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TRIPS AND PHARMACEUTICALS; INQUIRY INTO THE FOUNDATIONS OF THE INTERNATIONAL POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS;

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> « The Public will learn that patents are artificial stimuli to improvident exertions; that they cheat people by promising what they cannot perform; that they rarely give security to really good inventions, and elevate into importance a number of trifles […], no possible good can ever come of a Patent Law, however admirably it may be framed. »
>
> -*The Economist*, 1851.

The XXIth century is auguring a world where production has shifted literally from 'hardware' to 'software'. This new economy brings in new realities that are difficult to cope with using the traditional tools provided by political economy. One of these new realities is the importance intellectual property has taken as a form of capitalized value. Since it is taken for granted that the market provides the optimal allocation of scarce resources, it is considered that by commodifying ideas and knowledge, the market will permit the same optimal allocation. This assumption was behind the Trade-Related Intellectual Property Agreement (TRIPS) that was negociated and ratified during the Uruguay Round. Nevertheless, we intend to show through a closer on the pharmaceutical industry that the legitimacy of the implementation of Intellectual Property Rights (IPR) may sometimes be disputed. Trade-Related Intellectual Property is not a natural right, it is a social construction aiming to ensure the greatest social welfare by encroaching the market through provisional monopoly rights. In this paper, we will first introduce the theoretical aspects of intellectual property rights (IPR) by analysing the different elements used to legitimize intellectual property. Second, we will show how intellectual property is managed in international trade through the international agreement of 1993 on Trade-Related intellectual Property (TRIPS). Finally, we will analyse concretely the impact of the TRIPS agreement for producers and consumers in the pharmaceuticals industry. In our conclusion, we will show how our analysis of the pharmaceutical industry allows us to question more deeply the justification of intellectual property in terms of economic efficiency.

INTELLECTUAL PROPERTY RIGHTS IN THEORY

Intellectual Property Rights (IPR) usually refers to three elements: Patents, Trademarks and Copyrights. In this paper we will focus mainly on patents. The existence of IPR is generally justified as a palliative to the inherent incapacity of the market to reward innovation, be it industrial, intellectual, artistic or commercial. Without a doubt, innovation requires important costs in Research and Development (R&D). Any useful innovation, if not protected by a legal right, can usually be reproduced or copied by others at low cost in generic versions. If not protected, the innovation means no potential profits for the innovator and will not permit him to compensate for the costs entailed in R&D. Because of the presence of increasing returns to scale, R&D firms couldn't survive as price takers (if output is priced at marginal cost, the R&D firms would not cover the cost of developing the technological innovation that gave the firm its increasing returns-to-scale "production function") [Fulton, 1997]. Hence, without IPR, the market doesn't give any incentive to invest in R&D for innovation. IPR are mechanisms put in place by existing authorities to guarantee an earning-capacity (a rent) from creative and innovative activities by granting a monopoly right to the innovator over his realization. IPR have therefore the incentive role for innovation by making the private investments in R&D profitable. The nature of IPR is not without contradictions; it seeks to compensate the deficiencies of the market by granting "legal monopoly rights" (over ideas, knowledge and techniques). But granting exclusive rights of exploitation also means compensating market deficiencies by distorting the market even more.

IPR is a property right not over a commodity but over capacities of production, ideas or informations (fabrication processes, softwares, etc.). By securing a greater earning-capacity (higher rent due to stronger IPR), the greater will be the incentive to innovate and to develop new technologies. Stronger IPR means a faster pace for technological progress, contributing more to common welfare. Nevertheless, once the innovation exists, the logic is inverted: stronger IPR means a greater net loss for the general welfare of the community since innovations will be less diffused (the cost to access the protected informations being greater). The absence of IPR would then mean a greater technological diffusion and a maximal general welfare. As the economist Joan Robinson has put it: "The justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse" [cited in Hettinger, 1989, p.48]. The dilemma over IPR is thus as follows: how can we ensure the greatest technological development (necessitating stronger IPR) while maximizing technological diffusion (necessitating weaker IPR). The duration of patents must be determined in a way that maximizes the social welfare of the community. In the case of TRIPS, it has been fixed to twenty years.

Note that experience shows that the absence of IPR does not necessarily mean a greater technological diffusion since firms can also maintain a position of technological monopoly by industrial secrecy. Some argue, like Thurow [1997], that industrial secrecy is in fact a more important constraint to the diffusion of knowledge than legal IPR since a patented invention has at least a minimal diffusion by the selling of the patent or the selling of licences (right to access and use patented informations without appropriating it).

Different philosophical schemes are used to justify IPR. In his book on the *Global Political Economy of Intellectual Property Rights*, May introduces three conventional schemata that usually justify IPR: 1-The hegelian self-developmental scheme 2-The lockean instrumental scheme 3-The economic or pragmatic scheme (by enhancing economic productivity) [2000, chap 1 & 2, see also Steidlmeier, 1993].

First, for Hegel, an author's ideas are expressions of his self and are part of his inalienable development as a sovereign human being; private property is thus tied to the liberty and creative self-development of the individual and refrains the dissolution of the self in the collectivity. But we should here remember Marx's critique of Hegel's self-developmental scheme through private property: for Marx, private property, in a capitalist society, is rather a mean for the alienation of the self. Through commodification, the worker's labour is robbed of its self-developmental potential for the individual who, through private property, is alienated both from the product of labour and the productive activity itself. The justification of IPR through the hegelian self developmental scheme is thus far from convincing since it is still nowadays confronted to the critique that commodification causes alienation of the self rather than its realisation.

Second, U.S. businesses have sometimes presented the lockean "fruits of labor" argument in terms of their enterprise. For example, according to the industry, it costs approximatively US$ 500 million to develop a new drug and bring it to market [Trouiller & Olliaro, 1999]. Since pharmaceuticals are easily cloned and the industry is extremely affected by pirating, pharmaceutical companies assert that cloning unjustly robs them of the "fruits of their labor"; IPR must then be implemented in the name of economic justice. However, the lockean natural law argument to achieve "economic justice" does not hold because of all the problems inherent to this "jusnaturaliste" tradition. As Proudhon showed [1840], the natural law of property is based on a "Droit d'Aubaine" (Windfall Right) which impedes economic justice. Proudhon's argument is that economic justice through appropriation of the fruits of his own labor can be achieved only if conditions of economic equality exist. Since the appropriation of land by some takes away the means of production for others, the lockean natural right of property is based on usurpation. The conclusion of Proudhon is thus that "All property is theft". Nevertheless, one could agree with Fichte [1800] that the instrumental lockean justification of private

property holds but only if the means of production are constantly redistributed in equal shares between all individuals [see Merle, 1997]. But Locke himself [1690, chap. 5] never intended to show that property through labour was a mean to achieve economic justice but was rather a mean to achieve economic efficiency. The claims for economic justice are irrelevant for Locke since "a King of a large and fruitful territory [in America] feeds, lodges, and is clad worse than a day labourer in England" [1690, §41]. Usurpation of the fruits of the workers' labor is thus justified by economic growth, which benefits to all.

The last justification of IPR brings us back to the argument about economic efficiency: how to maximize the social welfare of the community? Since the traditional optimization of resources allocation is through the market, it is considered that to achieve this economic efficiency with ideas and knowledge, we just have to treat knowledge as a conventional commodity —as something that is "trade-related"— and market efficiency will do the rest. Commodification of knowledge thus becomes the way to increase economic growth and consequently social welfare. The most convincing argument in favor of TRIPS was that conservative estimates showed that if these agreements were implemented, it would stimulate world economic growth by adding more than US$ 200 billion annually to global output [Maskus, 1994]. This justification of IPR in terms of economic efficiency thus seems to be the only legitimate one.

Since the justification in terms of economic efficiency is the only one to consider, we can sum up the argumentation justifying the existence of IPR in 3 points:

1- Innovation contributes to economic growth and social welfare

2- Innovation is costly since it necessitates a lot of investments in R&D

3- IPR permits to compensate for the costs of innovation, ensuring more innovation

Nonetheless, three comments are here necessary. First, we have to keep in mind that there is no convincing economic demonstration of the superior contribution to social welfare of investments in R&D as compared to investments in traditional production. One cannot tell if a shift of all investments in R&D to traditional sectors would mean an inferior social welfare. One cannot tell quantitatively if the enhancement of traditional production at the expense of innovative production would mean less social welfare. The only possible demonstration is a qualitative one in terms of the bettering of the human condition (which is always a subjective interpretation). Economists usually agree that prices and profits in the context of pure competition are indicators of the contribution to social welfare; as Hayek puts it in the *Fatal Conceit* [1988, p.104]: «Prices and profit are all that most producers need to be able to serve more effectively

the needs of men they do not know». Nevertheless, the determination of prices and profits by granting IPR for innovative firms corresponds to the degree of protection granted through IPR and is arbitrarily set by the authorities. For this reason, profits cannot be here considered as such an indicator.

Second, we must look more closely at the cost of innovation. We can agree that innovation proves to be costly. For example, the biotechnology industry ploughs some 45% of its annual income into R&D [Moise, 1999]. However, since knowledge is incremental, we must keep in mind that the greatest cost in R&D is the cost to access existing patented knowledge. One could argue with May [2000, p.53] that the acceleration of innovation could make a case against the role of intellectual property: « Technological innovation reached a critical mass *because* ideas were widely available, not because they were scarce, expensive and well protected ».

Finally, we must keep in mind that a great part of R&D is financed by public funds. Private firms sometimes get a patent on knowledge generated in its greatest part from public source. In 1990, from US$ 149.7 billions spent in R&D in the U.S., the industry spent US$ 73.95 billion, US$ 69.2 billion came from government sources while universities and other institutions contributed for US$ 6.7 billion [Steidlmeier & Falbe, 1994]. In 1996, a study showed [cited by Thurow, 1997] that "73% of private patents were based on knowledge generated from public sources such as universities and non-profit or government laboratories."

IPR IN THE GLOBAL POLITICAL ECONOMY

The importance of IPR in international trade is difficult to measure since we find no valid economic indicators of traded IPR value. Official statistics usually show the U.S. superiority in terms of absolute number of patents registered every year but we find very few indications about their value in foreign trade. Still, OECD provides some statistics on the trends of the knowledge composition of world-trade.

TABLE 1

OECD Classification of Manufacturing Industries Based on Technology

Technology level	***Industries***
High	industries Aircraft; Office & computing equipment; Drugs & medicines (pharmaceuticals); Radio, TV & communication equipment
Medium-High	Professional goods; Motor vehicles; Electrical machines excluding (comm. equip.); Chemicals (excluding drugs); Other transport; Non-electrical machinery
Medium-Low	Rubber & plastic products; Shipbuilding & repairing; Other manufacturing; Non-ferrous metals; Non-metallic mineral
Low	Paper, products & printing; Textiles; apparel & leather; Food, beverages & tobacco; Wood products & furniture.

Source: OECD, 1997

TABLE 2

Average Composition of Manufactured Exports by Technology Level, for OECD (per cent)

	1980-1984	1990-1994
High	11.7	16.2
Medium-High	44.1	46.1
Medium-low	23.4	17.8
Low	19.9	19.3

Source: OECD 1997

We must keep in mind that IPR have proliferated quickly in all spheres of production since the ratification of TRIPS in December 1993 by the end of the Uruguay Round. For example, even agricultural products now contain some degree of IPR (the example of Monsanto and their genetically modified seeds is well known). Even if IPR may constitute only a little portion of the added value of a good, we must remember that IPR means net earnings (a net margin of profit) since this added value usually doesn't cost anything to reproduce.

The Trade-Related Intellectual Property Agreement (TRIPS), implemented with the Marrakech agreements, which gave also birth to the WTO, introduces a global minimum standard (historically based on the standards of developed countries) for the protection of intellectual property, including those of pharmaceuticals. The standard introduced by TRIPS establishes the supremacy of the rights of individuals on intellectual property over collective rights. TRIPS is only a minimum standard since a state can choose to implement even stricter IPR laws but only if compatible with TRIPS standard and key principles of the WTO: national treatment, most favoured nation treatment and reciprocity. TRIPS provides transitional periods during which the different countries are required to bring their national standards to the level requested in TRIPS: developed countries had until 1996, developing countries had until 2000 (2005 for developing countries who never introduced patents before TRIPS), and 2006 for the least developed countries.

The ratification of the TRIPS by developing countries came as a surprise since they never favoured this kind of agreement. They argued that any agreement based on the supremacy of private rights over collective rights benefits only developed countries (capable of innovation) while endangering their means of development[1]. In fact, it makes little sense for developing countries to "protect" R&D investments that simply do not exist in their countries. By increasing consumption prices with IPR protection, they are just facilitating foreign profit making at the expense of domestic consumers. As explains Maskus [1994, p.81]:

> « Each country's interests in such policies depends on a host of national characteristics, including its innovative capacity, its ability to absorb foreign technology, and its preference for quality in consumption. Within each country innovative firms would gain from harmonization, while users

[1] Another surprising point about the ratification of TRIPS is that there was no parallel ratification of an "Antitrust Legislation Agreement". WTO is thus granting monopoly rights without having a legislation to bound monopolies. The antitrust legislation has been relegated to the national level. But as notes Marschall [1997], most countries don't have the ressources to implement such antitrust legislations. For example, the antitrust case with Microsoft in the U.S. necessitated, in 1994-1995, 14 000 attorney-hours, 5500 paralegal-hours, 3650 economist-hours and roughly one million pages of document; and the U.S. had to go over the whole process again in 1999. This kind of ressources is far from available in most countries, making national antitrust policies usually totally uneffective.

> of products will suffer higher costs. Overall, highly innovative countries would gain, while poorer countries would experience net losses. »

The *Economist* [2001] arrives to the same conclusion: "Governments of poor countries are being asked to co-operate in a redistribution of global income that will cost them hundred of millions of dollars". During TRIPS negotiations, developing countries wanted to maintain the existing international conventions on IPR (namely with the World Intellectual Property Organization (WIPO)) since they had a larger margin of manoeuvre to adapt national IPR legislations to national interest. The position of the government of India in his official papers presented in Uruguay Round talks reflected the flexibility reclaimed by developing countries [cited in Steidlmeier, 1993]:

> « The essence of the intellectual property protection system is its monopolistic and restrictive character; its purpose is not to "liberalise," but to conferexclusive rights on their owners. Recognising the extraordinary implicationsof the system, international conventions on this subject incorporate, asa central philosophy, the freedom of the member states to attune theirintellectual property protection system to their own, needs and conditions. This fundamental principle should inform and guide of the discussions theNegotiating Group on the intellectual property protection system. »

The traditional position of developing countries was that individual claims on intellectual property should be subordinated to more fundamental claims of social well-being. IPR shouldn't be an inalienable right, it should be a limited private right subordinated to greater interests; namely the right of a people to livelihood. For India and other developing countries, the principles which govern intellectual property should be relative to their socio-economic, developmental, technological and public interest priorities and to their needs as developing countries. India's position was followed by a set of very concrete propositions [Steidlmeier, 1993]: 1-patents must be fully worked (or exploited) in the host country 2-licensing of rights may be made compulsory 3-certain areas can be excluded from patentability for ethical reasons (namely food, pharmaceuticals, agricultural chemicals and biogenetic innovations).

TRIPS reflects mostly the interests of developed countries by implementing strong IPR protection based on the standards of the United States. In fact, the United States account for 40.6% of global spending in R&D [Economist, 2002]. TRIPS fails to recognise that there are perfectly legitimate reasons for different calculations of the socially optimal length of time for protecting a patent. Its ratification by the developing countries was therefore unanticipated by a lot of people. Some consider that developing countries joined TRIPS in exchange of some trading advantages from developed countries but also because they were subject to a lot of pressures. Let us remind

that the U.S. implemented the Special 301 clause[2] at the same time they started pushing to include TRIPS in the Uruguay Round. Another fact that could explain partly the acceptation of TRIPS by developing countries is the inclusion of a get-out clause (Article 31, reproduced in the appendix) which permits compulsory licensing and parallel imports (but only under strict conditions). Nevertheless, the United States has adopted a TRIPS+ point of view where TRIPS is considered as a minimal standard and all countries are encouraged (strongly) to implement even stricter IPR laws. Hence, the legal use by a country of Article 31, even when justified, is usually followed by an inscription on the Special 301 Watch list by the U.S.; which is usually a prelude to trade sanctions. In fact, just appearing on the list is a form of sanction because it discourages investments, turning a country's business sector and commerce ministry against generic production using compulsory licensing, forcing local officials to concede to U.S. demands by getting back in line [Rosenberg, 2001].

Note that the predominance of the interests of developed countries in TRIPS is also clearly illustrated in the article 34, which reverses the burden of proof for process patents from the plaintive to the defendant:

> « Article 34. *Process patents: Burden of proof*. For the purposes of civil proceedings in respect of the infringement of the rights of the owner […] if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process»

Since it is assumed that most legal disputes over process patents will be between firms holding IPR in developed countries and generic firms in developing countries, the burden of proof will then rest on the shoulders of the latter. TRIPS may be considered as one of the very first contemporary legal framework where the presumption of innocence is no more.

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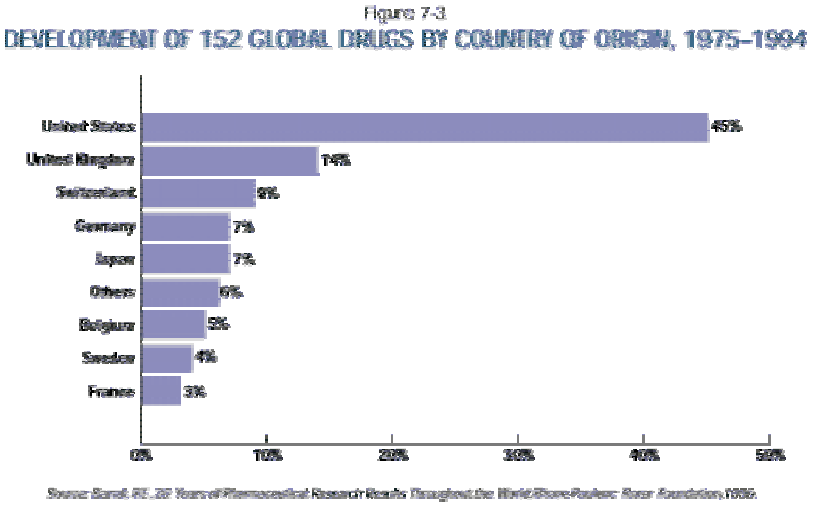
[2] The Special 301 clause, implemented as the Section 1303 of Omnibus Trade and Competitiveness Act of 1988, is a broad interpretation of the section 301 of the 1974 U.S. Trade Act. It allows the U.S. Trade Representative to sanction unilaterally countries regarded as engaging in "unfair" trade practices. The clause is designed to enhance the United States' ability to negociate improvements in foreign intellectual property regimes [See Grier, 2002]. Note that the "Special 301", just as the "Super 301", implements a watchlist where the US Trade Representative identifies the "priority foreign countries" that deny "adequate and effective" protection of IPR or "fair and equitable market access" to US persons relying upon IPR protection. The countries put on the watchlist are investigated to determine if unilateral trade sanctions by the United States are necessary. However, for any country, to be put on the watchlist causes foreign investments to flee the country just in case of American sanctions. To be put on the list is a sanction in itself.

IPR IN PRACTICE: THE CASE OF PHARMACEUTICALS

Patents are crucial in the pharmaceutical industry which has been particularly active in the lobbying for implementing TRIPS. Annual world sales of drugs amount to about US$ 400 billion [McNeil, 2000]. Production rests on a cleavage between patent holding multinational pharmaceutical giants (the most well-known being Pfizer, Bayer, Bristol-Myers Squibb, GlaxoSmithkline, Wyeth, Merck, Novartis, Aventis, Johnson & Johnson, Roche, Schering-Plough) and generics firms in developing countries (especially in India, Brazil, Argentina, Thailand, Egypt and China). Table 3 indicates the origin of patents over the most important medicines since 1975.

TABLE 3



To avoid the cost of patents held in developed countries, some developing countries resort to generic production. Note that generics are not illegal since most developing countries patent legislations normally do not include patents over products but only over production processes; reverse engineering is thus possible and so is the generic production and the commercialization of those products. Since most developing countries do not have to adapt their patent law to TRIPS standards before 2005, generic production cannot be sanctioned in those countries until then. It is only when generic drugs are sold in countries where a patent has not yet expired (without recourse to Article 31 of TRIPS) that a "generics manufacturer" becomes a "pirate counterfeiter" [McNeil, 2000].

IPR protected drugs are usually unaffordable for most patients (or "consumers") in developing countries. For example, 95% of people infected with HIV worldwide live in the world's poorest countries. Since effective treatments are patent protected, the result is that the

annual cost to treat a single patient with AIDS is up to 100 times the average GDP per capita in developing countries [Schull, 2000]. A generic drug is usually 80% to 98% cheaper than the corresponding IPR protected drug. In most countries, access to essential medicines thus means producing or importing generic drugs.

The amount of losses due to such drug counterfeiting is in dispute. Some executives claim that Western pharmaceutical manufacturers are losing at least US$ 40 billion every year. But we must keep in mind that Western pharmaceutical manufacturers would sell very little in the developing world at the price they charge in U.S. or Europe. Harvey E. Bale Jr., director general of the International Federation of Pharmaceutical Manufacturer Associations, a Geneva-based trade association, estimates the lost sales at about US$ 3 billion [McNeil, 2000]. However, the pharmaceutical industry is ranked as the world's most profitable (See Table 4).

TABLE 4

Top Five Most Profitable Industries Worldwide, 1996

Rank	Industry	Median return on revenues (%)	Industry	Median return on assets (%)
1	Pharmaceuticals	17.1	Pharmaceuticals	13.8
2	Diversified financials	10.6	Telecoms	6.8
3	Telecoms	10.1	Food	6.7
4	Beverages	6.1	Beverages	6.0
5	Chemicals	5.1	Specialist retailers	5.1

Source: *Fortune*, 4 August 1997, F-29 – F-30.

As shown by the Public Citizen [April 2001], the drug industry's success in the Fortune 500 profitability rankings has become a rite of spring. In the 1970s and 1980s, profitability of Fortune 500 drug companies (measured by return on revenues) was two times greater than the median for all industries in the Fortune 500. In the 1990s the drug industry's profitability was almost four times greater than the median for all industries in the Fortune 500.

The Pharmaceutical Research and Manufacturer of America (PhRMA), an industry lobby group, argues that "we need to be profitable in order to attract the capital to sustain innovation" [cited in McNeil, 2000]. This argument is being criticized both pragmatically and historically. Pragmatically, according to the data of the Fortune Magazine, the Fortune 500 drug companies dedicated in 2000 12% of their revenues to R&D while dedicating 17% to profits

and 30% to marketing and administration [see Public Citizen, April 2001]. Historically, for organisations like the 1999 Nobel Peace Prize Médecins Sans Frontières (MSF), this argument does not hold for developing countries [MSF & al., 1999]:

> « Among the 1223 new chemical entities commercialized from 1975 to 1997, […] only 13 (1%) are specifically for tropical diseases. A close analysis of these results shows that 2 out of those 13 drugs are actually updated versions of previous products, 2 are the result of military research, 5 come from veterinary research and only 4 (0.3%) may be considered as direct results of R&D activities of the pharmaceutical industry. »

The actual profit-driven system of innovation seems unable to meet current and evolving social needs of the poorer populations. R&D focus on the most profitable pathologies, namely heart diseases, cancer, AIDS but also "comfort illnesses" like obesity, impotence or pilosity [Losson, 2000]. For example, it has been known for more than ten years that eflornithine is an actual "miracle cure" for sleeping sickness which infects 300 000 people each year and kills 150 000. However, stocks have run out because early hopes that it would help fight cancer have dashed and production stopped abruptly because judged unprofitable. Though, production has resumed since it was discovered that eflornithine could help remove facial hair[3].

Furthermore, as notes MSF, competition between pharmaceutical companies over high rates of profit is such that investments in promotion and publicity are usually greater than investments in R&D [cited in Losson, 2000]. Another argument against the "necessity" of high profits in order to attract more capital concerns the sources of financing for R&D. Even PhRMA estimates that private industry finances only about 43% of drug development [cited in Schull, 2000]. Especially if we look at patents on an individual basis, some seem clearly unjustified since they are private appropriation of researches mostly resulting of public funds. For example, five commonly used drugs against AIDS (didanosine, lamivudine, nevirapine, staduvine and zidovudine (AZT)) were financed by taxpayers and not by shareholders (those are the drugs the most in dispute actually between patent holders and developing countries who try to find alternative generic supply). The actual high price of around US$ 10 000 for a year's triple therapy (cocktail of medicines against AIDS) is hardly justifiable. As Pierre Chirac & al. [2000] explain:

> « Zidovudine was first synthesized in 1964. Most of the research that showed the drug effectiveness as an antiretroviral was done by the U.S. National Institutes of Health. Nevertheless, Glaxo Wellcome [merged in

[3] Bristol-Myers Squibb in association with Gilette announced in February 2001 that they would use the compound in a new facial cream, Vaniqa. The World Health Organisation (WHO) and MSF is close to an agreement for the companies to make an injectable form to treat sleeping sickness [McNeil, 2001].

> 1999 with SmithKline Beecham to form GlaxoSmithkline], having obtained the patent for zidovudine for the treatment of AIDS, brought the drug onto the market in 1987 as one of the most expensive ever sold. 13 years later, the drug remains unaffordable for most people with AIDS. They will have to wait another 5 years before the patent expires.»

But whatever may be the origin of existing patents, all pharmaceuticals firms have a direct interest to enforce the IPR conferred by held patents. With TRIPS, pharmaceuticals firms have now access to an international legal framework to impose disciplinary measures to enforce their rights as owners of knowledge. Medicines thus have become the theatre of different international disputes where pharmaceuticals firms try to implement a narrow and strict interpretation of their IPR to force "contravening" countries to discontinue production of generics. Developing countries represent a very low portion of the pharmaceuticals market (the whole African continent represents less than 1%). However, the endeavour to discipline the states is less a question of profit than a question of "principle" for the pharmaceutical industry: future earnings must be secured through the establishment of a strict legal framework. Any pattern where a country could use generics is interpreted as dangerous for the whole system; it is a threat to the business model. Thus, while some developing countries try to access cheaper essential medicines by resorting to Article 31 of TRIPS in order to use the provision of compulsory licensing, the pharmaceutical industry has deployed all necessary measures to enforce its rights.

The way the American pharmaceutical industry structured its lobbying is quite impressive. Organized around the Pharmaceutical Research and Manufacturer of America (PhRMA), an industry lobby group, the different pharmaceuticals giants manage to voice their interests very well in the American political arena. In 1998, pharmaceutical companies spent more than US$ 77 millions on lobbying in the United States (a level surpassed only by the tobacco industry) [Hoffmann, 1999]. But they spent more than any other industry in 1999-2000 by spending $262 million on political influence during the election cycle, that is $177 million on lobbying, $65 million on issue ads and $20 million on campaign contributions. The industry hired 625 different lobbyists in 2000 (or more than one lobbyist for every member of Congress). More than half the 625 hired lobbyists were either former members of Congress (21) or others who previously worked in Congress or in other federal government positions (295). It is thus not surprising that the Clinton and Bush administrations have been very receptive to the demands of that industry. In fact, only two countries adopted a hardline position (the TRIPS+ approach) concerning international patent laws: United States and Switzerland.

Note that among the 100 world largest firms in any industry, 14 are pharmaceutical giants according to the 2001 FT Global 500. Among

those 14 giants, 10 are based in the United States while 2 are based in Switzerland [see Table 5 below].

TABLE 5

PHARMACEUTICAL GIANTS AMONG THE WORLD LARGEST 100 FIRMS ACCORDING TO THE FT GLOBAL 500, 2001			
FIRM	**COUNTRY**	**MARKET CAPITAL (US$M)**	**RANK**
Pfizer	United States	263 996	4
Merck	United States	195 743	13
GlaxoSmithkline	United Kingdom	160 406	19
Johnson & Johnson	United States	135 007	24
Novartis	Switzerland	123 428	26
Bristol Myers Squibb	United States	123 310	27
Eli Lilly	United States	91 450	42
Roche	Switzerland	87 013	48
Schering-Plough	United States	76 340	58
American Home Products (now *Wyeth*)	United States	73 496	63
Pharmacia	United States	71 895	65
Abbott Laboratories	United States	66 116	72
Amgen	United States	65 291	73
Aventis	France	57 146	86

The United States have been particularly active in defending the interests of the pharmaceutical lobbies by promoting a hardline for the respect of pharmaceutical patents. Armed with a whole range of unilateral trade sanctions, the United States, since the Uruguay Round, constantly maintained the pressure to "discipline" the contravening countries producing generic medecines. But the pharmaceutical industry also puts pressure using other means at its disposal. The different events surrounding AIDS medecines in developing countries can be used as an illustration of the disciplinary power of pharmaceutical firms to increase their profit margins. In the following lines, we analyze briefly four concrete cases where pharmaceutical industry attempted to discipline "contravening" countries.

Thailand:

One and a half million out of 61 million Thais are infected with HIV. The monthly price for AIDS cocktails is US$ 675 whereas the typical monthly wage of an office-worker is US$ 120 [Wilson & al., 1999]. In 1992, Thailand was forced to implement a new Patent Act under the threat of unilateral trade Sanctions by the United States. In September 1992, the Thai Supreme Court issued a report entitled "National Experience on Judiciary and Intellectual Property System". It stated that "Thailand is not ready to change and improve the level of (pharmaceutical) patent protection," in other words, to move from the Act of 1979 which "intends to protect the public" to the new Act of 1992 which "aims to protect the inventors." However, Thailand has been forced by "countries who own technologies of producing pharmaceutical products to improve patent law for the exchange of trade benefits." Two weeks later, contrary to the recommendations of the Thai Supreme Court, the new Patent Act was implemented. Still, the Thai government, in harmony with its new patent law and Article 31 of TRIPS, allowed the production of generic versions of AIDS related drugs. In 1998, Thai pharmaceutical companies managed to produce legally generic versions of fluconazole, a drug for the treatment of cryptococcal meningitis (a fatal disease often associated with AIDS). The price of flucozanole, formerly manufactured locally only by Pfizer at the price of 12 000 baths (around US$ 330) for a pack of 50 tablets, dropped to 4000 baths a pack. Pfizer alerted the US government to intervene in the matter. U.S. put Thailand on the Special 301 list and threatened Thai authorities that it would impose a duty on their main exports (timber, jewellery, microprocessors) if they did not stop making fluconazole [Bulard, 2000]. The U.S. market represents 25% of Thai exports. Six months after the beginning of generic production, sales of generic fluconazole were banned in Thailand. The case of Thailand is a striking example of how the US bypassed WTO agreements to protect its drug companies [Boseley, 1999].

Ghana:

In sub-Saharan Africa, 25 million people are infected with HIV. At the beginning of 2000, a pharmaceutical distributor in Ghana purchased from Cipla (India's most famous generic firm) a small consignment of Duovir, a generic version of Combivir (a combination of two principal AIDS drugs). Combivir is patented by the giant Glaxo-Wellcome. Glaxo moved aggressively in Ghana to force the suspension of the sale. In letters sent to Cipla, Glaxo threatened the Indian generic drug producer with lawsuits if it continued to export to Ghana. In its letter, Glaxo said four patents issued by the African Regional Industrial Property Organization (ARIPO) provide exclusive marketing rights to its drug in Ghana. However, the ARIPO replied against Glaxo showing that the patents are in fact invalid in Ghana

since they were issued at a time when Ghana didn't provide patent protection to pharmaceuticals. As said an ARIPO spokesman: "if [Glaxo officials] went to court they would lose" [cited in Schoofs, 2000]. To avoid judicial procedures, Cipla stopped selling Duovir in Ghana.

Brazil:

Brazil is often depicted as a model in the fight against AIDS in developing countries [Rosenberg, 2001]. Brazil's government provides a state of the art treatment to anybody infected with HIV by distributing freely antiretroviral drugs (many of which are produced generically by Brazilian companies). In 1994, the World Bank estimated that by 2000 Brazil would have 1.2 million HIV-positive people; recent surveys showed that about only 530 000 people are infected. The Health Ministry spent US$ 444 million on AIDS drugs in 2000 (4% of its budget). The savings in terms of hospitalizations is estimated to US$ 422 million for the period from 1997 to 1999 (the savings in terms of halving the expected infection rates and in terms of productivity are not taken into account). In his article on the Brazilian model, Rosenberg concludes by praising Brazil for having understood the importance of generics [2001]:

" AIDS can become a manageable disease in the third world, but it takes power, in addition to other things. The ability to pull the price of AIDS drugs within reach of those who need them may someday come from the backing of some international organization, or the pharmaceutical industry might find religion. But at the moment, it arises only from the threat to make or buy generic drugs. AIDS is turning the third world's human landscape into a parched wasteland. Brazil has shown that, armed with the power of competition, a government can do more than sit and watch the desert encroach. ".

At the beginning of January 2001, Washington complained at the WTO that Brazil was violating TRIPS agreement by granting compulsory licensing for pharmaceuticals not produced in the national boundaries at least three years after the apparition of the drug. Article 68 of Brazil's Patent Law permits compulsory licensing to address (1) abuse of patent rights, (2) abuses of economic power and (3) failure by the patent holder to supply the needs of the domestic market. In the beginning of February, the WTO agreed to set up a panel to review the case. But with public attention mobilized in 2001 in favour of access to essential medecines due to the very mediatized lawsuit of pharmaceuticals giants against South Africa, the United States withdrew their complaint June 25, 2001 after an agreement with Brazil to use the newly created bilateral Consultative Mechanism to promote cooperation on HIV/AIDS and address WTO patent dispute. Brazil always maintained that Article 68 was fully consistent with the TRIPS agreement.

South Africa:

4.7 million South Africans are infected by HIV. In 2000 alone, 250 000 people died of HIV/AIDS. Infecting one South African adult out of five, HIV is considered as a threat to national productivity and development by the 1999 African Competitiveness Report. Following the end of Apartheid in 1994, the South African government inherited an health sector representing the racial divide. On one hand, a private health sector made up with advanced medical facilities and highly paid doctors that serves 20% of the population and accounts for 80% of national spending on medicines. On the other hand, the public health sector that serves 80% of the population but accounts for only 20% of national spending on medicines.

The new South African Constitution stipulates that "Everyone has the right to have access to health care services" [cited in MSF, 2001]. In 1997, the Mandela government passed the *Medicines and Related Substances Control Amendment Act* (Act 90 of 1997) to help realise this constitutional duty by setting a marketplace for medicines based on affordable prices. The amendment relies on Article 31 of TRIPS and resorts to generic medicines and parallel imports to lower the costs of treatments. However, PhRMA, an industry group based in the U.S., labelled the legislation "piracy" [cited in Vulliamy, 1999]. South Africa was immediately put on the "Special 301 Watch list" by the U.S.. On April 1998, Congressman Rodney Frelinghuysen of New Jersey (where Bristol-Myers is based) even introduced a provision into the Foreign Operations Bill to cut off all aid to South Africa until Mandela's proposals were dropped. U.S. dropped the sanctions threats in September 1999 but the Pharmaceutical Manufacturers' Association of South Africa, backed by 38 giants of pharmaceuticals [see appendix 2], had already launched a lawsuit against the South African government (blocking *de facto* the implementation of the bill) arguing that Act 90 was, among others, incompatible with TRIPS. After a three years delay (the bill still blocked), the case was heard in the Pretoria High Court from March 5 to 13, 2001. But the lawsuit was extremely mediatized and the public started to consider the pharmaceutical giants as bad guys feeding on the death toll of poor people to increase their profit margins. To say the least, the lawsuit was a fiasco in terms of public relations for the drug giants. The South African case set an important precedent in the jurisprudence of IPR in pharmaceuticals since April 19 2001, Drug giants dropped the charges and recognized the right of the South African Government to provide cheap AIDS-related medicines if some amendments were included in Act 90. The South African government agreed to the demands.

Those four examples show an evolution toward a softening of the American position following the different scandals over the access to essential medecines. In fact, in the debate over how to interpret the TRIPS agreement (a TRIPS+ approach or an Article 31 oriented approach), it seems that the Article 31 oriented approach gained the

advantage due to a worldwide public awareness surrounding the problems entailed in developing countries with TRIPS. The predominance of the Article 31 oriented approach of TRIPS was confirmed in November 2001 with the Doha *Declaration on the TRIPS agreements and the Public Health* by the ministerial conference of the World Trade Organization [See appendix 3]. Especially Paragraph 4 of the Declaration confirms the adoption of the Article 31 oriented approach by the members of the WTO:

> « 4. 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. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. »

But Article 31 concerns only the recourse to mandatory licensing for national production. One major problem thus subsists since most of the needing countries do not have the capacities to produce the medecines themselves (the WTO acknowledges this problem in Paragraph 6 of the Declaration and affirms their will to find a solution). Therefore, the problem is far from being solved to the developing countries' satisfaction. Nevertheless, The Doha Declaration can be considered as a spectacular U-turn of the American position.

There are at least two major reasons why the United States and the drug giants backed off from their original position. First, the anthrax crisis that followed the September 11 attacks. The United States threatened Bayer, producer of Cipro (used against anthrax), that they would produce a generic version of the drug if the company didn't accept to grant a substantial rebate. After this successful blackmail, it became impossible for the United States to oppose the assertion of other States of the primacy of the right to health before the right of patents.

The second reason is the implementation of a new strategy by the drug firms to differentiate prices between countries. With the disaster in terms of public relations because of the lawsuit against South Africa, drug giants started pushing for price differentiation between countries; a practice less controversial to the public eye since it reduces the price of drugs in developing countries but a practice that goes against existing anti-trust laws. The World Health Organization (WHO), criticized by many to be too close of the pharmaceutical industry [see Motchane, 2002], backed up those propositions. In May 2000, the WHO announced that they reached an agreement with the pharmaceuticals companies to lower the price of AIDS medicines in "qualifying" developing countries. Six months later, nothing had been done since the agreement was incompatible with existing anti-trust laws. In February 2001, only Senegal, Uganda and Rwanda had

reached an agreements with the multinationals (the price of AIDS related drugs dropped by 85%). Country-by-country negotiations (and firm-by-firm negociations) continue for pharmaceuticals companies to reduce the price of AIDS related drugs according to the income level of the country. In March 2001, while the trial started against South Africa, the drug majors chose to improve their public image by offering some African countries to supply them with drugs even at cost-price. But all "gentlemen's agreements" are conditional to the goodwill of the firms. However, for drug giants, the implementation of such price-differentiation according to income levels seems the long-term solution to supply essential medicines, it can be interpreted as their new long-term strategy. By granting pharmaceuticals giants the possibility of price differentiation (which is contrary to anti-trusts laws), they are granted the possibility to determine the price to maximize profits in each country. One needs to understand that the demand for drugs is very inelastic. Drugs are not everyday products; for the "consumer" it can be a matter of life or death so he can be ready to give everything he has to get it. Price differentiation, by setting the "optimal price" according to income levels makes sure that consumers will do so. Note that the WHO agreed only in May 2002 to a resolution designed to "give access to essential medecines". The resolution asks the WHO director to favour measures to promote price differentiation. Price differentiation is more and more perceived as the institutionnal long term solution to harmonize the access to essential medecines with a high rate of profits for the pharmaceutical industry.

CONCLUSION

We saw that the only possible legitimation of intellectual property was in terms of economic efficiency. Still, even this justification is very problematic. The case of pharmaceuticals allows us to identify two deeper problems. First, since national contexts are different, implementing a universal standard for protecting intellectual property as an inalienable right fails to recognize that national differences may demand different types of management of IPR legislations. TRIPS fails to recognise that there are perfectly legitimate reasons for different calculations of the degree of protection of IPR. IPR legislations were created to settle an optimal framework according to the social needs of the community; but by granting the supremacy of private rights over social rights, IPR can lead to abuse under certain conditions.

Second, the justification in terms of economic efficiency, through the contribution to social welfare, hides another problem: how can we measure economic efficiency? It can only be determined in terms of economic growth, in terms of accumulation of wealth. But what is wealth? Economists can only measure wealth in terms of value. Hence, a greater value created implies greater wealth and thus greater contributions to social welfare. This idea is the basic legitimation used in the economic discourse (be it neoclassical or marxist). The case of pharmaceuticals unveils a real problem. In their undertaking to discipline the market by doing away with generics and selling pharmaceuticals at higher prices (and by differentiating prices according to income levels), pharmaceuticals giants are capable of increasing the general price level of drugs in developing countries. Higher prices mean less consumption; but since the demand for pharmaceuticals has generally been very inelastic, the general decrease of demand is less than proportional to its increase in price. The result is that with the legal framework instituted by TRIPS, the overall value of drugs sold in developing countries is increasing while the quantity of drugs produced is decreasing. Economic growth is observed since there is accumulation of wealth in terms of value; but this accumulation of value is made by refraining of the overall production. Traditional analytical tools of political economy are unable to provide us here a good indicator for the economic contribution to social welfare in a particular sector. The legitimation of IPR in terms of economic efficiency thus falls apart.

If economic efficiency is determined by economic growth being the accumulation of value, theoritically IPR in pharmaceuticals really contribute to economic efficiency since it creates value. In practice, however, it is rather a net loss for the social welfare. Orthodox economics consider that « profit are all that most producers need to be

able to serve more effectively the needs of men they do not know » [Hayek, 1988, p.104]. Nevertheless, this assumption of the invisible hand where everyone contributes more to society by following his self-interest than by any other way just cannot be applied in the case of IPR. If the case of pharmaceuticals shows one thing, it is that profits have less to do with "serviciability to the community" than with political and economic power to coerce others and to induce dearth. Profitability depends less on the capacity to produce than on the capacity to control and refrain that capacity to produce. By settling a universal minimum to IPR in every WTO-member countries, TRIPS fails to recognize that the level of IPR can only be the result of a pragmatic political decision taken in accordance with the needs and the welfare of a community. One could rather argue that TRIPS is only an American strategy to discipline other countries so to ensure a favorable world income redistribution.

Some can argue that, even if a temporary redistribution of global income from developing to developed countries will occur, stronger IPR protection in developing countries will create better incentives for local development of new ideas. And the more important the reforms in favour of strong IPR, the bigger the gains in the long run for developing countries. Meanwhile, the WHO estimates that in 2020 there will be half a billion people infected with HIV/AIDS. Maybe it is time to remember what Keynes once said to criticize dogmatic liberal economists who considered that laissez-faire was more efficient in the long-run: "In the long-run, we're all be dead".

APPENDIX 1

TRIPS: AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, INCLUDING TRADE IN COUNTERFEIT GOODS

ARTICLE 30

Exceptions to Rights Conferred

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.

ARTICLE 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.

The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in sub-paragraphs (b) and (f) above where such use is permitted to remedy a practice determined after judicial or administrative process to be anti- competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non- assignable except with the assignment of the second patent.

APPENDIX 2

DRUG COMPANIES INVOLVED IN THE LAWSUIT AGAINST SOUTH AFRICA:

The Pharmaceutical Manufacturers' Association of South Africa
Alcon Laboratories (S.A.) (Proprietary) Limited
Bayer (Proprietary) Limited
Bristol-Myers Squibb (Proprietary) Limited
Byk Madaus (Proprietary) Limited
Eli Lilly (South Africa) (Proprietary) Limited
Glaxo Wellcome (South Africa) (Proprietary) Limited
Hoechst Marion Roussel Limited
Ingelheim Pharmaceuticals (Proprietary) Limited
Janssen-Cilag Pharmaceutica (Proprietary) Limited
Knoll Pharmaceuticals South Africa (Proprietary) Limited
Lundbeck South Africa (Proprietary) Limited
Merck (Proprietary) Limited
MSD (Proprietary) Limited
Novartis South Africa (Proprietary) Limited
Novo Nordisk (Proprietary) Limited
Pharmacia & Upjohn (Proprietary) Limited
Rhone-Poulenc Rorer South Africa (Proprietary) Limited
Roche Products (Proprietary) Limited
Schering (Proprietary) Limited
Schering-Plough (Proprietary) Limited
S.A. Scientific Pharmaceuticals (Proprietary) Limited
SmithKline Beecham Pharmaceuticals (Proprietary) Limited
Universal Pharmaceuticals (Proprietary) Limited
Wyeth (Proprietary) Limited
Xixia Pharmaceuticals (Proprietary) Limited
Zeneca South Africa (Proprietary) Limited
Bayer AG
Boehringer-Ingelheim International GmbH
Boehringer-Ingelheim KG
Bristol-Myers Squibb Company
Byk Gulden Lomberg Chemische Fabrik GmbH
Dr. Karl Thomae GmbH
Eli Lilly and Company
F. Hoffman-La Roche AG
Merck KgaA
Merck & Co., Inc.
Rhone-Poulenc Rorer S.A.
SmithKline Beecham

APPENDIX 3:

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001 at Doha Ministerial Conference

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. 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.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

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 effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 & 4

6. 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.

> 7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

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