alii, 1997, Srinivasan, 2001, OPPI, 2001, Kunnapallil, 2003). In practice, the public authorities published a list of the most essential drugs with a large volume of sale. Henceforth, the retail price of these drugs was fixed at a reasonable level. This price was supposed to enable manufacturers cover the cost of raw materials, formulation, packaging and distribution while at the same time ensuring a reasonable profit margin. The price for most essential drugs was fixed in such a way as to ensure a margin of 75% taking into account various production costs for the company. The margin for non-essential drugs

[7] Seven years from the patent application date or 5 years from the date of obtaining the patent.

[8] In the vital nuclear, agriculture and food supply sectors patenting has been totally banned. We should remember that by adopting short-term process patents, India was but following the example set by the developed countries, which belatedly opted for a more relaxed IPR to encourage the growth of national champions based on a sufficiently large reserved domestic market and enhance healthcare self-sufficiency in their country (Mfuka, 2002).

was fixed at 150%. Later, this price control system underwent recurrent changes (Gross, 1999, Govindaraj & Chellaraj, 2002, Lalitha, 2002a, 2002b)[9].

Thus, the 1970 IPA along with the DPCO, sought to reconcile the aims of diffusing innovation in the country and fulfilling the needs of people as regards quality drugs at affordable prices (Keayla, 1995). Since only processes could be patented, at that time it was possible for local companies to copy molecules developed by MNCs. Working on the basis of reverse engineering and learning by copying, these companies could market generic drugs or less expensive versions of drugs patented by MNCs elsewhere.

Coming into force in 1972, this new IPR regime had a substantial impact. First of all, it allowed the growth of the fragmented domestic pharmaceutical industry. In 1953, the sector consisted of 1,752 companies as against 5,126 in 1980. Today, there are 20,000 companies with 250 big timers and about ten public sector enterprises (Mittal, 1993, OPPI, 2002)[10].

Moreover, the country was able to make good its backwardness as regards domestic production of raw material and formulations. Raw material production rose from 180 million rupees in 1965 to 9 billion rupees in the early nineties and rose further to 45 billion in 2001. As for formulation, it recorded an even higher growth. At the end of the sixties, the industry formulated drugs worth 1.5 billion rupees. This turnover went up to 60 billion rupees in 1993 and settled at above 183 billion in 2001 (Mittal, 1993, OPPI, 2002).

As of the 1980s, the pharmaceutical industry's exports to the rest of the world have gone up. Initially, these exports mainly concerned finished products: 76% as against 24% of raw material exports. Later, considerable growth in the export of both raw materials as well as finished products was observed at the end of the nineties. Indeed, exports increased respectively more than 100 times and more than 300 times during this period. Finally, a more even distribution of exports in this sector was observed: 55% of exports pertained to formulation as against 45% for active substances in 2000 (Mittal, 1993, OPPI, 2002)[11]. Besides, the dynamism of exports manifested in a trade surplus right from the end of the eighties. Thus, the chronic deficits between the 1960s and 1980s began to decrease and disappear as of 1989. Today, the pharmaceutical sector trade surplus is nearly 51.3 billion rupees (IDMA, 2001, Chaudhry, 2002)[12].

Since the 1970 IPA, Indian pharmaceutical industry's growth has meant enhanced self-sufficiency as far as the country's healthcare is concerned. The industry produces 70% of raw material and 80% of finished products in the Indian market (Lanjouw, 1997). In addition, the grading of the top 10 companies in the Indian market reveals the performance of the domestic

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[9] At present, drugs with a sales volume higher than 1 million dollars or which hold monopoly over the market come under the purview of the DPCO. Monopoly here means a medicine that has a turnover of more than 250,000 dollars and is supplied by a single manufacturer with at least 90% of the market share. Medicines for which competitive pressure is deemed to be sufficient are exempt from this purview: at least five raw material manufacturers and ten finished product manufacturers who have each less than 40% of market share either for raw material or the finished product.

[10] At present, the sector directly employs 250,000 persons and indirectly 750,000 individuals, especially in distribution (Felker & alii, 1997).

[11] This phenomenon can be explained by the very high taxation imposed by the Indian government on the import of finished products, which in turn induces domestic production of these products.

[12] Indian industry exports a large chunk to the developed markets, especially to the United States. Generic drug manufacture has grown by leaps and bounds impelled by the public authorities seeking to bring healthcare expenditure under control.

industry. Four of these companies are from India and have almost 16% share of the Indian market (OPPI, 2002).

Moreover, comparison between the drug price index and the price index of other goods between 1961 and 1989 evidences the positive effect of the DPCO. In the beginning of the sixties, the drug price index was almost at par with the general price index: 2% inflation for drugs as against 3% for all other goods. Till 1966, a restrained price increase for drugs as compared to other goods could be noted - an effect that could be attributed to the first steps taken towards drug price control during the Sino-Indian war (Singh, 1985, Felker & alii, 1997). Then, from 1970s onwards, the gap between the drug price index and the price index of other goods began to widen. In general, between 1961 and 1989, the price index for all products increased by 676.6% as against 386.6% for drugs (Government of India, Indian Drug Statistics, cited by Chandra Prasad & Bhat, 1993).

We should dwell a little further on this point. When we compare the relative prices of some of the essential drugs 16 years after the DPCO came into force, we notice that the prices in India were among the lowest in 1986. Of eight essential drugs belonging to seven therapeutic classifications, Mittal (1993) maintained that the Indian prices were lower than the prices prevalent in countries like Pakistan or the United Kingdom. For example, the price of an antibiotic in India was 82.5% of the price in Pakistan and 32.2% of the price in Britain. For the most expensive drug, a hypertensive drug, the Indian price was equivalent to approximately 69% of the British price and 42% of the Pakistani price. Similarly, according to a study conducted by Keayla (1995) on the prices of largest selling drugs during the years 1991 and 1992, India enjoyed attractive prices. For an antibiotic (Ciprofloxacin), the Indian price was 5.66 times lower than the Pakistani price. Even for an ulcer drug (Ranitidine), the American price was 25 times higher than the Indian price.

Recently, the presence of Indian pharmaceutical firms has been highly appreciated and received wide coverage in the media for the supply of antiretroviral drugs (ARVs) at competitive prices in the developing world.

2.3. Global effect of a relaxed IPR regime: Indian competition and prices of ARV

ARV production began in India in 1991. At that time, Cipla wisely had a go at the manufacturing of the less costly ARV formulations, whose active substance content was low and whose manufacturing process was relatively less complex[13]. A decade later, there were on the whole five Indian companies (Cipla, Ranbaxy, Hetero, Aurodindo and Cadila) who had developed the wherewithal for this formulation and this allowed each one of them to market more than fifteen ARVs especially in the form of double and triple therapies.

The entry of these generic drugs in the ARV market brought the cost of treatment crashing down. For the price of a therapy combining three ARVs, Médecins sans Frontières (MSF) (2003) clearly demonstrated that the sharp decline started with Cipla announcement in February 2001 that it would sell its triple therapy in the form of a cocktail at $350 per year per patient to non-governmental organisations (NGOs)[14]. At that time, a triple therapy cost $931 with brand-name

[13] In practice, generic drug manufacturers confess that they are not much inclined to market ARV whose production costs are very high, or whose active substance content is very high or whose manufacturing process is complex.

[14] A cocktail is a treatment composed of three drugs that are present in a single pill to be taken 2 or 3 times a day. This innovative dosage brings down the number of pills to be taken every day and improves patient compliance (WHO, 2002).

medicines. From March 2001, the price of triple therapy with brand-name drugs fell to $727. Moreover, competition between Indian generic drug manufacturers triggered a new decline in prices. Two months after Cipla's announcement, Hetero joined the fray and declared its intention to sell its cocktail at $347 to NGOs. Few months later, Ranbaxy raised the stakes by fixing the price of its cocktail at $295 for NGOs. In its last report, MSF states that prices are still decreasing. Last year, Hetero was selling the tri-therapy at $152 to NGOs against $562 for brand-name drugs. Thus, between January 2001 and June 2005, the price of the triple therapy fell by more than 83% thanks to the most effective means of lowering medicines price, i.e. generic competition (MSF, 2006).

On the whole, the beneficial effects of a relaxed IPR regime (patents on manufacturing processes alone) were confirmed as seen in the Indian experiment. By making its IPR regime more flexible, India had encouraged the growth of a pharmaceutical industry and improved accessibility to drugs. Further, this high-performance industry had recently succeeded in pushing ARV prices down and improving accessibility. As a WTO Member, India has to amend its laws by 2005 to make them TRIPS compliance. What is the content of this agreement and what impact can it have on the Indian trajectory as regards pharmaceutical development and access to treatment? To answer these questions, it is imperative to spell out clearly the contents of this agreement.

3. Strengthening of the IPR regime at the international level: Patentability under the terms of the TRIPS agreement

The TRIPS agreement attempts to reduce the differences in the manner by which IPR is protected around the world by fixing a minimum level of intellectual property protection that each of the WTO's member-states ought to guarantee. Thus, Articles 17 and 34 of this agreement lay down common minimum international regulations. These regulations specify what is patentable, what is not patentable and the extent to which the rights are protected under the patent (Gervais, 1999, Boulet & Velasquez, 1999).

3.1. General provisions

First of all, the agreement defines the patent as "any invention, whether products or processes, in all fields of technology, provided that they are new, and involve an inventive step", (…), "that they are capable of industrial application" or it be "non-obvious and useful" (Article 27.1 and the linked footnote).

As regards the patent's term, it is fixed at a minimum of 20 years from the date of its application (Article 33). In this respect, the industrialised countries' standard has prevailed. Indeed, the lengthy administrative procedures to determine the product's safety and effectiveness before marketing approval (MA) tended to eat so much into the effective duration of the patent[15]. As *quid pro quo*, the American authorities, on one side and the European authorities, on the other, granted an extension of the patent term to 20 years.

As regards patent validity, Article 27 lays down that "patent rights shall be enjoyable without discrimination, (…), whether products are imported or locally produced". In other words, whereas the national laws of developing countries such as India and Thailand stipulated that local

[15] The time taken between the patent application as such and the obtaining of a MA can add up to several years, which brings down by as much the effective monopoly granted by the patent and eats into the pharmaceutical firms' profit meant to cover R&D expenditure.

production alone could validate a patent, henceforth import would also validate the actual use of the patent. Thus, WTO Member states no longer had any discriminatory tools to encourage access to technology and medicines.

3.2. Patentability conditions

The issue of patentability conditions, in other words the patentability criteria (positive and negative), is not merely technical. These criteria define what can be appropriated by private parties and what cannot be monopolised or withdrawn from free use. These criteria formalise the old social contract between the community and the inventor.

As per article 27.1, the member states are beholden to offer protection granted by a patent for any invention whether it is a product (medicine) or a process (a method to produce chemical ingredients for a drug composition). Thus, whereas a number of developing countries had opted for patenting only the process, henceforth they are bound to grant patents both for the process and the product under certain conditions.

First condition, the process or product should establish its novelty. The agreement does not give any details on this point. However, it is generally considered any thing not previously included in a technique is new. Therefore, any previously unknown invention regardless of the place and time under consideration is accepted as new. Thus, any past disclosure, to be understood as any revelation, written or oral, express or implicit, including that which is known through usage, will limit the innovative character and exclude a product or a process from being patented. Similarly, prior art can encompass past patent applications not yet published and limit the eligibility of a patent application. Finally, knowledge of local communities, traditional practices can be included *in prior* art and on this basis become non patentable.

Second condition, the innovation should be inventive, which corresponds to the "non-obvious" criteria. It is a filter, which makes it possible to refuse the grant of a monopoly for processes and products that are based neither on intelligence nor on any particular creative activity. The act of inventing is generally understood to have been achieved if, for a person skilled in the art, the invention does not obviously follow prior art.

Third condition, invention is "capable of industrial application" (Article 27.1). Here too, the agreement does not provide any details, thereby giving the States sufficient room for manoeuvre. This criterion is generally understood to be a means to ensure that the monopoly is granted solely to processes and products likely to result in material manufacture of a product and industrial production.

Last condition, supposing that the invention is new, inventive and capable of industrial application, "Members shall require that an applicant shall disclose the invention in a manner sufficiently clear and complete for an invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date" (Article 29)[16]. Therefore, the product features shall be described in the

[16] The applicant can also be asked to give details of all the biological sources involved in the invention. Thus, by ensuring respect for the 1992 Biological Diversity Convention (BDC) clauses, biopiracy can be curbed. Further, by proclaiming the States' sovereignty over national resources, the agreement aims at preserving traditional knowledge and biological diversity. Therefore, the applicant has to be capable of proving that the materials' country of origin had given its prior informed consent as per the regulation in force in that country. This also helps in ensuring the creation of a just and equitable system of sharing benefits resulting from the use and marketing of this material. For problems of articulation between the TRIPS agreement and the 1992 convention, cf. Chapman (2002).

patent application and made public. Disclosure is an indispensable factor in the contract drawn between the inventor and the society. In fact, in exchange for the grant of monopoly, the applicant shall make public the technical information that helps technology progress and guarantee that after the patent's expiry, the invention shall truly fall in the public domain. After the patent's expiry, based on the information disclosed by the applicant, it will become possible for professionals in that sector to easily copy the concerned process or product, without having to display any creativity on their part. In addition, a clear and complete disclosure helps in restraining the patent's scope. A clear and complete description limits excessive claims from the applicant, which, consequently, avoids the grant of a sweeping monopoly liable to stifle competition to a great degree.

3.3. Limitations to patentability

On the grounds of public order or morality, Article 27.2 provides that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law". The notion of public order is, however, not defined in the agreement. Room for manoeuvre is thus available to the Member-States to meet their particular ends. Thus, it is possible to exclude certain drugs from patentability for reasons of public health. However, these exclusions can be contemplated only under exceptional circumstances, subjected to the limitation laid down in the article that such restrictions can be applied only to inventions "the prevention of the commercial exploitation of which is necessary"17. In any case, an object cannot be declared as non-patentable, if its distribution or sale has been authorised in the national territory at the same time.

Medical methods. Article 27.3a authorises the Member-States to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals". Such an exclusion is of great importance to developing countries inasmuch as the patenting of these methods may have repercussions on public health and reduce accessibility to healthcare.

Diagnostic, therapeutic and surgical methods or plants and animals and biological processes for the production of plants or animals. Under the terms of Article 27.3b, "plants and animals and other micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes" can be excluded from patentability. In this matter, the latitude granted to the States is limited by the obligation to patent micro-organisms. Now, inventions concerning micro-organisms are common and useful in the pharmaceutical industry. For example, a surgical sequence or a new medical test can be excluded from patentability in that it is a diagnostic, therapeutic or surgical method. On the other hand, medicines can be patented as a microbiological process (antibiotic) or simply a chemical process used for therapeutic purposes. In all these scenarios, they are not considered as therapeutic methods (Luff, 2004).

On account of public health, nutrition and public interest. Article 8.1 allows certain pharmaceutical products to be excluded from patentability. This clause permits the Member States to adapt their national policies based on public health concerns. It is thus possible to exclude from patentability certain pharmaceutical products, as a temporary measure, to deal with a national emergency as far as public health is concerned. However, the article sets limits to such

[17] For the interpretation of the necessity criterion refer to Luff (2004).

measures by specifying that they must be indispensable and consistent with the agreement. These possibilities would thus be limited by nature and their use would require justification. These provisions complement article 7 according to which IPR "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." On principle, protection of patent rights should, thus, be commensurate with the interest of the society and should establish "social and economic welfare". To do so, additional and necessary measures can be taken under the terms of Article 8.

3.4. Limits to the rights ensuing from the patent

In accordance to the principles laid down by the TRIPS agreement, a country can disregard the rights of the patent holder to promote public health objectives such as accessibility to medicines or for treatment in case of national emergencies such as an epidemic. Once the patent has been granted, WTO members are permitted to waive the protection conferred by the patent under circumstances that have been provided and enshrined in the agreement.

The general principle of exceptions to rights conferred. As per Article 30, the patent owner enjoys monopoly over the product or process, with certain exclusive rights. Basically these rights pertain to the right to forbid a third party to manufacture and use the patented product or exploit the patented process, to sell or offer for sale patented products and products derived from the patented process and finally to import these products. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts (Article 28)[18].

These rights are not without limits. In this regard, Article 30 leaves a certain latitude to the Member-States to provide for "exceptions" to patentee's rights, under the following three conditions: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." The aim of these exceptions is to create a competitive environment favourable to a decrease in drug prices and enhancement of people's access to medicines. However, the three conditions are cumulative, each being a separate and independent requirement that must be satisfied. "Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed", as underlined by the Panel in the Canada – Patent Protection of Pharmaceutical Products case[19].

Exception for research and experiment and specific provision. Some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. In addition, by allowing researchers to use a patented invention for experimental purposes, third parties are encouraged to work on or around the invention to understand it better and possibly surpass it. The declared purpose is to advance technological progress. This pharmaceutical sector specific provision, inherited from the American IPR regime, is called the "Bolar" provision. It has been covered in

[18] The patent holder enjoys the rights of use of the product or the process (usus), the voluntary right of disposal of the said product or process (abusus) and the right to enjoy the benefits (fructus) (Mfuka, 2002).
[19] Report of the Panel, *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, 17 March 2000, §7.20.

Article 8 of the TRIPS agreement and confirmed by a WTO's Panel report adopted by the Dispute Settlement Body (DSB)[20].

Extemporaneous preparation of medicines. This enables a pharmaceutical board to authorise the preparation of a compounded mixture, in units, to meet the needs of a particular patient's medical prescription. Only this particular case is dealt with in this exception. Thus, it has a limited scope of application and is of lesser interest compared to the applications accepted in the Bolar provision.

Compulsory licensing[21]. In accordance with Articles 8 and 40 of the TRIPS agreement, governments can take steps to prevent patent owners from abusing their rights, by "unreasonably" restraining trade or hampering the international transfer of technology. In practice, public authorities can authorise a third party to manufacture a patented product or to use the patented process without the patent owner's consent. Most developed countries and developing countries provide for CL concession in their legislation22.

Recourse to CL is based on Article 31 of the TRIPS agreement devoted to "other uses without authorization of the right holder". The article aims to strike a balance between the concern to promote access to medicines and provide protection/incentive for R&D in the pharmaceutical field (Luff, 2004). The objective is to create a more competitive environment without, however, ignoring the rights of the patent owner, who ought to be adequately compensated whatever the circumstances.

It is possible to issue a CL under certain conditions to ensure that the legitimate interests of the patent owner have been protected[23]. In particular, an attempt should have been made to obtain a voluntary license (VL) from the right holder on reasonable commercial terms (Article 31.b)[24]. However, this article provides for making the VL redundant in case of a national emergency, circumstances of extreme urgency, public non-commercial use (or government use) or anti-competitive practices. The CL is of particular importance for developing countries that are subject to epidemics such as HIV/AIDS. Their objective is to improve patients' access to drugs. Thus, certain countries see this as a means to stymie the negative effects of patents on prices and availability of medicines, insofar as it makes it possible to reduce prices of drugs protected by a patent in force and to obtain technology.

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[20] Report of the Panel, *Canada – Patent Protection for Pharmaceutical Products*, WT/DS114/R, 17 March 2000, §4.15.

[21] For a critical legal review of the notion of CL, refer to Matsushita and alii. (2003).

[22] Besides, as can be seen from the anthrax episode, which pitted the American public authorities against Bayer that held the patent.

[23] Article 31 of the Agreement sets out to determine, as accurately as possible, a framework for the CL regime. The list of conditions for the use of CL consists particularly of the following points: authorisation to use without the patent owner's consent should be reviewed based on the circumstances peculiar to this problem; a voluntary license should have been requested from the patent owner, at reasonable commercial conditions and within a reasonable period of time (except in times of national emergencies or other circumstances of extreme urgency or in cases of public non-commercial use purposes) ; the CL's scope and the duration should be limited to the purpose for which it was authorised; its use should be non-exclusive; the use is authorised mainly for replenishment of the domestic market of the member state that granted this license; the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization and the remunerations are likely to be revised.

[24] A VL means that the patent holder has given his consent to a local company to copy the concerned drug, against royalty payments, which shall be marketed only in the internal market.

Nevertheless, certain difficulties continue to exist. First of all, the lacks of a clear definition of these scenarios and the resultant legal insecurity have led developing countries to demand a specific statement on this matter. Further, a CL is normally granted mainly to replenish the local market. So what about developing countries reeling under a national emergency or victim of a monopolistic practice who do not have local manufacturing capacities?

Parallel import (PI). PI allows imports and resale in a country without the authorisation of the patent owner of a product patented and marketed in another country by the patent owner himself or through a duly authorised agent. This measure also stems from the concern to strike a balance between adherence to the patentee's monopoly and the principle of free flow, in order to create as competitive as possible an environment. In practice, this has to do with drugs produced and marketed by the patent owner in one country that are subsequently exported to another country without his permission. Thus, if a drug X has been patented and manufactured in countries A and B and if the price of the drug is cheaper in country A, then country B would be tempted to import the drug from country A to benefit from a lower price. This practice is known as parallel import[25].

Recourse to PI is governed by the principle of exhaustion of rights retained by the Members. Exhaustion of rights can be at the national, regional or international level. According to the principle of exhaustion of rights at the national level, the patent owner's rights are considered to have fulfilled their objective once the patent owner has marketed the product anywhere in the national territory. This means that the patentee no longer holds any rights over his product's subsequent sale and resale, his rights having been "exhausted", once it has been marketed. However, marketing of his product outside the national territory does not exhaust his rights. In other words, exporting the product, to a third country is prohibited. This system is in force especially in the United States. At the regional level, there is exhaustion of rights the moment the product is put up for sale in the regional market. This mechanism also prevails in the European market, which for example allows a product marketed on Spanish soil to be subsequently exported to another European Union member country. Finally, at the international level, once the patent holder consents to market his product in one country, the international exhaustion of his rights takes place: the product can be exported to any other country without the consent of the patentee. As a result, if the principle of exhaustion of rights at the international level is retained, as soon as the patent holding company has sold its product in country A, its rights are exhausted as regards all other countries and therefore all other markets; country B can then proceed to imports from a more competitive source of supply.

On this point the TRIPS agreement lays down that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights" (Article 6). By its refusal to arbitrate, the WTO thus gives wide latitude to Members to legislate. As a result, if a country authorises PIs based on modalities that infringe on the agreement, the matter cannot be brought before the WTO's DSB, unless the fundamental principles of non-discrimination are at issue under the terms of Article 6 of the agreement.

At the end of this overview, we can ascertain that the TRIPS agreement controls a certain number of factors. For example, product and process patents have a lifespan of minimum twenty years. Nevertheless, the agreement leaves other more or less important factors to the discretion of

[25] Trade practice, which, in extreme cases, results in the reshipment of those drugs that MNCs sell at preferential tariffs in developing countries, to developed countries to be sold at a higher price by smugglers.

the Members. In particular, a State must define what constitutes a national emergency or the choice of the principle of exhaustion rights to be retained. And finally, in the case of India, for instance, there are many differences between the IPR regime based on the TRIPS agreement and the IPR regime inherited from the 1970 IPA. These have been summarised in the table given below.

1970 Indian Patent Act	TRIPS agreement
Patents only on processes in the pharmaceutical sector.	Patents on processes and products.
Fields in which patenting has been excluded: nuclear, agriculture.	Fields in which patenting has been excluded: diagnostic, therapeutic and surgical methods for treating humans or animals.
Patent duration: 7 years in the chemical and pharmacy sectors from filing of application and 14 years in other sectors.	Patent duration: minimum 20 years from filing for patent.
Discrimination: Patent valid in case of local manufacture.	Discrimination: Patent valid for both local manufacture and imports.
Compulsory licensing, Parallel imports and other assignment of rights.	Statutory license.
	Parallel imports not excluded.
According to the TRIPS agreement, the following falls under the States' discretion	
National emergency	
Exhaustion of rights (at national, regional or international level).	

4. Ensuring the TRIPs-Conformity of Indian IPR law

4.1. Determination of Non-Conformity by the Dispute Settlement Body

The WTO system imposes stiff conditions regarding conformity to the international trade law. Any national law must conform to WTO requirements and this requirement for conformity of the national law with the WTO law is something quite unique in international public law (Chaisse, 2005). All the WTO Members must then implement the TRIPS agreement. Indeed, Article XVI.4 of the agreement lays down that "each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed agreements". Also, WTO Members must provide for civil and administrative procedures for the enforcement of intellectual property rights to holders. As had been pointed out earlier, the agreement provides for a moratorium for developing countries. For the least advanced countries, the agreement should be ratified before 1st January 2016. For other developing countries, the ratification must take place before 1st January 2005. Despite repeated protests, India was placed in the other developing countries' category. In fact, a low per capita income ($530) places it among low-income countries. However, it appears that India was done in by the demographic factor. Its high population was put forward as a reason for justifying its classification under the other developing countries' category. Therefore, it is obliged to amend its national laws pertaining to patenting in order to comply with the TRIPS agreement by 2005.

Apart from the discussions regarding the time frame granted to one or the other category for compliance with the TRIPS agreement, other difficulties too surfaced. They concern the violation and interpretation of certain provisions in the agreement. In this respect, the key element in the WTO is its DSB, which does exert a considerable influence on world trade and diplomacy (Chaisse, 2006). Its aim is to maintain the judicial rights and obligations of each of the WTO Members. Moreover, unlike other judicial systems of this type, its mechanism is based on a large jurisprudence that clarifies and develops laws that stem from the Marrakech agreement. On the whole, more than any other international organisation, the WTO is truly capable of ensuring the effectiveness of all its regulations laid down in the agreement it administrates. The immediate consequence of such a system is that the developing countries take frequent recourse to this dispute settlement mechanism, bringing before it litigation against developed countries as well as other developing countries (Chaisse & Chakraborty, 2006). In fact, with the establishment of the WTO, dispute settlement under international trade laws has become judicial and much more efficient[26]. An important feature of the DSB system is that it has mandatory jurisdiction over all disputes arising out of the WTO agreement. The Members cannot take recourse to any other process to settle disputes. In other words, litigation is centralised within a single body, which de facto results in the creation of a homogeneous jurisprudence. Finally, it must be underlined that once a report has been adopted, all the parties involved in the dispute must accept all its elements, which means that the "loser" must make its legislation compatible with WTO laws as expressed and explained in the DSB report. This far-reaching change has surely made the DSB one of the most effective mechanism in international law even if some improvements are still necessary (Chaisse & Chakraborty, 2004).

In the field of IPR and with regard to India in particular, we have already confirmed the important role played by the DSB. As examined earlier, with the amendment made to the IPA in 1970, India did not grant patent protection for pharmaceutical products when the TRIPS agreement came into force. But, Article 70.8 states the obligation to create a system by which patent applications can be filed for such inventions. This provision is generally known as "mail box application" and generated the "*India - Patent Protection for Pharmaceutical and Agricultural Chemical Products"* case which is the first litigation on intellectual property settled within the WTO framework. Regarding the conformity with Article 70.8 TRIPS, the DSB noted that "the absence of judicial security in the functioning of the mail box system in India [was] such that the system did not [permit] Article 70.8 to be fulfilled appropriately and protect the legitimate expectations implied for the pharmaceutical products and agricultural related chemical products inventors"[27]. The DSB did not fail to support its argument by observing that "foreseeability as regards the intellectual property regime is essential for citizens of WTO countries when they take decisions pertaining to trade and investment in their commercial transactions"[28]. Subsequently, this analysis was by and large confirmed. It added that members

[26] The GATT's effectiveness in settling disputes was limited, since the agreement (consensus) of all contracting parties was required for adopting a report (judgement) formulated to settle a case. The expected refusal from the losing party was sufficient to stop the adoption of the report. With WTO, the consensus rule has been reversed: henceforth a unanimous decision is necessary to reject a report (negative consensus). In other words, a report can only be rejected if the "winning" State rejects a decision given in its favour by the DSB, a hypothesis that has never come true since 1995.

[27] Report of the Panel, *India - Protection granted by a patent for pharmaceutical and agricultural chemical products*, WT/DS79/R, 24 August 1998, §7.41.

[28] Report of the Panel, *India - Protection granted by a patent for pharmaceutical and agricultural chemical products*, WT/DS79/R, 24 August 1998, §7.30.

were not obliged to guarantee that patent applications deposited in the mail box would not be rejected or invalidated because they preceded the enforcement of any legislation. **Merely, subject sets up a judicial mechanism based on the "mailbox system"[29].** It did not in any way challenge India's right, by virtue of the transitional provisions in paragraphs 1, 2 and 4 of Article 65, to defer the implementation of Article 27 pertaining to patents on pharmaceutical and agricultural chemical products until 1st January 2005.

4.2. 1995-2005: India's sluggish approach on patent law compliance

After having signed the agreement, between 1994 and 1998, and despite the bilateral and multilateral trade pressures exerted by the United States and Europe, India did not amend its IPR regime. The sluggishness evidenced was due to the opposition of players who benefited from the IPR regime inherited from the 1970 IPA. In particular, the generic drug manufacturer Cipla continues to plead in favour of a moratorium extending up to 2015. It is demanding that India be classified under the list of the least advanced countries regardless of its large population. Another example of India's sluggishness pertains to a bill introduced in Parliament in March 1995 to amend the 1970 IPA. This bill was not approved by the Parliament and was sent back to a committee. It is only from 1998 onwards that there have been significant changes.

On that date, the political parties changed their position under the delayed effect of the liberalisation policy initiated in 1991 (Ramanna, 2002). The Congress Party changed its stance in favour of amending the IPR regime. On its part, having come to power in 1998, the BJP went on record that it is for the establishment of a stronger IPR regime. At the same time, the lobbies also geared up. The Confederation of Indian Industry ensured that the IPR reform would help the country attract foreign direct investments (FDI) and gain access to new technologies, a factor necessary for a modern and professional management of the Indian industry, according to this body. The Federation of Indian Chambers of Industry and Commerce set up the International Institute of Intellectual Property Development in 1997. The latter has launched a campaign with the slogan "patent or perish". The public scientific bodies have taken a positive view at the possibility of patenting the knowledge they have developed. Following the lead given by the Council of Scientific and Industrial Research, these bodies have declared their support for strengthening the patent laws. Finally, in 1998, following a complaint brought to the DSB by the United States, India was asked ensure compliance of its legislation as of April 1999.

As the first sign of an effective modification of patent laws, India signed the Paris Convention on 8th December 1998 and ratified the Patent Cooperation Treaty (Kumar, 1998). In 1998, the BJP introduced a motion for amending the patent law. In 1999, the first amendment was adopted (Watal, 2001, Bhattacharya, 2002, Chaudhuri, 2002). It authorised product patenting in agro-chemical and pharmaceutical sectors. Patent applications could thus be deposited in a "mail-box". The applications would be reviewed in 2004 and could be possibly accepted in 2005. Since the TRIPS agreement came into force in 1995, only those molecules that were discovered and were the subject of patent applications in another WTO Member after this date are patentable. Thus, the countries would have to ensure in 2005 that applications filed are indeed for drugs invented after 1995. In addition, as provided in the TRIPS agreement for the transition period, exclusive marketing rights could be granted for 5 years to companies that file their application under certain conditions.

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[29] Report of the Appellate Body, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, 19 December 1997, §57-71.

In May 2001, India was placed under the "Special 301 Priority Watch List", an instrument the United States employs to exert trade pressures on countries that adversely affect their economic interests either by adopting protectionist measures or by not bringing about a desirable change in their IPR regime. In 2002, a new amendment was adopted. Amongst other issues, it provides greater clarification about the definition of the term "invention", non-patentable elements, patent owner's rights, CL and even PI (Bhattacharya, 2002, Keayla, 2003).

In short, making its legislation fall in line with the TRIPS agreement was not a smooth process for India and much still needs to be done. Based on the points presented above concerning the history of patent protection in India and its pharmaceutical industry, we can understand better the reticence shown in this matter by the public authorities. The implementation of the TRIPS agreement constitutes a renewed fortification of patent protection. Thus, the country fears that this renewed fortification would apply the brakes on the growth its industry had enjoyed till now and eat into the progress achieved towards self-sufficiency in healthcare and peoples' access to medicines. Furthermore, Thailand's experience, another country that had to bring about strengthening of patent protection earlier, has put the promises associated with TRIPS ratification in a different perspective.

5. Prospects of reinforcement of legal pharmaceutical patent system in developing countries

When the TRIPS agreement was being ratified, the developed countries had repeatedly stressed on the fact that the developing countries too would benefit by strengthening their IPR regime. First of all, it was stated that a strong IPR regime would promote FDI and technology transfer, which would at last help the developing countries stimulate their industrial growth and gain access to the latest therapeutic innovations (Correa, 2001a, 2002b). Then, it was stated that public health objectives would not be threatened by the TRIPS agreement insofar as exceptions had been built in to deal with medical emergencies or to remedy abusive trade practices such as market rationing or fixing of prohibitive prices. What has happened with these promises?

5.1. Two different paths followed by developing countries: lessons learnt

First and foremost, let us recall that the analysis revealed that the Indian pharmaceutical industry's growth curve was largely due to the relaxation of its IPR regime. By switching from a stringent IPR regime to a more flexible one in 1970, the Indian authorities managed to ensure their pharmaceutical industry's growth and improve accessibility to medicines. Furthermore, the growth of the domestic Indian industry does present definite benefits for the rest of the world as suggested by the impact of the competition war unleashed between MNCs and Indian generic drug manufacturers in the ARV market (Guennif, 2004, Guennif & Mfuka, 2005). In this sense, this industry has helped to improve global welfare by offering treatment at more affordable prices to persons infected by HIV/AIDS.

Moreover, Thailand's experience in this matter is enlightening. The country took the opposite path compared to India's journey by strengthening its IPR regime as early as 1992 under US trade pressures and subsequently due to the ratification of the TRIPS agreement. To this date, if the benefits of this reinforcement remain hard to pinpoint as regards FDI and transfer of technology, the disadvantages in terms of patients' access to treatments are, on the contrary, clearly perceptible.

In fact, as regards FDI and transfer of technology, it seems that between 1984 and 1998, Thailand companies remained mostly in the hands of Thai nationals (Supakankunti & alii, 2001).

Therefore, it appears that there was very little FDI inflow in the local pharmaceutical industry since 1992. If the FDI amount increased by very little, it is because MNCs preferred to import rather than manufacture medicines locally as is evident from the growing share of imported medicines in Thailand since 1992. In real terms, following the amendment of patent laws, the imported products' share in the local drug market was 42.8% in 1999 as against 23.5% in 1984. In short, having obtained patents on drugs and not being bound to make actual use of their patents in the form of local manufacturing, the MNCs were tempted to simply take advantage of existing formulation capacity in the country (Guennif & Mfuka, 2003a, 2003b) and very rarely promoted technology transfers to the country.

As regards accessibility to treatment, between 1979 and 1992, a generic medicine usually became available in the market 1 or 2 years after the launch of the brand-name drug. However, following the strengthening of the IPR regime in 1992, a generic version could be made available only 5 years after filing of patent (Kwa, 2001). Thailand also experienced great difficulties in meeting public health objectives when for example the HIV/AIDS epidemic had to be dealt with and patients' access to treatment facilitated. The "ddl affair" is a perfect example of the magnitude of these difficulties. Ddl is an ARV whose patent is held by the American company Bristol-Myers & Squibb (BMS). Having managed to develop a generic version of ddl, the public sector unit, GPO, under the aegis of the Thai Health Ministry, was forced to stop marketing this drug due to the modification in the Thai Patent Act and the introduction of patents on processes and products. For want of a generic version, ddl became an inaccessible drug for infected persons: it was offered for $0.5 a pill by BMS whereas GPO had sold it for $0.15 in 2001 (Guennif & Mfuka, 2003a, 2003b). Not willing to give up, in 1997, GPO filed a request for a CL in view of the national emergency created by the HIV/AIDS epidemic. BMS then exerted pressure on its government, which in its turn interceded with the Thai authorities. Under commercial pressure[30], the Thai Government had to give in and refuse the grant of the CL. In 2001, an association of people living with HIV/AIDS sued BMS and asked for the revocation of its patent for lack of significant inventive steps or novelty. Since then, the patent was not invalided but its scope reduced so that GPO could produce tablet larger than 100mg dosage form (Oxfam, 2004). The generic was marketed at half price of the brand-name drug. At the end, under the pressure of the civil society, BMS gave up its patent.

After all, in response to the question whether a stringent IPR regime promotes transfer of technology and improves accessibility to medicines, the past Indian experience and the present Thai experience would raise serious doubts. Of much more concern is the recourse to exceptions provided for by the TRIPS agreement in theory, which remains problematic, especially when we take into account the developing countries' place in world trade and the import of trade pressures emanating from the developed world.

5.2. Room for manoeuvre for India and developing countries?

How can we ensure that patent protection does not impede access to medicines in poor countries, while at the same time preserving the patent's incentive role in the R&D field? A compromise seems difficult to reach. The developed countries are clearly at an advantage with respect to the developing countries (Ramappa, 2000). As a matter of fact, the industrialised nations, cradles of pharmaceutical firms that are patentees of most drugs, are the main exporters of both processes and products. It is natural that their interest lies in a stringent protective IPR

[30] The United States used "Special 301" against Thailand too.

regime in as many countries as possible. The TRIPS agreement affords them this protection and therefore further strengthens the MNCs' predominant position and their income throughout the world[31].

On the other hand, the developing countries are, for the most part, importers of both processes and products. They are likely to be subjected to a rise in prices for imported patented drugs. At the same time, the market launch of generic drugs, which provoke a significant drop in prices, would be delayed due to the extension of the protection period granted by the patent. Consequently, there is already a fear of foreign monopolies in the domestic market and the transfer of profits to industrialised nations, as well as a loss of public control over drug prices, promotional campaigns and national drugs policy. It will then become very difficult for developing countries to protect their imperatives for public health – imperatives that had been put forward in the objectives and principles of the TRIPS agreement (Articles 7, 8.1 & 8.2) and reaffirmed at Doha (Article 4).

In fact, given the difficulties and pressures encountered by developing countries in making effective use of flexibilities provided for in the TRIPS agreement, the Members at first reaffirmed at Doha their commitment to the principle of IPR protection as the driving force behind innovation: "We recognize that intellectual property protection is important for the development of new medicines." (Article 2 of the Declaration on the TRIPS agreement and public health adopted on 14th November 2001 at Doha). Then, it was reiterated that the principle of IPR protection was subordinate to the principle of public health: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health", (….), "Accordingly, 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." (Doha Declaration, paragraph 4). It was thus that the possibility available to the Members to take recourse to PI and CL in case of national emergencies, and the sole discretion to define what "constitutes a national emergency" was reaffirmed (Paragraphs 5b and 5c). On the one hand, each State was left free to establish its own regime of exhaustion of IPR (Paragraph 5d), which will determine the practical possibility of recourse to PIs at a regional or global level. However, on the other hand, faced with the objections raised by African countries, which were unable to take recourse to CL due to insufficient manufacturing capacities in their territory, the ministerial WTO conference held at Doha instructed the Members to find a solution before the end of 2002 (Paragraph 6). This proposal was rejected by, among others, the United States[32].

Indeed, in August 2003, a few months before the Cancun summit, an agreement was reached (WTO, Press Release dated 30th August 2003). The press release provided for an additional flexibility: the possibility for Members to import medicines under CL. Thus, a country like Botswana could very well issue a CL and ask a company established in a third country (where the patents would possibly be recognised) to proceed with the manufacture of drugs and export them to its territory enabling it to deal with a national emergency such as the HIV/AIDS epidemic.

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[31] Besides, the proposal came at a moment when the companies were going through a serious crisis. Whereas the R&D programmes were becoming costlier by the day, the number of molecules being patented was decreasing substantially every year. To add to the woes, a large number of blockbusters were falling and would be falling in the public domaine, eating into the profits of corporations holding patents that had expired or were about to expire (www.cptech.org, Pignarre, 2001).

[32] For a presentation on the Indian position, refer to Sen (2001).

Further, the WTO General Council's President's statement laid down a series of undertakings to avoid possible abuse and committing the country to use this mechanism in "good faith". The statement aimed at reassuring the United States about the unjustified use of the notion of national emergency as a cover for commercial interests. Similarly, the CL issued by exporting Members would set out a series of strict conditions: a predetermined production volume, unequivocal identification of products, notification of these conditions and the country of consignment as well as adequate remuneration to the patent owner as provided for in Article 31h of the TRIPS agreement. All in all, since the Uruguay Round, though not reversed, a distinct change had taken place in the balance of power between developed countries and developing countries, as evidence by the Doha declaration adopted on 14th November 2001 and the agreement reached in August 2003.

Finally, in the matter of treatment accessibility, it must be added there is yet some more room for manoeuvre for developing countries in general, and India in particular. There is nothing in the TRIPs agreement that prohibits Member from taking institutional price control measures once the principles of national treatment and the most-favoured nation treatment have been met. Indeed, in France, such price control processes do exist. On the one hand, drugs are classified either as reimbursable medicines or as non-reimbursable medicines. On the other hand, negotiations between the public authorities and pharmaceutical companies are arranged to fix the prices of the first category of drugs. Thus, in order to control its health expenditure and unlike the United States, France has learnt to maintain a balance between compliance to patent laws and controlling public healthcare expenditure.

For all that, recourse to both the flexibilities contained in the TRIPS agreement and effective price control measures presupposes a very strong political will on the part of Indian authorities as well as adequate economic ability to withstand trade pressures from developed countries. Indeed, the last amendments of the patent law made in 2005 indicate that India is strongly committed to the protection of public health within its territory, and abroad. On one side, the scope of patentability was restricted. As a consequence, new forms and new uses of a known drug are not patentable. Additionally, a pre-grant opposition is provided: people can oppose a patent application filed by a firm. Due to these two provisions, Novartis was denied market exclusivity rights for its Gleevec in 2005. The Patent Controllers state that Gleevec was not a new drug but a new use of a previously known drug. Presently, Novartis is challenging the decision. Besides, numbers of NGOs oppose the patent application filed by the firm Gilead on Tenofovir (an anti-AIDS medicine) on the same ground. NGOs are willing so to ensure patients' access to this essential ARV. Earlier, an opposition was made to GlaxoSmithKline's exclusive market rights on Combivir, an anti-AIDS bi-therapy. Since then, Gilead announced its intention to grant voluntary licenses to Indian manufacturers for Tenofovir … after obtaining a patent in India. On the other side, India has amended its patent law in order to allow exportation of drugs produced under compulsory licence. Thus, domestic firms can produce patented drugs and export low-cost generics to an African country for instance, as soon as other regulatory conditions are met.

6. Conclusion

The IPR regime adopted by any country is essentially a tool that strives to ensure both the growth of the domestic pharmaceutical industry and people's access to medicines. But, contrary to the very easily advanced theory, there is no paradox between the two. From this perspective, the Indian experience has shown that it is precisely the relaxation of its national IPR regime that promoted the growth of its domestic industry, thereby ensuring a better patient access to

medicines. However, the globalisation process does not overlook any sector, which means that medicines too are submitted to the new legal framework established within the WTO.

Confronted with this new framework, which constitutes a reinforcement of the legal patent system the world over, India is witnessing a reappraisal of its industry and as a corollary, of patients' access to medicines. The problematic of self-sufficiency in healthcare has resurfaced with the danger of India once again becoming dependant on foreign products, which are themselves fortified by guarantees granted at the international level. It is the main stance taken by some developing countries, which would like the WTO to acknowledge the priority of patient care over drug manufacturers. In other words, these countries would appreciate it if the WHO logic is given more evident and effective weight, for it is a logic that recommends healthcare for all and the recognition of health as a global public good for this new millennium (Kaul & alii, 1999, WHO, 2001, Correa, 2001a).

Admittedly, the Doha declaration does highlight the right to healthcare and access to medicines, but the international rules as they exist today are still markedly in favour of manufacturing in developed countries to the detriment of poor countries. This is the entire point of the developing countries' and in particular India's position, who are currently engaged in fresh international negotiations in search of a better balance between the urgent necessity to guarantee the most underprivileged populations an as satisfying as possible access to medicines, especially to fight against epidemics, and the consideration of the drug industry's financial compulsions. In any event, this problem has transcended from the national level into the international level.

Yet, to conclude, we must add that for the past five years, far from the logic of "multilateralism" recommended by the WTO, the US has been going on a tour of developing countries in Latin America, Africa and Asia, with a view to making them sign Free trade agreements (FTAs). Since 2000, bilateral or regional agreements have been signed with Jordan, Morocco, Chile or Central America. This tendency to develop trade diplomacy out of the WTO system will surely be reinforced since the WTO General Council formally suspended global trade talks on 27th July 2006, following the collapse of last-ditch efforts to overcome divisions on farm supports. To that extent, the growing number of these FTAs may be much more harmful in matters related to strengthening of IPR protection in the world and could very well make economic compulsions run counter to healthcare imperatives of developing countries. More precisely, many provisions may undermine the recourse to TRIPS flexibilities, prevent the supply of generic drugs and finally damage drugs accessibility in developing countries. Among others, efforts are made to broaden the scope of patentability so that new forms and new therapeutic uses can be patented; data protection is ensured for 5 years, even 10 years; and provisions governing CL and PI proved to be more restrictive compared to the ones in the TRIPS agreement. To sum up, these provisions could well strengthen in a more than a reasonable manner the interests of the MNCs by ensuring the protection and the extension of monopolistic positions in developing countries (Cptech, 2004, Oxfam, 2004, Abbott, 2006, Guennif, 2006).

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