WTO, Intellectual Property and AIDS

Case Studies from Brazil and South Africa

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The TRIPS Agreement establishes minimum norms for the protection of intellectual property rights. In certain fields, especially the pharmaceutical, it provides for an important degree of flexibility that the southern countries may be able to use to their own benefit. However, these countries frequently do not know how to take advantage of this flexibility, choosing instead to rely on the intellectual property criteria adopted by the northern countries. In other cases, this flexibility is insufficient to avoid problems in access to medications, as is the case for AIDS treatments.

Before analyzing the TRIPS rules, we would like to begin by outlining the basic idea behind the classification system for developing countries, as proposed by J. Sachs. Countries from the southern hemisphere may be classified into three categories as follows:

- Those countries that produce technology, such as some regions of Brazil (south and southeast), of India (central region), and of China (east coast), as well as Mexico, in some specific domains[2];
- Those countries able to adapt this technology to their own needs, such as the countries already mentioned, as well as Argentina and South Africa; and
- Those countries completely excluded from technological innovation.

For the first group (innovators), a flexible intellectual property system, which may be used to best address their needs, is most appropriate. This system must facilitate recourse to intellectual property rights in order to protect inventions, as well as provide for the possibility for competing southern countries to use the protected items in their research, and if possible, to also claim intellectual property rights.

For the second group, which includes the majority of the southern developed countries, an intellectual property system is of no interest at all. These countries lack the

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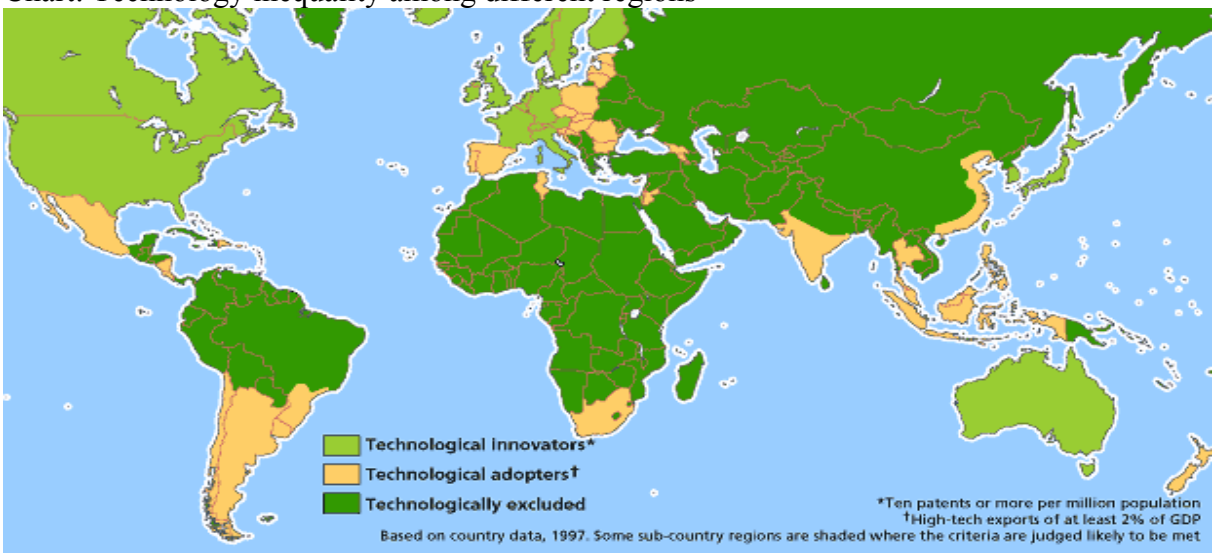
[2] Some authors, such as Jeffrey Sachs (see map above), consider that none of the southern countries are able to produce leading-edge technology. In this case, the southern countries would be concentrated within the two succeeding categories.

capacity to copy technology or to develop it, in order to compete with the northern countries.

Chart: Technology inequality among different regions



Source : SACHS, J. A new map of the world. The Economist. Article spécial, le 19 avril 2001.

However, given the current stage in the evolution of international law, the recognition of intellectual property rights is essential. The only way around this is to change the TRIPS norms, which is quite unlikely at the present time. These countries should fight to maintain at least a minimum degree of freedom, and to allow their industries and the neighboring industries to produce the patented products. In this way, when the monopoly on the marketing of a patented product ends, prices will be more accessible and the creation of jobs in the local industries will be more intense, as was once the case in the developed countries.

The majority of the southern countries are classified within the third group, which includes those countries excluded from technological production and even technological adaptation. For this group, the importance of a flexible intellectual property system is the same. Although they are excluded from production, many of these countries are consumers of products and technological advancements. The most remarkable example involves African countries and medications to fight AIDS. These countries are not in a position to

develop innovative new remedies against AIDS and, except for a private laboratory in South Africa, they are unable to copy already-existing pharmaceutical products through domestic production. Instead, these countries need to purchase them from multinational industries to fight the disease that decimates populations. Within the context of a rigid patents system, the cost of medications is controlled by only one patent holder, which fixes the prices as high as possible. As a result, these countries are interested in a less rigid intellectual property system, allowing for a degree of competition among companies able to produce such remedies.

In this text, we intend to address mechanisms already existing under the intellectual property legislation, which may be used especially by the second and third groups of countries mentioned above. Firstly, the TRIPS Agreement rules should be analyzed in order to understand how the Post-Marrakech negotiations developed on the interpretation of intellectual property norms, particularly with respect to the Doha Ministerial Conference. We can draw on this in order to understand the interpretation that governs the current legal system.

1. The TRIPS Agreement

Currently, the TRIPS Agreement provides a set of minimum rules for the protection of intellectual property, or, rather, it sets out the minimal level of protection that the countries must establish in order to be in agreement with the WTO international norms. It provides, therefore, an array of possibilities for the countries to introduce flexibility mechanisms that could operate in favor of the developing countries. Articles 8, 27 and 31 provide some examples. Article 8, which sets out the basic principles, provides for the adoption of measures applicable in special situations. Article 27, which provides for the definition of patentable products, also provides an outline for what can be excluded from patentability, and can therefore be freely copied or adapted. Finally, in providing for non-voluntary licenses, Article 31 makes the utilization of patented products in certain emergencies possible.

TRIPS provides for the granting of obligatory licenses in Articles 30 and 31:

> "**Article 30: Exceptions to the rights granted**

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

When 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: (…)

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; (…)

d) Such use shall be non-exclusive;

f) 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 that 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 subparagraphs (b) and (f) 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 that led to such authorization are likely to recur;

The obligatory licenses may be of three types[32]: licenses granted in the public interest, regardless of an action by the right holder; licenses to compensate a abusive or anti-competitive practice by the patent holder; and licenses designed to allow for the exploitation of another patent. The first one is the most interesting for our purposes, because the Government may establish it for public health reasons. The concept of emergency used by the international norm is flexible, as it is not clearly defined. The emergency could be, for example, the mass production of vaccines to fight an epidemic.

Unless undertaken in an unjustifiable manner, members may limit the rights of a patent holder. The justification for the limitation is evaluated by the member countries, and is limited by Article 31. This Article establishes that the license should be justified; the patent holder should be informed; the license should be fixed for a reasonable period of time; and it should be periodically reviewed in order to verify whether or not the original conditions for the granting of the obligatory license still exist. Its use should be non-exclusive (except in the case of sanctions for anti-competitive behavior) and inaccessible, and the right holder should be paid adequate remuneration. The level of remuneration varies in accordance with the legislation. In France, it is fixed through an agreement between the company and the government, or, if no agreement is reached, by the judicial system. Finally, the obligatory license may be officially granted by the administrative authority or by judicial decision.

The patent legislation has provided for the possibility of obligatory licenses for a long time. However, most countries have never made use of this instrument. The United States possesses the most experience in this area, especially with respect to antitrust legislation. The objective of this legislation is to avoid the formation of broad market monopolies as a result of the patents, as was the case in the merger of the transnational companies Ciba Geigy and Sandoz, in 1997, for *citoquina* products. The patents for the products were annulled. During the Dow Chemical acquisition of the Rugby-Darby Group, the Federal Trade Commission also demanded the *dicicolmina* license, as well as all the information related to the research and the product[4]. The objective of the disclosure of all

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[3] REMICHE, B. and H. DESTERBECQ. "Les Brevets Pharmaceutiques dans les Accords du GATT: L'enjeu?", *op.cit.*, p.41.

[4] CORREA. Integration Public Health Concerns into Patent Legislation in Developing Countries, *op.cit.,* p.112

pertinent information is to facilitate the participation of new competitors in the market within a shorter period of time.

The bases for the granting of a license are consistent between many countries, without much variation. The national legislation of many countries addresses the capacity to supply products, anti-competitive practices and the use of licenses by governments that seek to purchase medication for the poorer populations. The legislation also sets out the requirements for support for, or the refusal, to grant voluntary licenses under appropriate market conditions. Before entering into the North American Free Trade Agreement, Canada provided for automatic obligatory licensing, thereby allowing the Canadian industries to produce all of the medications, while paying a 4% royalty to the patent holders. Some authors credit this rule with the fact that medication prices in Canada are, on average, 21% below those in the United States[5].

A 1999 law in India provides for the granting of obligatory licenses three years after the patent grant, upon request by an interested party, if the production is insufficient to address the public need or if the price is unreasonable. Article 84 (1), should be read, after the normative modification, as follows:

> "At any moment, after the expiration of the **two-year term, calculated from the date of approval of the exclusive right for sale and distribution,** any interested party may submit a request to the Patents Office, claiming that the patented invention is not produced in India, or that the **reasonable needs** relating to the invention were not satisfied or that the invention is not **available at a reasonable price,** and may request the granting of an obligatory licensing to work with the invention"[5].

Where medication is concerned, the use of obligatory licensing may be decisive, above all for the poorest countries, which do not possess sufficient financial resources to purchase the medication. The justification for classifying the situation as an emergency is conditional upon the seriousness of the disease. However, it is not certain that the Dispute Settlement Understanding ("DSU") would accept this argument as another justification. In this case, it would be necessary to also have another supplier that offers the product at more reasonable prices than those of the patent holders. The obligatory license on medications is

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[5] SCHERER, F. M. " Le Système des Brevets et L'innovation dans le Domaine Pharmaceutique. "Révue International de Droit Économique., 2000, **Numéro Spécial : Brevets Pharmaceutiques, Innovations et Santé Publique**, p.120.

limited in its application to only those medications that are required. It cannot be applied to all medications.

The patenting issue has been amply discussed with respect to AIDS and it will be the focus herein.

2. Measures to Facilitate Access to Medication in Brazil and South Africa

Brazil and South Africa have adopted legal measures to facilitate access to medication in the struggle against AIDS. Each of these countries has used different legal mechanisms that are interesting for the international repercussions that they have caused and for the legal issues that arise with respect to their legality under the TRIPS Agreement.

2.1. Brazil

The Brazilian patents law of 1995 provides for non-voluntary (or obligatory) licenses in the following cases:

a) The Patent holder uses the patent in an abusive manner, which abuse must be declared through a judicial or administrative procedure;

b) The lack of exploitation of the subject of the patent within Brazil, as a result of either a lack of domestic production or incomplete domestic production of the product, or the non-utilization of the entire patented process, except where it is proven that economic production is unfeasible, in which case importation is allowed;

c) Insufficient availability of the product on the market; and

d) An emergency situation, as declared by an act of the federal executive power, which necessitates national production or where it is in the public interest. [6]

In the first three situations, any interested party that possesses the technical and financial capacity to produce the patented item may submit a request for a license to the National Institute for Industrial Property. In the first case – abusive utilization – the license holder will have a period of time to import the product. Third parties may also be authorized to import the patented item as long as they respect the international law on intellectual property. In other words, they must import the patent holder's product from abroad or from other licensed producers.

[6] Arts. 68 to 71, Law 9.279/95

The obligatory license may be requested only after at least three years have passed since the granting of the patent. It will not be granted if the patent holder, at the moment that the license is declared, justifies the non-utilization of the patent for legitimate reasons, demonstrates that preparations are underway for the exploitation of the patent or justifies the non-use of the patent on the basis of legal obstacles.

The fourth situation was regulated in 1999 though Presidential Decree 3.201, which addresses national emergency or public interest situations. The Decree establishes that a Minister of State may declare a situation of national emergency, in a part of or throughout the entire national territory, as a result of an actual or imminent public hazard. The public interest is based on issues of public health, nutrition, environmental protection or protection of sectors of prime importance for the economic and social development of the country.

If the patent holder is unable to deal with the situation, the public authorities may request an extendable, non-exclusive, remunerated obligatory license, for a fixed period, for the purpose of public usage. In the case of "public interest or extreme national emergency", the public authority may authorize the production of the patented object, even in the absence of an agreement on an extension or on the remuneration to be paid to the patent holder. This provision impedes the patent holder from invoking obstacles to the public production through jurisdictional claims, by claiming disagreement with the remuneration to be paid or with the term fixed by the government.

Even though this obligatory licensing system has never been used, the simple threat of its use contributes to the public discussion on access to medication and to a negotiated solution.

In response, on June 8, 2000, The United States Government requested the opening of consultations with the Dispute Settlement Body on the Brazilian norm, claiming that the obligation for local production imposed by the Brazilian law violated Articles 27 and 28 of TRIPS[77]. During the consultations, the Brazilian Government organized its defense based

[7] "Article 27. Patentable subject matter
1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

on the argument that the national legislation was in agreement with the TRIPS provisions. The United States supported the contrary position, particularly with respect to the need for the national production of the patented object. We can distinguish two distinct analyses of the Brazilian law: one with respect to the need for national production, and the other with respect to a more concrete definition of public emergency.

1. National production TRIPS makes no reference to the need for national production. Therefore, national production imposes a limitation on the patent holder's rights, which are those provided for in the Agreement. This text has been the subject of discussion since its proposal, in the beginning of the 1990's, in the Brazilian Congress. The Brazilian Government aims, through this provision, to foster the maintenance of local industries that depend upon the transnational companies. On the contrary, since the beginning of the legislative discussions in1990, many industries have ceased local production and have simply imported products from the large production centers, such as Johnson & Johnson, Pfizer, Bristol-Myeres Squibb, Wyeth and Merrel-Lepetit. Thus, importation increased by 4,752% between 1982 and 1998[8], and the intellectual property norms guaranteed to the multinational companies exclusive access to the local market for their patented products. Prior to the new law, these companies could have considered

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2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *public order* 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.
3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.
Article 28 Rights Conferred
1.A patent shall confer on its owner the following exclusive rights:
(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[7] for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2.Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts."

[8] Between 1982 and 1998, importation increased by 4.752%, in other words, from US$ 25 million to US$ 1.2 billion. In the three years following the promulgation of the patent law, the purchases of pharmaceutical products increased by three times and general importation increased by 174%, over the same period. See BEMUDEZ, EPSZTEJN, OLIVEIRA, HASENCLEVER. The WTO TRIPS Agreement and Patent Protection in Brazil: Recent Changes and Implications for Local Production and Access to Medicines, p. 15.

themselves prejudiced by the tariff and non-tariff barriers placed on the imported products and therefore at risk of losing the world market, given that Brazil was one of the five biggest consumers in the world of pharmaceutical products. It was this fact that encouraged Brazil to initiate local production. Between 1990, the year in which the new patent law was proposed, and 1998, more than one thousand production units were closed and 500 projects were cancelled in the chemical sector[9].

Table: Raw-material importation by multinational companies in Brazil and the respective final product

Company	Raw-material	Product
Johnson&Johnson	Cetoconazol Loperamida Miconazol Cainanzina	Nizoral/Cetonax Imosec Daktarin Stugeron
Pfizer	Clorpropamida Doxiciclina Piroxican Tetraciclina Oxamniquina	Diabenese Vibramicina Feldene Terramicina Mansil
Bristol-Meyers Squibb	Amoxilina Tetraciclina Nistatina	Hiconcil Tetrex Micostatin
Wyeth	Ampicilina sódica Penicilina Benzatina Penilina Potássica/Procaína	Amplacilina Benzetacil Wycilin
Merrel-Lepetit	Cloranfenicol Rifampicina Metoclopramida	Rifamicina Plasil

Adapted from Alanac *et al. Medicines: Who Are the Pirates?* O Estado de São Paulo. São Paulo, 09/08/95.

During that time, in order to save the local production of the multinational industries, Brazil argued that the TRIPS text was explicitly based on the agreements of the World Organization for Industrial Property, of which the Paris Convention is one of the most important texts[10]. According to the Brazilian government, the absence of local

[9] Data from the National Association of Chemical Industries, as cited by BEMUDEZ, EPSZTEJN, OLIVEIRA, HASENCLEVER. The WTO TRIPS Agreement and Patent Protection in Brazil: Recent Changes and Implications for Local Production and Access to Medicines, p. 30.

[10] TRIPS makes direct reference to the Paris Convention. This relationship with Agreements that are not related to the WTO contributes to the complexity of its analysis. See: RUIZ FABRI, H. "Le Contentieux de

production is a situation of non-utilization of the patent and can, therefore, be considered as a justification for the granting of a license. Brazil had already adopted a position contrary to the text during the GATT negotiations. During the first discussion of the TRIPS text, Brazil's proposal to remove the part of the paragraph relating to the possibility of importation by the patent holder was refused.

As a result of an agreement between the parties, the case was never judicially determined. Based on a restricted interpretation of TRIPS, some authors[11] are hostile to the possibility of requiring local manufacturing. However, we believe that a more detailed analysis of the Agreement text must be undertaken before coming to any conclusion. The subject is dealt with in Articles 27 and 28 of TRIPS. Article 27.1, which stipulates that discrimination as to the place of invention is not permitted, determines its nature, on the basis of whether or not the products are imported. Article 28.1 *a* grants to the patent holder the exclusive right to import or export the product, and the corollary right to impede third parties from importing or exporting the patented product.

Article 27 (1) prohibits all discrimination based on whether or not the product is imported or locally manufactured, but this provision should not be read in isolation. It is part of an Agreement involving other provisions and, as it deals with intellectual property, it should also be interpreted consistently with other international agreements, as provided for in Article 2 of TRIPS. Article 2 establishes the requirement for systemic interpretation of the international norms of intellectual property.

Article 2: Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).
3. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention,

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L'exécution dans L'Organe de Règlement des Différends de L'Organisation Mondiale du Commerce". Journal du Droit International, 2000 (3), p. 637.

[11] Subramanian, Arvind and Watal, Jayashree, (2000) *Can TRIPS Serve as an Enforcement Device for Developing Countries in the WTO?* Journal of International Economic Law (2000) pp. 403-416; Subramanian, A., 1999, a) *TRIPS and Developing Countries: The Seattle Round and Beyond,* Paper presented to the Conference on Developing countries and New Multilateral Round of Trade Negotiations, Harvard University, November 5-6, 1999. Fink, Carsten, *Entering the Jungle of Intellectual Property Rights Exhaustion and Parallel Imports,* paper prepared for Competitive Strategies for Intellectual Property Protection Conference organized by Fraser Institute in Santiago, Chile, April 19, 1999. Pour l'opinion contraire, see SHANKER, D. Brazil, Pharmaceutical Industry and WTO International Law and Trade. **2001,** 2000.

the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 5 of the Paris Convention for the protection of industrial property also establishes norms dealing with the abuse of intellectual property rights and obligatory licenses. It guarantees to the Government the right to impede abuses of intellectual property rights resulting from the lack of the exploitation of the right. It imposes two conditions for the obligatory license: the first one is the establishment of a minimum period of four years for its exploitation, counting from the date in which the request for the patent is made, or of three years, counting from the date in which the patent is granted, whichever period has a later expiry date and, if there is no exploitation within this period, the application of a sanction; the second condition is the non-application of the measure if the patent holder presents legitimate reasons[12].

Therefore, the Brazilian law is in agreement with the Paris Convention given that local non-exploitation is considered as abusive, when the economic conditions are favorable for its exploitation, and provisions are made for the party to claim and demonstrate justification. The periods imposed by the Paris Convention are also respected, in that the Brazilian legislation prohibits any licensing before three years, counting from the date on which the patent is granted.

Two interpretations of the TRIPS text are possible. Either the TRIPS text and the Paris Convention are contradictory, and this contradiction should be resolved through the usual rules for legal interpretation; or there is no contradiction, and it is necessary to establish coherence between these two texts. The first choice is excluded by Article 2.2 of TRIPS, already mentioned, because it expressly declares that "Nothing in Parts I to IV of

[12] "Article 5 (1) When the patent holder introduces, in the country it has been granted, objects manufactured in any Union country, such procedure does not lead to the patent expiration.
(2) Each Union country will be able to adopt legislative measures foreseeing the granting of obligatory licenses in order to prevent abuses as result of the exclusive right conferred by the patent, for instance, the absence of exploitation.
(4) No obligatory licensing shall be granted, based on the absence or insufficiency of exploitation before the expiration of the four-year period counting from the date of entry or three years counting from the patent granting, considering the longest period, if there is no exploitation within this period, the application of the sanction; the second condition is the non-application of the measure if the patent holder presents legitimate reasons. Such obligatory licensing shall be non-exclusive and it shall only be transferable, even under sub-licensing granting manner, as part of the company or commercial establishment that explores it.

this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention".

"Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention." The only remaining solution is the application of both Agreements in a complementary manner, always seeking a non-divergent, common interpretation[13]. In other situations, the Dispute Settlement Body has already had the opportunity to confirm this position, asserting that the agreements concluded under the ambit of the WTO should be simultaneously and cumulatively interpreted[14]. Internal coherence should be preserved.

A common interpretation should also take into consideration Articles 1, 7, 8 and 30 of TRIPS. The first of these allows for the adaptation of the Agreement to national legislation without offending the obligations contained therein[15]. Articles 7 and 8 emanate from general principles and from the TRIPS objectives, being the promotion of technological development, social and economic welfare, a balance between rights and obligations, respect for public health and a censure of the abuse of rights by patent holders[16]. Article 30 guarantees the governments the right to limit the intellectual property rights of patent holders, without causing unjustified harm to their legitimate interests.

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[13] See SHANKER. Brazil, Pharmaceutical Industry and WTO, *op.cit.*

[14] See WT/DS54/R

[15] "Article 1.1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own judicial system and practice."

[16] "Article 7. Objectives
The protection and enforcement of intellectual property rights 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.
Article 8. Principles
1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices, which unreasonably restrain trade or adversely affect the international transfer of technology."

Article 31 is not applicable to a practice provided for in article 30, which the footnote on page 7 of article 31 expressly excludes.

Article 30: Exception 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

When 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 (…)

Note 7: "Other use" refers to use other than that allowed under Article 30.

Therefore, an interpretation of the Paris Convention together with TRIPS cannot arrive at a different result. The government may grant an obligatory license in cases involving the abuse of an intellectual property right, which, according to the Brazilian legislation, is characterized by the lack of domestic production, when such production is possible. However, in the case of Brazil, the abuse of an intellectual property right cannot be claimed when local production is impossible. Such discrimination is, therefore, prohibited[17].

The Brazilian legislation is not the only one to provide for this possibility. The United Kingdom and Moroccan legislation also contain this provision. Under the United Kingdom patent law[18], Section 48 (3) allows the patent registrar to grant an obligatory license under an even broader array of conditions, as the issue of economic feasibility is not taken into account:

"(a) When the patented invention may be commercially produced in the United Kingdom, not being produced in all its extension rationally applicable;

(b) When the patented invention is a product, and its demand in the United Kingdom is sufficiently large to require (…) (ii) strong importation;

(c) When the invention patent may be established commercially in the United Kingdom, avoiding its importation and making it easier (…) (i) when the invention is a product (…);

(d) When the patent holder refuses to grant license with reasonable terms (…) (i) a market for the exportation of any patented product manufactured in the United Kingdom is not open (…) (ii) and that the establishment or development of

[17] SHANKER. Brazil, Pharmaceutical Industry and WTO, p.17-37.
[18] UK Patent Act

industrial or commercial activities in the United Kingdom suffers unfair impairment."

The British norm, even though more rigorous than the Brazilian norm, does not conflict with the intellectual property agreements. This is true particularly with respect to the abuse of intellectual property rights, and specifically with respect to the lack of domestic exploitation of the patent. It is also true for the situations where the agreements permit a lack of domestic production when economically feasible. The Brazilian norm, questioned by the United States, is even more generous than the American norm itself, given that the Brazilian norm accepts an inadequacy of economic conditions as a justification for the lack of local production.

Indirectly, the United States gives preference to local production, particularly where micro and small businesses, non-profit institutions and public institutions are concerned. They justify this preference based on a limitation on production authorization in The United States.

"**35 Sec. 204 Preference for The United States industry**

Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible"

2. Emergency. The second point deals with the definition of national emergency and public interest. The public interest is a criterion, adopted through an Executive Power norm during international discussions, used to regulate the national norm according to TRIPS. It is designed to protect public health, nutrition, the environment and sectors important for socio-economic development. This article was clearly copied from the TRIPS text, and in

particular from Article 8[19], but is included for the application of Article 27 (2). It does not create supplementary conditions nor restrictions to be added to the already-existing international agreements. On the contrary, it provides for the same conditions, such as indemnity, a periodic review of the license and the patent holder's right of response. On this particular point, the Brazilian norm and the TRIPS text do not conflict.

The publication of this Decree, in 1999, occurred within a broader context in which Brazil and the United States were debating the price of AIDS-related medications. For a long time, Brazil had been one of the countries with the largest number of HIV-positive individuals[20]. Beginning in the 90s, the country initiated a campaign related to access to medication and prevention, the results of which were significant. The constant, large-scale, public prevention campaigns included the free distribution of medications for the treatment of AIDS. Of note is that Brazil is the only developing country, and, in fact, one of the only countries in the world to distribute free AIDS cocktails to all infected individuals.

Distribution of the cocktail is a delicate operation because it is composed of 20 different medications. Seventeen of them are already in the public domain, being produced by different industries around the world. As a result of the centralization of purchasing[2121], the Brazilian Government possesses significant negotiating powers to reduce prices. If the negotiations to reduce the price fail, the possibility always exists for the country, itself, to produce the medications, given the existence of excellent public centers for pharmaceutical production, such as the Fundação Osvaldo Cruz[2222]. It is important to note that the laboratories capable of guaranteeing local production are mostly public research institutions that function at only half of their overall capacity. They are capable of supplying the domestic market and other developing countries[23]. This reality is quite different from

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[19] "Article 8. Principles
1 - Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

[20] There were 203,353 known HIV-positive cases between 1980 and 2000, distributed as follows: 151,055 men, 52,055 women, 7,086 children. However, the total is estimated to be 597 thousand infected. Official data from the Brazilian Government available on the site www.aids.gov.br, accessed on February 2, 2002.

[21] The Brazilian Government centralizes 35% of its medication purchasing, in general, and almost its entire purchasing of anti-AIDS medications.

[22] 40% of all purchases comes from this Foundation

[23] Local production started in 1993, with the production of AZT by a private laboratory. Public production started a little later in the following laboratories: FarManguinhos/FIOCRUZ, Fundação para o Remédio

India's, for example, where it is the private laboratories that possess the capacity to produce anti-AIDS medications.

Between 1996 and 2001, the prices of the generic medications decreased by an average of 72.5% and 85,000 people were placed under continual treatment. Some prices of remedies, such as Zalcitabina (ddC), decreased from US$ 1.15 per capsule of 0.75 mg to US$ 0.08 per capsule, or a reduction of 95%[24]. World Bank estimates predicted that, in the year 2001, there would be 1.2 million people infected with HIV. As a result of the public prevention campaigns, this number was halved. The number of deaths caused by AIDS was reduced by 50% and the quality of life of the infected people improved significantly, with a 25% reduction in hospitalization and a 50% reduction in the incidence of tuberculosis.

Medication	**Price in 1996**	**Price in 2000**	**Price in 2001**	**Best international price in 2000**
AZT (100mg)	0.5	0.18	0.15	0.32
AZT (300mg) + 3TC (150mg)	3.3	0.72	0. 68	2.74
ddI (100mg)	1.8	0.51	0.49	1.00
ddC (0. 75mg)	1.5	0.08	Unknown	Unknown
3TC (150mg)	2.8	0.83	0.35	3.12
d4T (40mg)	2.2	0.28	0.27	3.51
Indinavir (400mg)	N/A	1.72	1.6	1.67
Nevirapine (200mg)	N/A	2. 68	1.25	4.35

Source: Treatment Action Campaign. Brazil's HIV/AIDS treatment programme. Johannesburg, 2000
N/A = not available

The savings realized in the purchase of the medications was significant. It totaled US$ 200 million, when compared to prices in Canada or US$ 540 million if we consider

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Popular/SP, Laboratório Farmacêutico do Estado de Pernambuco, Fundação Ezequiel Dias/MG, Indústria Química do Estado de Goiás e Instituto Vital Brasil/RJ. These laboratories produce seven antiviral medications: zidovudina (AZT), didanosina (ddI), zalcitabina (ddC), lamivudina (3TC), estavudina (d4T), indinavir and nevirapina, and the zidovudina+lamivudina group (AZT + 3TC). MARQUES, M. B. "Brevets pharmaceutiques et accesssibilité des mécidaments au Brésil. "Reuve International de Droit Economique, 2000, **Numéro Spécial: Brevets Pharmaceutiques, Innovations et Santé Publique**, p.101 and the official site of the Brazilian Govenment, www.aids.gov.br, accessed on February 2, 2002.

[24] Official data from the Brazilian Government available on the website www.aids.gov.br, accessed on February 2, 2002.

prices for the products in the United States[25]. The Ministry of Health spends 4% of its budget on AIDS-related medications, or the equivalent of US$ 444 million. However, the decrease in hospitalizations allowed for a savings of US$ 677 million between 1997 and 2000[26].

The case involving three other medications (Efavirenz, from Merck ;[26] Nelfinavir, from Roche;[27] and Kaletra, from Abott) that were patented in Brazil in 1996, after the Brazilian norm on patents came into effect, is different from the cases for the generic medications[28]. However, at the beginning of the discussion on the obligatory licensing, these three medications corresponded to 70% of the total expenditures by the Ministry of Health in the fight against AIDS. Nelfinavir, alone, consumed 28% of the AIDS budget, totaling US$ 85 million. These numbers clearly show the weight of patents and their influence on the final prices of pharmaceutical products. They also show how difficult it is for the developing countries to negotiate as a result of the production monopoly conferred by the patent and the lack of choices, even for large consumers such as Brazil.

Initially, the Brazilian reaction was to rely on the clause pertaining to the lack of local production, given that these products were not produced in Brazil. The simple threat had important repercussions and resulted in governmental pressures on American and Swiss companies. The Brazilian Government demanded that Glaxo reduce its prices by 30% for medications marketed within Brazil. Glaxo, in turn, defended itself by arguing that these prices were already less than half the prices charged in The United States. And, The United States, in turn, alleged the non-conformity of the Brazilian norm with the international norms.

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[25] Official data from the Brazilian Government available on the website www.aids.gov.br, accessed on February 2, 2002.

[26] Official data from the Brazilian Government available on the website www.aids.gov.br, accessed on February 2, 2002. ROSEMBERG, T. Brésil, un Exemple à Suivre. Courrier international. **538,** 20001 affirms US$ 422 million without indicating the period. Thus the number of hospitalizations between 1997 and 2000 was 234 thousand less than predicted.

[27] Two products were negotiated with the company Merck Sharp & Dohme: Enfivarenz and Indinavir. The price reductions were 64% and 77%, respectively. Other important reductions should be mantioned: Nevirapina (58%), 3TC (71%) and ddC (95%).

[28] Other medications related to other diseasaes, such as interferon from Schering-Ploughé and Roche, were also threatened by the Brazilian Government. The difference achieved in prices for these medications was 27.5 times the price for local production.

In order to foster a favorable legal discussion, the Brazilian Executive Power published the decree regulating the obligatory licensing, under the same terms as found in TRIPS. With this new legal norm, Brazil was in conformity with the international norms and its negotiation power was more consistent. Internationally, Brazil supported a declaration at the Summit of the Americas, within the scope of the Organization of American States, and a resolution in the Human Rights Commission of the United Nations all in the same week, which affirmed that the access to remedies is a basic right. The last resolution was approved with 52 votes in favor and only one abstention, the United States[29]. These discussions were occurring simultaneously with discussions in South Africa. Non-governmental organizations were able to place the subject on the agenda. In order to understand the Brazilian position, it is necessary to first study the issue of South Africa and then to analyze how each country responded to the international pressures.

2.2. South Africa

South African law number 90, 1997, an initiative of Nelson Mandela, implemented three important measures against AIDS:

a) The production or importation of generic products to replace the products existing on the market;
b) The granting of authorization for the parallel importation of patented products; and
c) The implementation of a transparent price control system, with prices to be determined by a committee, for medications that are supplied by health institutions.

The first measure - the production or importation of generic products – facilitated the marketing of cheaper products. It obligates the pharmacist to inform the consumer about the existence of another, generic, medication with the same chemical properties but cheaper than the remedy the client intended to purchase. The pharmacist is also obligated to sell the cheapest product except if the physician writes “no substitution” on the prescription.

The second measure is the granting of authorization to undertake the parallel importation of patented products. The measure permits the parallel importation of a given

[29] See resolution 2001/33, dated April 20, 2001, from the Human Rights Commission, on access to medications within the context of a pandemic, such as HIV/AIDS, and the Quebec Declaration, dated April 22, 2001.

medication by a party other than the patent holder or authorizes the marketing of the product within the country conditional upon the imported product having the same composition, the same standard of quality and the same name as the product for which a patent is registered in the country.

The norm does not require the importation of a product placed on the market in a legal manner. Even if this could be inferred, given the fight against the contracting, to "produce legally" does not mean that there must exist a patent on the product in the exporting country. It simply means that the production is not illegal, such as in the case where a country is not a member of the WTO, or where the norms of intellectual property are not yet in effect, or in a country where the product is produced by a company that benefits from the obligatory license. In the case of AIDS, India produced, for domestic use, anti-AIDS medications at much more accessible prices. However, India did not yet have a patent law and was not engaged in an illegal practice from the point of view of the international legal system, because it was still within the grace period, granted by the WTO, for the implementation of the TRIPS norms. Before establishment of the norm, the South African Government purchased the 250 mg capsule of ciprofloxacin for 2.93 rupees from the Bayer laboratory, while in India, the price was set at 0.65 rupees.

The third measure consists of the implementation of a transparent price control system for medications, which involves the creation of a committee to evaluate the prices. The pharmaceutical industries are obligated to justify their pricing policy, demonstrate the production costs for the medication and show that their profit margin is acceptable. This Committee, which is part of the Ministry of Health, prohibits the sale of products at prices above those fixed by it.

This norm provoked a reaction from the transnational companies, which did not want to lose their profits in South Africa and which were concerned that this example would be followed by other developing countries. Thus, 40 pharmaceutical companies[30]

[30] The following entities participated in this process: South African Association of Pharmaceutical Producers, Alcon Laboratoires, Bayer, Bayer Ag, Bristol-Myers Squibb, Bristol-Myers Squibb Company, Byk Madaus, Ely Lilly, Eli Lilly And Company, Glaxo Welcome, Hoechst Marion Roussel, Ingelheim Pharmaceuticals, Janssen-Cilag Pharmaceutica, Knoll Pharmaceuticals South Africa, Lundbeck South Africa, Merck MSD, Novartis, Novo Nordisk, Pharmacia & Upjohn, Rhone-Poulenc, Rorer, Roche Products, Schering Schering-Plough, Scientific Pharmaceuticals, Smithkline Beecham Pharmaceuticals, Universal Pharmaceuticals, Wyeth, Xixia Pharmaceuticals, Zeneca, Boehringer-Ingelheim International Gmbh, Boehringer-Ingelheim Kg, Dr. Karl Thomae Gmbh, Hoffmann-La Roche Ag, Merck Kgaa, Merck & Co, Rhone-Poulenc Rorer S. A.,

took legal action against the South African Government for a declaration that the norm was not in conformity with the international agreements on intellectual property. The World Health Organization and NGOs immediately publicized the process in the media. As a result, one South African NGO, the Treatment Action Campaign, participated as *amicus curiae.* Other NGOs, such as "Doctors Without Borders" and "Oxfam", soon followed the example.

From a legal perspective, the process was based on a conflict between South African norms and the international trade norms, such as those of the WTO. The most controversial point was the possibility for parallel importation. Therefore, it is interesting to discuss the legality of parallel importation according to TRIPS.

In the case of South Africa, parallel importation is permitted in all situations, without any requirement for local production. Provided that a cheaper equivalent product exists on the international market, other parties may import it, even without the authorization of the patent holder. Under other legislation, such as in Brazil, the patent holder is not permitted to undertake parallel importation and such importation is limited to cases where the technical and economic conditions make local production infeasible.

The main argument used against parallel importation is contained in Article 28 of TRIPS, which provides for the exclusive right of the patent holder to import the product.

> **Article 28. Rights conferred**
>
> 1. A patent shall confer on its owner the following exclusive rights
>
> a) When the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;"

Analyzed in an isolated manner, the verb "to import" in this Article argues against the South African decision. However, it is linked to other provisions in the Agreement, as seen by the footnote corresponding to this paragraph. The restriction established in Article 28 refers to article 6.

Smithkline Beecham Plc, and Oliver Cornish. The citation repeats some companies due to the fact they are representing the umbrella company, such as a local branch company.

> "Article 28 (…) this right, as all other rights conferred due to the present agreement in respect to its utilization, sale, importation or other forms of distribution of goods **is subordinate to the provisions of article 6**" (…)
>
> **Article 6: Exhaustion.** For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights".

This means that the importation is limited by Article 6, as are the other rights of the patent holder. Thus, after selling the product, the patent holder loses his rights over the product. The party who purchases it may sell it to any person, in any country. This encourages the development of wholesalers and negotiations specialized in the international circulation of pharmaceutical goods. Only the license holder is prohibited from selling the product outside of the exclusive territory that was granted to it[31].

The exhaustion of rights means that once the product has been put into circulation, whether directly by the patent holder or indirectly with his authorization, the patent holder is considered to have received due payment for his invention. Thus, the patent holder can no longer impede circulation of the product, if the first sale was legal[32]. This position is accepted by most of the jurisprudence in many countries[33], with a few exceptions[34] in the jurisprudence and principles[35].

However, the theory of the exhaustion of rights may be interpreted differently. The Pharmaceutical Researchers and Manufacturers of America ("PhRMA") holds the position that TRIPS refers exclusively to the national exhaustion or to the patents territoriality principle. This means that a product legally introduced into the market of a given country, under the protection of a patent granted by that country, may not be imported from another country, where a patent also exists, even if both patents have the same owner"[36].

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[31] SHANKER. Brazil, pharmaceutical industry and WTO, *op.cit.,* p. 45.

[32] REMICHE, B. and H. DESTERBECQ. "Les Brevets Pharmaceutiques dans les Accords du GATT: L'enjeu?", *op. cit.*, p.50.

[33] Smith Kline & French Laboratories Ltd. v. Salim (Malaysia) Sdn Bhd (1989). Centrafarm BV v. Winthrop BV, Case 16. 74, [1974] ECR 1183. Other decisions are dealt with by SHANKER. Brazil, Pharmaceutical Industry and WTO. *op. cit*

[34] See in the United States, Minnesota Mining and Manufacturing Company c. Geerpres (194) RPC 35.

[35] Some authors disagree, such as Abbott, Frederick M., (1998) in *First Report (Final) to the Committee on International Trade Law* of the International Law Association on the subject of parallel importation (June 1997), 1 Journal of International Economic Law 607 (1998) and SHANKER. Brazil, Pharmaceutical Industry and WTO.

[36] REMICHE, B. and H. DESTERBECQ. "Les Brevets Pharmaceutiques dans les Accords du GATT: L'enjeu?", *op. cit.*, p.50.

However, the text of the Agreement does not provide for any difference between exhaustion on the national and international levels. Thus, the PhRMA statement seems to be unfounded. The argument is based on the negotiations history, which would have led to the drafting of the text as argued. Therefore, it deals about a historical exegesis. In fact, if we allow for the territorial exhaustion of rights, the patent holder would be able to establish an importation monopoly. The industry would not need to offer more attractive or lower prices than those established by other licensees from other countries, because the possibility of selling the products on the local market would not be open to the other licensees. Although this topic was discussed in the Agreement negotiations, this is not sufficient to conclude that the obligations of the member countries extend beyond those provided for in the international treaty. And, thus, we find in favor of the freedom of action for each country. Other countries, such as Argentina and Thailand, have adopted this same interpretation, although, in the case of Thailand, the country authorizes the importation of products manufactured by enterprises licensed by the patent holder only if that patent holder allows the sale of the product[37].

The American and European practices conflict with the concept of the international exhaustion of rights. The United States wants to avoid the sale, in America, of products that are not controlled by quality agencies in other countries, or in other words, products that might have a lower quality in comparison with the products produced in The United States. The European union accepts the exhaustion of rights within European territory based on Article 30 of the Rome Convention, but does not accept extra-communitarian, or international, exhaustion. Some authors[38] consider that this constitutes an offense to the

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[37] WATAL, J. Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It? Discussion Paper, no. 8, . Cambridge, Center for International Development, Harvard University, 2000, p. 4. B. REMICHE makes interesting observations in this respect: "Actually there are justifications for these countries, such as India and Brazil – and we are not talking about the less developed countries (LDC), to grant to the holder of a pharmaceutical patent, that produces the patented remedy in a third country, the exclusive right to import to these countries, under conditions fixed by the company and without the need for any counterpart-installment by them?
Even if one can affirm that there will be an abuse of the obligatory licenses, they would be an adequate response, actually operational, to this unique monopoly that is the importation monopoly?" *in* Remiche, B. "Le Brevet Pharmaceutique entre Intérêts Privés et Public: Un Équilibre Impossible ?" Revue de Droit International Économique, 2000 (numéro spécial), p.206.

[38] SHANKER. Brazil, Pharmaceutical Industry and WTO, *op. cit.*, p. 543-55.

GATT 1994, as it means that special treatment is given to some products in function of their origin, thereby offending the national treatment principle.

The first results from the discussion on interpretation emerged only during the Fourth Inter-Ministerial Meeting in Doha, in 2001. The Member States opted for the complete freedom for each national legislation to choose its position on the exhaustion of rights. Although the Doha declaration is not mandatory, it should be used in any controversy on the issue as an instrument for the interpretation of TRIPS:

> "5. d) 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 and 4.".[39]

These provisions allow interested countries to purchase patented products from laboratories in countries where patents do not exist or from third parties, which purchased the product from a licensee or from the patent holder. It is a measure that could have concrete effects, such as price reduction, but these effects are limited. Considering that all of the countries capable of producing the medication belong to the WTO and that new pharmaceutical inventions will probably be protected by intellectual property rights, it will become increasingly difficult to find useful medications that are not patented. The purchase from third parties may contribute to an increase in the offer of pharmaceutical products. This concern is mostly based on the different pricing policies used by the patent holders and by the licensees in different countries, but, given that this situation involves the third stage in the sale, it will probably result in an increase in prices. Another possibility would be to purchase the product from a producing company, licensed by the patent holder, which has a contract that does not prohibit exploitation of the product. This could contribute to a significant decrease in medication prices on a global level. However, it would be difficult because their licensing contracts with the umbrella company usually prohibit the company from exporting to other protected markets.

In the case of South Africa, the norms of international economic law have not been violated as a result of the parallel importation, if we consider that it involves the exclusive application of articles 28.1 and 6 of TRIPS. In any case, the country could also claim a

[39] Declaration on the TRIPS Agreement and public health.

public health emergency situation as a basis for the implementation of such measures. Such a claim is provided for in the text of the Agreement and has already been discussed in terms of the situation in Brazil. The number of HIV-positive individuals and the results of this epidemic on the South African population could certainly lead to characterizing the measure as resulting from an emergency situation.

This process presents another interesting aspect. It creates a context that allows the raising of numerous non-legal arguments in defense of the validity of the South African norms. Many representatives from NGOs were either heard by the judges or provided documents in order to demonstrate the injustice of the actions by the transnational companies, regardless the WTO agreements. Among the most debated arguments were: the insistence by NGOs that the patents granted to companies for products resulting from the participation of American public institutes for scientific research are contestable; on the different pricing structure for generic and patented products; and on the differences in the prices charged in different countries.

With respect to the first, non-legal argument, the process raised dozens of examples, such as d4T, discovered by the Yale University Medical School in the United States, and patented by Brystol MyersSquibb, or the Abacagir, developed by the University of Minnesota and licensed by Burroughs Welcome. The researchers and the NGOs wanted to demonstrate the injustice hidden behind the patents in a system in which part of the financing for the medications was guaranteed by the public purse, while the profits arising from these medications accrued only to the private companies, without any equitable compensation for the public research. According to their arguments, of the 30 medications studied, half had been financed by the American government at all stages of the research. Of the 17 medications invented in the United States, 12 had benefited from federal financing and most of them had received a significant amount of public resources[40]. This

[40] According to the declaration of James Love: "half of the priority medications (15 out of 30) classified in The United States as orphan medications have a classification corresponding to benefits of the United States legislation, including a seven-year period of exclusivity for the product's advertisement, which always applies, even when the medication is not patentable, plus a credit that covers half of the clinical research. Two thirds of medications financed by the government (10 out of 15) were classified as orphans. Eleven out of the 17 medications discovered in The United States were classified as orphans", paragraph 12.

fact directly conflicts with the argument of the pharmaceutical industries that insist on compensation for the companies' efforts, a basic tenet of the intellectual property system[41].

On the same topic, the NGOs also argued that the pricing control system for medications was not illegal. Most of the developed countries employ this system, including the United Kingdom, which limits profit margins to 17% to 21% for these products. According to the NGOs, the research costs claimed by the companies were false, given that a significant part of the research had been financed by non-repayable, public money.

The objective of the other arguments was to raise the awareness of the actors involved in the process and the world population, in general. People need to know that Africa concentrates 95% of the 36 million AIDS victims worldwide, and must be made aware of the lack of access to medication as a result of its cost and the inefficiency of the African health systems.

Due to the *mis en scène* of the process organized by the NGOs, the transnational enterprises were forced to retreat and adopt a new strategy. The local government obtained the necessary support to endow local and international public legitimacy on its legislation, before the international community. At first, the companies offered a price reduction on the patented products for the South African Government. The Government accepted it, but refused to revoke the law that was already in force. Next, the companies offered to supply, at no cost, the primary inputs necessary for the local manufacture of products that are part of the AIDS cocktail, and to supply the medications at no cost. Bristol-Myers Squibb offered the retroviral ddI and d4T at a price of one dollar per day and would not enforce the patent norms in Sub-Saharan Africa. However, the Government once again refused to revoke the law. In fact, according to the Government, the free distribution of raw materials or medications would solve the problem only temporarily, and would result in the dependence of the South African population on the transnational companies. Moreover, this benefit did not extend to other important diseases, equally provided for under the law.

Given the obstacles, the companies initiated a campaign of questioning the quality of the Indian products, from where Africa would purchase most of the medications. The NGOs and the Indian laboratories refuted all of the arguments, disclosing contracts, for the

[41] See Case 4183/98, affidavit of Treatment Action Campaign, paragraphs 40 and 41.

supply of products to large transnational companies, by the same Indian companies that were being accused of poor quality, as well as by companies from Korea and China[42].

The pressure from NGOs increased until 2001[43], when the companies retreated and withdrew the process, paying the costs. The retreat of the pharmaceutical enterprises demonstrates the effectiveness of organized action by a southern government, but this action was possible only as a result of the formation of a coalition of NGOs to address the issue and the political importance of AIDS, a disease that also attacks the northern populations. Other diseases that are also frequently a target of discussion, such as malaria and tuberculosis, are not often the subject of similar actions nor of mobilization by the northern populations, perhaps because the effects are not so devastatingly felt in the north.

The project of the South African Government was not to produce the medications itself, but to be able to purchase them from other producing developing countries such as Brazil and India. In the case of Brazil, the Fundação Oswaldo Cruz used only 40% of its productive capacity for the domestic supply, and, thus, would be able to supply part of the South African market, particularly with respect to the non-patented products[44]. In the case of India, two large local laboratories, Cipla and Ranbaxy, also had the capacity to produce non-patented remedies, which included a significant number given that the patent system for pharmaceutical products and processes had not yet entered into force in India. In other words, all remedies were available.

Table. Causes of Mortality by Region, 1999 Estimates

Cause of Death	World	Africa	America	Middle East	Europe	SE Asia	East pacific
Tuberculosis	**3**	**3**	**1**	**3**	**1**	**5**	**3**
HIV/AIDS	**5**	**21**	**1**	**1**	**0**	**3**	**0**

[42] See TREATMENT ACTION CAMPAIGN. Brazil's HIV/AIDS Treatment Programme. Johannesburg, 2000, p.2 and MCNEIL JR., D. G. Le Roi des Pirates. Courrier International. **538,** 2001.

[43] They succeeded in collecting 260 thousand signatures from 130 countries for a petition requesting the withdrawal of the process, see MÉDECINS SANS FRONTIÈRES. La Protection des Vies Humaines doit Passer Avant celle des Brevets. Procès de L'industrie Pharmaceutique contre L'Afrique du Sud. Paris, MSF, 2001, p. 3.

[44] The Brazilian Government entered into agreements with Mozambique, Guinea-Bissau and São Tomé and Princípe to transfer technology and medication.

Diarrhea	**4**	**7**	**1**	**7**	**0**	**7**	**1**
Infantile Diseases	**3**	**7**	**0**	**5**	**0**	**4**	**0**
Malaria	**2**	**9**	**0**	**1**	**0**	**0**	**0**
Respiratory Infections	**7**	**10**	**5**	**8**	**3**	**11**	**4**
Cardiovascular Diseases	**30**	**9**	**34**	**32**	**51**	**29**	**32**

Source: Oxfam. Pfizer. Formula or Faintness?: Patient Rights Before Patent Rights. Oxfam, 2001, p.14. Values in percentages.

The transnational companies wanted to avoid the possibility that the India, Brazil and South Africa examples would be followed by other developing countries. Such an event would certainly result in the loss of important markets and, in particular, the formation of a parallel and legal market for medications produced by countries where the patents from the northern counties had obtained a license.

The NGOs, in turn, wanted to publicize, in the international media, the issues surrounding the intellectual property agreements. They also defended the granting of licenses to developing countries and the search for new sources for the supply of medications, essential for the fight against serious diseases. In fact, this objective was achieved through the broad reach of the campaign. In response to pressure from the media and the population, the White House was forced to retreat and change its discourse to one that favored increased access to medications.

However, at the peak of the international negotiations, Brazil accepted a bilateral agreement with Merck. Under this Agreement, Brazil agreed that is would not produce the medications on the local level, and, in counterpart, would receive a 60% reduction in the prices[45]. Roche also entered into an agreement with the Brazilian Government for the sale of Nelfinavir at a price 87% lower than the price established for the North American market. Glaxo, in addition, offered to negotiate a reduction in the prices of two other medications, Abacavir and Amprenavir. The budget for the acquisition of medications for AIDS treatment would then be reduced from US$ 240 to US$ 88 million. The American Government accepted an agreement with the Brazilian Government and the consultation process within under the WTO was terminated. Consequently, Brazil no longer participated

[45] OXFAM. Pfizer. Formula or Faintness? Patient Rights Before Patent Rights, Oxfam, 2001, p.23

in the lobbying activities of the developing countries, leaving India and South Africa to fight alone. The withdrawal of Brazil represented an important loss for the joint actions of the developing countries. Instead of working together to pressure the World Trade Organization for the establishment of a panel and a trial on the issue, Brazil preferred to enter into a bilateral agreement, leaving the other countries, temporarily weaker, to negotiate by themselves[46].

However, Brazil began to review its position when Roche refused to enter into an agreement to reduce the price of the third patented medication. Now, the Brazilian Government is once again entering the campaign against the patents, particularly on the eve of the Doha Ministerial Meeting. Unlike the Seattle meeting, where the discussions were directed at creating a TRIPS Plus for even stronger intellectual property norms, in Qatar, the negotiations agenda proposed by the southern countries included the access to medications and the flexibility of intellectual property norms. In short, the actions taken by NGOs and the WHO allowed the southern countries to invert the situation within the ambit of the WTO and to change the normative evolution of the intellectual property agreements.

3. Doha Inter-Ministerial Conference

The fourth Doha Ministerial Conference recognizes the right of the various countries to grant obligatory licenses, as they judge necessary, and to establish norms for the exhaustion of rights. The conference declaration is important in the case of a possible interpretation of TRIPS by the DSU:

> "5. c) 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 declaration clearly sets out the parties' rights. However, the possibility of using the obligatory license is effective only if conditions exist for the local production of the medication or if it is possible to purchase it from another country that can produce it at a lower price. Except for rare exceptions, such as Brazil, India, Cuba, Mexico and China,

[46] Other countries, such as Uganda and Senegal, were able to enter into bilateral agreements. However, the withdrawal of Brazil from the pressure group was more important given its weight in the negotiations, arising from its capacity to produce and purchase medications.

with respect to medications in general, and other countries, with respect to specific medications, the other southern countries do not possess the technological and financial means to locally produce the pharmaceutical products that they need. With the production of new medications, the proportion of patented pharmaceutical products and processes will increase. In the same way, the possibility of producing locally and exporting will be reduced. Except for cases where the southern countries have benefited from the aid of NGOs or where they have put up a common front, the intellectual property system will continue to contribute to the exclusion of the poor populations of the south from the access to patented medications. This leads us to the conclusion that, on the one hand, the dependence of the south on the north will continue to grow, and that, on the other hand, there is a necessity for cooperation between them, as well as for cooperation between the southern countries and the NGOs, for the advantageous evolution of the international right.

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Existing intellectual property norms impose severe and detrimental conditions on the development of the southern countries. These norms operate contrary to the need for the transfer of technology and the reproduction of such technology in the south. Furthermore, these norms create conditions for a significant transfer of financial resources from the south to the north in the form of royalties. Where medications and the pertinent diseases are concerned, scientific research focuses on the diseases of the north. Biochemistry has developed much more in function of the anxieties of the northern populations than in function of the anxieties of the south, thereby exacerbating the north-south inequality. In relation to the diseases that are most at the forefront, such as AIDS and cancer, the intellectual property system that was in force until 2001 favored high prices, inaccessible to the southern populations. In 2001, as a result of joint action on the part of some of the southern countries, which were severely affected by AIDS, the intellectual property rules were eased. For the countries able to negotiate prices, and that possess local production capacity, this represents an important victory. However, it is a limited victory given that the research continues to concentrate on diseases that do not create the greatest number of victims.