

**INTELLECTUAL PROPERTY RIGHTS AND  
DIFFERENTIAL PRICING FOR ESSENTIAL MEDICINES:  
PUBLIC HEALTH POLICY FOR DEVELOPING COUNTRIES\***

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**Summary:** The purpose of this article is to examine the fundamental relationship between intellectual property rights and public health access. The article deals with a number of issues related to patent protection in the pharmaceutical industry and the implementation of differential pricing policies for procuring essential drugs in developing and least-developed countries. The article also draws attention to questions on the current agenda of the World Health Organization and World Trade Organization concerning institutional instruments and public policies related to access to health in developing countries. Furthermore the authors seek to highlight the recent debate on the protection of intellectual property rights and the enforcement by member countries of the WTO, as well the key measures contained in the Doha Declaration on TRIPS Agreement and Public Health of 2001.

**Key terms:** international law of intellectual property, public health; policies regarding access to essential drugs; differential pricing; pharmaceutical industry; World Health Organization; World Trade Organization; industrial policies; enforcement of intellectual property rights; pharmaceutical patents; compulsory licensing; parallel importation; TRIPS/WTO Agreement; TRIPS flexibilities; Doha Declaration on TRIPS and Public Health.

**Classification JEL:** K32, K33, L41, L42, L65, O19 and O34.

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## 1. Introductory Notes

‘Access to health and essential drugs’ has been a constant topic on the agenda of the international community, particularly over the last 10 years during which efforts have been made by the World Health Organization (“WHO”) to define international guidelines for reformulating public health systems in member countries of the United Nations. Wide-ranging discussions have taken place about the ‘effectiveness of access to medicines’ in developing countries. The problem has also been addressed within the context of negotiations at the World Trade Organization (“WTO”), especially with respect to the models proposed for protecting intellectual property in WTO Members and the management of drug patents in accordance with the rules, safeguards and specific exceptions set forth in the TRIPS Agreement.<sup>3</sup>

The General Assembly of the United Nations prior has approved the Resolution 2001/33 which fundamentally addresses the access to drugs for the treatment of pandemic diseases among the populations of developing and least-developed countries.<sup>4</sup> This document demonstrates that the international community freely acknowledges that access to health is one of the most important fundamental individual rights. It highlights for instance that Member States should refrain from taking any measures that could limit access to drugs and to the biopharmaceutical technologies used in the prevention and treatment of pandemic diseases and the infections that are most frequently associated with them. The UN Resolution also draws attention to the obligations of the countries to adopt complementary measures in their relevant domestic legislation in order to ensure access to such drugs or preventive and curative technologies as well as to introduce public policies enhancing allocation of resources for promoting access to health.<sup>5</sup>

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<sup>3</sup> Such issues have been explored in key academic literature, as they appear in the following studies: S. STERCKX, *Patents and Access to Drugs in Developing Countries: An Ethical Analysis*, in *Developing World Bioethics*, vol.4, n.1, 2004. pp. 58 et seq.; P.J. HAMMER, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health* in *Journal of International Economic Law*, Vol.5, n.4, 2002, pp. 883 et seq.; J. NOGUÉS, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, in *Journal of World Trade*, vol.24, n.6, 1990. pp.81 et seq.; D. HENRY and J. LEXCHIN, *The pharmaceutical industry as a medicines provider*, in *The Lancet*, vol.360, 2002. pp.1590 and ss; R. LOPERT et alli, *Differential Pricing of drugs: a role for cost-effectiveness analysis*, in *The Lancet* vol.360, 2002. pp.2105 et seq.

<sup>4</sup> Cf. *Resolution 2001/33 on Access to Medication in the Context of Pandemics such as HIV/AIDS*.

<sup>5</sup> The Resolution carries details of the proposals for making the issue more widely known and enforced internationally: (i) “refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them; (ii) adopt legislation or other measures, in accordance with applicable international law, including international agreements acceded to, to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third

In Brazil, a wide range of institutions has been called upon to respond to the need for planning and ensuring the effectiveness of public policies regarding access to health. While the concept is accepted as a citizen's basic right, improved treatment methods for diseases that affect needy population groups are still needed throughout the whole of Brazil. Formulating strategies to provide an incentive for and to make concrete progress towards proper access to health, at all levels, has been a constant challenge. The Brazilian Ministry of Health for example has recently announced efforts to encourage negotiations between the federal government and pharmaceutical companies for procuring drugs at fair prices as well to conduct bidding operations (auctions) aimed at centralizing the bulk purchase of medicines either at a discount or at constant reduced prices.<sup>6</sup>

It is a well-known fact that Brazil contributed to the opening up of the international debate on access to essential drugs, especially towards the end of the 1990s. Brazil's main contribution was to draw attention to its own public policies relating to universal treatment for diseases associated with HIV/AIDS and to the campaign for free access to the anti-retroviral drugs cocktail. The merit of Brazil's argument was echoed in the reaction of various organizations and international bodies and effectively brought to the fore a »global humanitarian concept« of access to health among developing and less developed countries.<sup>7</sup>

Many problems remain to be overcome in this respect, not least domestically. Data issued by the Brazilian Institute of Geography and Statistics ("IBGE") indicates that 40% of all Brazilians have no effective access to essential drugs. Health spending by

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*parties; adopt all appropriate positive measures to the maximum of the resources allocated for this purpose so as to promote effective access to such preventive, curative or palliative pharmaceuticals or medical technologies".*

<sup>6</sup> A number of advertisements have been made by the government agencies about such issue, although there is lack of information confirming the effectiveness of those initiatives up to now, such as the so-called "Farmácia Popular do Brasil" Programme, which was launched by the Federal Government, aiming at widening access for the essential drugs consumers through price reductions directly at the drugstores. *Oswaldo Cruz Foundation* ("FIOCRUZ"), a technical department of the Ministry of Health, is in charge for the programme as well as for drugs procurement from both government-run and private-sector laboratories. The goals of the programme can be found at [http://www.saude.gov.br/farmacia\\_popular](http://www.saude.gov.br/farmacia_popular). The alternatives in reducing the costs of the procurement of drugs may provide some particular means to fund the health access, but it is also strongly recommended that such programmes be transparent and do not undermine the functioning and goals of the Brazilian Integrated Health System ("SUS").

<sup>7</sup> Official statistics provided by the Brazilian government indicate that between 1995 and 2000 access was ensured to about 92,000 patients. This produced a reduction of between 40-70% mortality caused by infection and made approximately 240,000 hospital admissions unnecessary. The same occurred with the average procurement prices of anti-retroviral drugs, which were reduced by about 72% over a period of 5 years. Recent figures can be seen on <http://www.aids.gov.br>

individuals is devoted mainly to purchasing medical drugs which are frequently very costly and generally out of proportion to the incomes of the Brazilian population (health takes fourth place among the top items of household expenditure, after accommodation, food and transport).

On the international level, a number of formulas have been put forward in an effort to respond to individual's fundamental right of access to health. These have specifically addressed both the question of modifying the structure of the economic processes involved - production, distribution and consumption - in the 'essential' pharmaceutical products market and clarifying the functionality of these products in terms of their ability to treat the most common diseases. In this specific context, the key idea of 'differential pricing of essential drugs' has been discussed as a viable alternative for promoting public policies targeted on access to health.<sup>8</sup>

This affirmative policy has reached a widespread recognition throughout the international arena and has been reflected in developing countries in a range of activities related to access to health based on the reduction of the prices of essential medicines. The policy aims overall at overcoming the drawbacks involved in health costs which effectively stand in the way of people exercising their fundamental right to access to health (guaranteed to all citizens of Brazil in accordance with the Constitution and, on the international level, in a number of treaties and international conventions).

The present study explores current initiatives regarding access to health, essential drugs and differential pricing for developing countries, with a view to determining their relevance and impact within a Brazilian context. The present article starts by defining differential pricing for essential drugs and the key role that this concept might play in affirmative actions and public policies. It also examines issues related to pharmaceutical patents, some aspects of competition standards in the market for drugs and the strategies of the pharmaceutical industry with respect to differential pricing policies for essential drugs. Finally, it turns attention to the treatment of this subject within the context of the World Trade Organization and the most relevant aspects of Doha Declaration on TRIPS and Public Health. The latter continues to provide useful opportunities for stimulating further debate on this issue.

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<sup>8</sup> The term refers to the expression "differential pricing", without necessarily carrying the concept of discriminatory pricing as it appears in the definition of price discrimination in antitrust law. For an overview of the different meanings and related difficulties, see P. J. HAMMER, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health*, cit., pp. 883 et seq.

## 2. Differential Pricing and Essential Drugs

### 2.1 Definitions. Functions of differential pricing and access to health

According to a broad definition reached by WHO, differential pricing (also known as *preferential or tiered pricing*) applicable to drugs that are classified as ‘essential’, refers to drug prices that are within the buying power of consumers in developing or least-developed countries. Basically, the ‘degree of accessibility’ of the consumer to essential drugs is the defining factor, reflected in the capacity of individuals, especially those from the most economically and socially deprived population groups, to purchase such products.<sup>9-10</sup>

Differential prices do not involve the whole range of products manufactured by the pharmaceutical industry - only those that are considered to be ‘essential’. The description by the WHO establishes that *essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford*.<sup>11</sup> Since the acceptance of the important principles emerging from the 1978 Alma-Ata Conference (in the former Soviet Union)<sup>12</sup> – which took place at a time in which the question had already begun to be

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<sup>9</sup> See basically WHO, *More Equitable Pricing for Essential Drugs*, Workshop on differential pricing and financing of essential drugs, Hosbjor, Norway, April 2001, item 2.1; and J.WATAL, *Differential Pricing and Financing of Essential Drugs*, WHO/WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, Hosbjor, Norway, April 8-11, 2001, document available online on the digital library of website: <http://www.wto.org>.

<sup>10</sup> See also C. PÉREZ-CASAS and N. FORD, *Pricing of drugs and donations: options for sustainable equity pricing in Tropical Medicine and International Health*, vol.6, n.1, 2001, p. 964. According to these authors: "Equity pricing is based on the principle that the poor should pay less for, and have access to, life-saving, essential medicines. The final aim is to make essential drugs available at a price that is fair, equitable and affordable for all in need. Access to essential drugs should not be a luxury of the privileged few but a matter of social equity and justice".

<sup>11</sup> The concept can be found in the list of essential drugs drawn up by the World Health Organization. The *12th Model List of Essential Drugs* (2002) contains 325 unitary drugs, among others 12 anti-retroviral drugs for treatment of diseases related to HIV-AIDS. The first list was published in 1977, identifying 208 unitary drugs. The current status of the essential drugs can be checked at <http://www.who.int/medicines>.

<sup>12</sup> *International Conference on Primary Health Care of Alma-Ata*, USSR, 6-12 September 1978. The Conference sought to launch of the bases for the worldwide publicity devoted to access to health through the provision of essential drugs. The Declaration considers that health is a state of overall physical, mental and social welfare. ("The Conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important worldwide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector"). In the Declaration, considerable aims are predicated for international regulation concerning access to health, such as the supply and provision of essential drugs. See §7, II of the Declaration, which expressly mentions: "immunization against the major infectious diseases, prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs".

widely aired in academic rounds - the concept of essential drugs has been extensively mirrored in international rules covering access to health. The concept is now no longer restricted to a list of formulas and pharmaceutical compounds for treating particular diseases. Rather, essential drugs have effectively become 'common goods' that should be universally accessible given that they are central to meeting basic health needs, to improving different forms of treatment and to ensuring better use of drugs and resources for enhanced access to health.<sup>13</sup>

Different studies have addressed the issue of 'dual function' of differential pricing: while facilitating access to essential drugs, it also provides an incentive to the inventive capacities of the pharmaceutical industry and therefore to new drug discoveries for treating existing diseases.<sup>14</sup> From this standpoint, differential pricing mechanisms should generate: (i) reduction of the barriers against access to essential drugs for people in the developing world; (ii) improved revenues for the firms operating in the international drugs market, especially those from the 'high-income markets'; and (iii) an solution to problems resulting from the lack of essential drugs for those who need them, thereby promoting better health and cures for diseases, whether epidemic, endemic, infectious or naturally occurring.<sup>15</sup>

In addition to the aforementioned three points, differential pricing is one of the factors determining the effectiveness of access to essential drugs. It establishes a basis for the rational employment of drugs as a whole, promotes accessibility, creates forms of sustainable financing and helps to strengthen ailing public health systems. The difficulties involved in giving concrete expression to the above *desideratae* - which in effect constitute a 'general formula' for access to health - can be explained to a great extent by the obstacles encountered by developing and least-developed countries to securing supplies of the essential drugs needed for treating

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<sup>13</sup> In this respect see also the key arguments of J. D.QUICK, *Essential medicines twenty-five years on: closing the access gap*, in *Health Policy and Planning*, vol.18, n.1, 2003, p.3, which develops the theme and draws attention to its importance including the question of incentives for the generic drugs industry: "At least 88 countries have introduced the essential medicines concept into curricula for medicine and pharmacy students, and the WHO Guide to Good Prescribing' has been translated into 18 languages and adopted by teaching institutions throughout the world. Generic competition is encouraged in scores of countries. Over a dozen countries provide price information on public world-wide-web sites and the WHO, with other partners, maintains pricing services for the full range of essential medicines, for active ingredients and for HIV-related medicines." This author concludes thus: "Over the last 25 years, the essential medicines concept has proven itself to be an effective global concept that is central to expanding access to medicines which improve health, reduce suffering and extend lives"

<sup>14</sup> On such 'double function', see remarks of J.WATAL, *Differential Pricing and Financing of Essential Drugs*, cit., especially item 3.

<sup>15</sup> Differential pricing appears to have a central role and specific legal function: to ensure that the price of essential drugs should not be hindered by barriers to access to essential drugs (consumption at a 'fair price') by the individuals, and to maintain the proportionality of the equation need/reinvestment. For more details see J.WATAL, *Differential Pricing*, cit., p. 5

diseases that affect their populations. These barriers to access exist on two levels: (i) between countries and the drugs industry and (ii) between the pharmaceutical firms and the consumers themselves.<sup>16</sup>

A similar situation prevails with respect to the relationship between access to health and dependence on the private sector. In least-developed countries a substantial gap exists between the two, particularly as regards financing. In the developing world, the governmental sector is generally not sufficiently well-structured to ensure the citizens the proper access to health as a fundamental right. This induces individuals to be even more dependent on private, non-governmental provision of healthcare. In the final analysis, access to health should ideally be provided on the basis of exclusive public service provision of 'essential goods', e.g: treatment of diseases, hospital admissions, medicines distribution etc.

Under the adequate conditions, differential pricing means more accessible (lower-cost criteria) purchase prices of drugs essential for treating infectious diseases affecting large numbers of people, especially in developing and least-developed countries. The purchasing power of consumers also depends significantly on the ratio between cost, time and need of treatment.<sup>17</sup> Determining differential prices depends upon a number of variables related to income levels in such countries and the wealth distribution situation prevailing within the various societies. Potential pricing mechanisms cannot be justified on a random basis but rather on the consumers' capability to pay and their need for treatment to confront particular diseases.<sup>18</sup>

At the international level, this same logic applies to facilitating access to the consumer markets of developing and least-developed countries - precisely those that are most heavily dependent on the drugs manufactured by the pharmaceutical

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<sup>16</sup> Many authors refer to this aspect, such as J.D.QUICK, *Essential medicines twenty-five years* cit, p.3., regarding the distinctions observed between countries: "In high income countries, consumer prices are rarely more than twice the producer or importer price. But in low-income countries, the combined effects of multiple middlemen, taxes, duties, distribution costs and retail margins result in a final price that is commonly more than double – and sometimes three to five times – the producer or importer price. Reducing the final price of medicines to health systems and to consumers depends on transparent price information, generic and therapeutic competition to reduce producer and importer prices, greater distribution efficiency, reasonable dispensing fees, and the elimination of duties and taxes on essential medicines".

<sup>17</sup> J. WATAL, *Differential Pricing* cit., p. 11, item 3.1; and R. LOPERT et alli, *Differential Pricing of drugs: a role for cost-effectiveness analysis*, in *The Lancet*, vol. 360, November 16, 2002, p. 1590. Principle of access to essential drugs at differential prices – drugs acquired in accordance with what the consumers can afford (*measure of affordability*).

<sup>18</sup> The approach to differential pricing and countries' incomes appears in much of the key literature, such as in R. LOPERT et alli., *Differential Pricing of drugs: a role for cost-effectiveness analysis* cit., pp. 1590 and ss.

industries of the rich developed countries. Some authors maintain that achieving a successful international policy of equity pricing requires a transparent and efficacious method for evaluating how such drugs should be distributed ('need versus economic feasibility').<sup>19</sup> From a social and economic standpoint, it would not be desirable for countries and consumers that have the means to pay the full normal prices for the essential drugs to benefit from differential pricing, as this would result in a deviation of function. The risk has also been highlighted with regards to drugs that have been acquired in the markets of developing countries finding their way into developed countries and subsequently sold at substantially higher prices.<sup>20</sup>

## *2.2 Differential pricing of essential drugs and global policies of access to health*

The approach to differential pricing, insofar as the production and distribution of essential drugs is concerned, raises many additional questions such as, for example, the general conditions of access to the essential drugs that are part and parcel of the structure of the pharmaceuticals industry, the monopolies conferred on manufacturers by patents, the scale of the economic barriers to market entry and the difficulty for determining the consumption patterns in low income markets. Furthermore, it has to be acknowledged that the whole subject does not simply revolve around international price regulation regarding differential pricing. Attempts, for example, to implement affirmative policies have exposed imbalances between the different countries, reflected in unequal income distribution, yawning social gaps and the low consumption patterns of the populations concerned.<sup>21</sup>

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<sup>19</sup> This reasoning is referred to by the majority of authors such as J. D. QUICK, *Essential medicines twenty-five years* cit., p. 3. The author explains as follows: "In high income countries, consumer prices are rarely more than twice the producer or importer price. But in low-income countries, the combined effects of multiple middlemen, taxes, duties, distribution costs and retail margins result in a final price that is commonly more than double – and sometimes three to five times – the producer or importer price. Reducing the final price of medicines to health systems and to consumers depends on transparent price information, generic and therapeutic competition to reduce producer and importer prices, greater distribution efficiency, reasonable dispensing fees, and elimination of duties and taxes on essential medicines")

<sup>20</sup> See for instance M.KINDERMANS and F.MATTHYS, *Introductory note: The access to Essential Medicines Campaign*, in *Tropical Medicine and International Health* Vol. 6, n. 1, 2001, pp. 955 and ss. The authors referred to the establishment of an international system of differential pricing. According to this approach, essential drugs could be acquired under special conditions in order to benefit poor and developing countries. This means a public campaign mounted to permit the world's poorest people to obtain the right to access to essential drugs through equitable reduction of prices for drugs, through employing instruments facilitating compulsory licensing and parallel imports while enforcing the rules and principles of price transparency within an international context.

<sup>21</sup> In this field, the essence of the debate about access to essential drugs and equity pricing becomes clearly apparent. On more than one occasion, the dichotomy is highlighted between developed, developing and least-developed countries, justifying access to health on the basis of income levels and underdevelopment indices. The differential prices measure these inequalities seeking a more equitable solution for the distribution of essential drugs.

It is worth noting that differential prices, once applied, could lead to higher prices being charged for certain drugs in developed countries and substantially lower prices to apply to sales in developing and least-developed countries, without the international pharmaceutical industry losing market share. If differential pricing for essential drugs were to be accepted as an alternative policy for the acquisition of pharmaceutical products, the approach could well become a useful instrument for mediating awkward situations between countries regarding public health access, thereby producing an important combined effect. While differential pricing mechanisms would maintain and re-enhance the value of intellectual property rights, they would also enable the humanitarian objectives of public health policies to flourish.<sup>22</sup>

On the other hand, it is true that the final consumer is directly affected by price variations. Patient consumers anxious to improve their health and well-being are required to pay high prices for basic medicines which they urgently need. Price variations can have a major effect on the sum total of a consumer's outgoings (compared with the purchase of other products) and the consumer is not always in a position to dispense with, or to find a suitable substitute for, a particular medicine.<sup>23,24</sup> Individual patients, once considered as consumers, are rarely in a position to negotiate with the pharmaceutical industry or to demand special benefits when purchasing medicines, unlike the State, governmental authorities or regulatory agencies and NGOs.<sup>25</sup>

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<sup>22</sup> D. HENRY and J. LEXCHIN, "The pharmaceutical industry as a medicines provider", in *The Lancet*, vol. 360, 16 November, 2002, p.1590. Along the same lines, see also J.D.QUICK, *Essential medicines twenty-five years* cit., p. 3.

<sup>23</sup> It is important herein to highlight some remarks of P. J. HAMMER, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health* cit., p. 884: "Under appropriate market conditions, price discrimination will arise naturally, as a profit maximizing business strategy. It is doubtful, however, that it is now, or will be in the foreseeable future, independently rational for first world pharmaceutical companies to cultivate and supply a market for low-cost drugs in developing countries. Markets cannot solve the AIDS crisis by themselves. Nevertheless, the classic economic model of price discrimination can serve as a useful 'political framework' to mediate first- and third-world tensions over essential drugs, providing a template that can maintain the integrity of intellectual property rights while respecting humanitarian concerns over access to life-saving drugs".

<sup>24</sup> The individual consumer of any essential medical drug is a "surefire consumer", especially since he is conditioned to paying any price for the drug that will help to improve his condition. In fact he is likely to be less sensitive to variations in the prices of other products that he also needs urgently such as a certain type of food or an article of clothing, or even non-essential goods. For this reason the variables (i) price of the drug, (ii) citizen's purchasing power and (iii) an increase in well-being, are of fundamental importance in the debate about access to health and essential drugs.

<sup>25</sup> see D. HENRY and J. LEXCHIN, *The pharmaceutical industry as a medicines provider*, in *The Lancet*, vol. 360, 16 November, 2002, p. 1590. The authors remark that in the United States the same problem would exist, with the absence of benefits related to the policy covering distribution of essential drugs not covered by health plans, involving a large part of the population paying the highest prices recorded for access.

With respect to the specific question of the institutionalization of uniform policies of differential pricing, many different agents are involved in the international regulation concerning access to essential drugs. Efforts to introduce across-the-board application of fair prices have been evident in bilateral and multilateral negotiations, frequently under the auspices of the World Health Organization (WHO). A range of different agents has been involved in such negotiations such as: (i) government bodies from interested countries concerned with the regulation and control of the public health systems or those involved in coordinating industrial policies which touch on the pharmaceutical sector; (ii) representatives of developed country governments involved in employing technical and financial resources to boost the domestic policies of developing or least-developed countries; (iii) drug companies involved in the production and sale of drugs based upon R&D platforms aimed at promoting the generics industry; (iv) groups and associations engaged in consumer protection, as well non-governmental organizations; and (v) international organizations and foundations such as UNICEF, UNAIDS, UNFPA and the World Bank.<sup>26</sup>

For its turn, the WHO has highlighted that a differential pricing policy or one that involves 'full accessibility' regarding the procurement of essential drugs necessarily calls for instruments for preserving competition in the market, a development which would lead to reduced procurement prices on the part of the drug manufacturing firms, with the ultimate aim of passing on the benefits of all-round lower prices to poor populations.<sup>27</sup> However, the situation of many developing countries is not particularly conducive to the proper working of differential price mechanisms, especially given (i) the essential medicines distribution in developing countries and least-developed countries which often involve drugs being sold to consumers at higher prices than in developed countries; (ii) problems in the publicly-planned and financed health systems and (iii) the lack of adequate lines of communication between pharmaceutical industry business strategies and civil society views regarding access to health. The proper functioning of an differential pricing system for essential medicines is, on the other hand, conditioned by the coordination and effectiveness of public policies, the establishment of an efficient distribution system for such medicines (including information about the benefits of particular medicines

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<sup>26</sup> see WHO, *More Equitable Pricing for Essential Drugs* cit., especially item 2.1. As far as NGOs in general are concerned, their contribution has been crucial in getting the private sector to participate in the discussions about access to essential drugs and equity prices. Public interest - as a general category of interest in the relations involving the right to access to health - plays a crucial role in justifying changing the purchase prices of essential drugs to differential prices

<sup>27</sup> see WHO, *More Equitable Pricing for Essential Drugs* cit., p.11.

and the scope for coverage of the care needs of poor population groups), to the point where a market in essential drugs materialises on the basis of differential pricing rules in line with the 'ability to pay' of the people most in need.<sup>28</sup>

### **3. Industrial policy, intellectual property and differential pricing of essential medicines**

#### *3.1 Intellectual property and differential pricing*

Substantial criticism has also been addressed to the specific issue of the relationship between differential pricing and intellectual property protection. The debate in this field involves the polarisation of apparently conflicting interests. On the one hand, the pharmaceutical industry, governmental authorities of the developed countries - in which a significant research and development capacity exists together with the manufacturing of essential drugs - and, on the other hand, international organizations, developing countries governments and NGOs.

The crucial question is to determine whether a differential pricing policy for essential drugs is likely to undermine intellectual property protection based on drug patents, especially in cases where the reduction of incentives for investment in R&D is concerned.<sup>29</sup> The same argument in the context of the World Trade Organization is approached below, where the concerns of certain countries regarding the apparent existing conflict between differential pricing and the patent protection measures provided by TRIPS/WTO are very much in evidence.<sup>30</sup>

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<sup>28</sup> With regards to this, reference is made to the article of P. J. HAMMER, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health* cit., p. 889. The author analyses the problems related to the consumer markets for essential drugs and the inefficiencies that are attributed to them therein: "*Pharmaceutical markets in developing countries are substantially underdeveloped, with current drugs prices set primarily to service developed markets. As a result, developing countries are essentially priced out of the market. From this starting point, if reforms could facilitate the creation of a sustainable regime of differential pricing to serve developing countries, the result would be welfare-enhancing.*" Hammer concludes (p.890) by asserting that the effectiveness of equity pricing ultimately depends upon institutional reforms in the countries in question. Among the much needed reforms are those applying to the public health systems: "*In the longer term, however, an initiative that synergistically pursued objectives of economic development, the building of a public health infrastructure, and the construction of a distribution system for the dissemination of low-priced drugs, could lead to the creation of stronger markets in developing countries.*"

<sup>29</sup> With regards to the emblematic relationship between the drug patents and access to health, see J. NOGUÉS, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, in *Journal of World Trade*, vol. 24, n. 6, 1990, pp. 81-103

<sup>30</sup> Some authors have addressed the theme by stressing the questions related to favorable interpretation of the TRIPS articles concerning patent protection and access to health. See basically S. M. FORD, *Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pill and Patents*, in the *American University International Law Review*, vol.15, 2001, pp.941 and ss; A. LACAYO, *Seeking a*

Studies dealing with industrial policies frequently attempt to demonstrate the various costs involved in pharmaceutical research, advertising and policies for applying the formulas discovered by the industry. The risks associated with the difficulty of testing new chemical substances on human beings and the unpredictability regarding prolonged use of drugs are also frequently highlighted. Furthermore, industrial policy studies also point to patents protection as an important instrument for guaranteeing ongoing research and development, which is able indirectly to impact on consumer welfare. J. Nogués <sup>31</sup> remarks, for example, that this argument has always informed the debate about access to drugs in accordance with pharmaceutical industry perceptions and by those countries most concerned with stressing rigid patents protection policies.

A significant part of the pharmaceutical industry is of the opinion that the exclusive rights conferred by patents in this sector ensure a full return on the investment in key research and in the manufacturing processes and distribution of such drugs. It is also believed that patents protection could ensure a greater chance of success in litigation involving the products developed by the pharmaceutical industry, simplifying procedures involved in proving the origin of formulas employed in the manufacture of the drugs (chemical composition, compound formulation etc), as opposed to what would occur with regards to complex components developed on the basis of mechanical and electrical systems.<sup>32</sup>

These are praiseworthy concerns since they highlight the importance of patents for providing incentives to the pharmaceutical industry and their innovative processes. But the same concerns take on a different hue in the face of the observations regarding the distribution of such products in the consumer markets of developing and least-developed countries. The question continues to arise concerning the effective relationship between the benefits produced by the drug patents and those benefits that could be shared with society, taking into consideration the long period of time during which the pharmaceutical industry - most of it headquartered in

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*Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism*, in *The University of Miami Inter-American Law Review*, vol. 33, n.2/3, 2002, pp. 295 and ss

<sup>31</sup> J. NOGUÉS, *Patents and Pharmaceutical Drugs* cit. p. 87.

<sup>32</sup> an overview of the technical application of drugs patents, see J. NOGUÉS, *Patents and Pharmaceutical Drugs*: cit., especially p.87-89.

developed countries - is able to manufacture such products under patent on an exclusive basis and thereby retain a monopoly.<sup>33</sup>

The key problem results from conflict between the protection of the innovative and inventive potential of the pharmaceutical industry and the need for access to drugs on the basis of accessible and competitive prices. Such questions are also associated with consumer welfare and the balanced functioning of the markets, mainly at the final point of the economic cycle of such products.<sup>34</sup> For this reason, a reduction of the exclusive term for manufacturing and distribution, conferred on the drug through patent, should be the first argument underlying a fairer distribution of intellectual property rights. It is well-known that the exclusivity term can vary between 15 and 20 years, which effectively amount to a monopoly over the sale of such products for around 12 to 14 years, given the time needed for a particular drug to gain market position.

However, it is not possible to assert that differential prices threaten the stability of patent rights protecting pharmaceutical products. Nor can it be averred that differential pricing mechanisms constitute an obstacle to effective R&D by the pharmaceutical companies operating in the sector. In his article, P.J Hammer<sup>35</sup> has observed that many curious and doctrinaire arguments have been employed to justify the 'supremacy' of intellectual property rights, but that the objective of these was effectively to quash, solely and exclusively, the debate about differential pricing in the pharmaceutical industry. Some authors even sustain that affirmative policies for access to health through differential pricing mechanisms could cause the value of drug patents to depreciate, leading to a reduction of R&D activity in this sector.

It has been observed that the effect of differential pricing is precisely the opposite. Such pricing policies could provide incentives for research and development in the

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<sup>33</sup> Acknowledgement of the purposes of patent protection policies for essential drugs was highlighted in WHO/WTO, *Report of the Workshop on Differential Pricing and Financing of Essential Drugs* especially item 3.6 and ss.

<sup>34</sup> Some studies also attempted to demonstrate that profit margins in pharmaceutical industry aimed at covering costs of research and development vary greatly. As mentioned before, the basic argument of this sector in particular is that protection of intellectual property ensures both the sufficient investments for research and development and the adequate manufacturing and distribution of drugs. One of the relevant issues would be to determine the effective profit margins that are needed to cover such costs and whether the pharmaceutical industry with most of its R&D platforms located in developed countries could likewise, in a legitimate way, recover the costs in developing and least developed countries. See also D. HENRY and J. LEXCHIN, *The pharmaceutical industry as a medicines provider* cit. pp. 1593 et seq., remarking that a very small amount arising from application of the patents expressed as a given purchase price for the drug would be earmarked for recovering the manufacturing costs of the product.

<sup>35</sup> *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health* cit. p.889.

‘essential’ drugs industry since the companies concerned would be encouraged to increase production volume and therefore be free to redirect their targets towards developing other formulas and compounds to treat the main diseases that affect many countries, both in the developed and developing worlds.<sup>36</sup>

### *3.2 Patents and differential pricing: exceptions and competition instruments for providing access to essential drugs*

As considered above, pharmaceutical industry-related patents are intimately linked to research and development in this particular sector. Patents are regarded as indispensable for protecting the research portfolio of the drug companies, for stimulating discoveries of new treatments in the field of biopharmaceutical research and for guaranteeing the appropriate application of the medicines manufactured for human consumption. On the other hand, we cannot fail to recognize that both the general and specific exclusive rights conferred by patents to the holders over a long period can in due course drive up the prices commanded, a practice which has proved to be undesirable for consumer markets, especially those in developing and least-developed countries.<sup>37</sup>

Considering the competition standards, there must be other factors influencing the non-existence of competitive prices for essential drugs, in addition to the exclusive manufacturing and distribution facilities afforded by patent monopolies. The pharmaceutical industry, for example, harbours a significant concentration of business talent on account of the fact that most of the economic agents operating in the markets consist of large conglomerates. Furthermore, most of the research and development platforms and facilities for manufacturing drugs tend to centre, together with their respective branded products, on developed countries. High tariff barriers also impinge on drug market access and the structural incentives for anti-competition and other restrictive practices by the drug companies are substantial. In

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<sup>36</sup> P. J. HAMMER, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health* cit., p. 890, casts a skeptical eye over the state of the debate in those sectors connected with the pharmaceutical industry and the fact that the problem has no solution over in the short run. Moreover, he admits that the drug market in developing countries does not function properly. Costs of access to health are high due to the inability of governments to create in developing countries sustainable policies to underpin the required negotiations with the pharmaceutical industry and to control effectively the distribution of the drugs in consumer markets in order to keep abreast of their coverage and the access that consumers have to them

<sup>37</sup> The monopoly over manufacturing and industrial exploitation of these drug patents on the one hand is aimed at ensuring resources for research and technology but on the other increases the costs involved. In markets where competition exists between different drugs, significant price reductions can occur and are not welcomed by the patent holder.

addition, many countries encounter difficulties to establish a generics industry and to introduce policies for the parallel importation of essential drugs which could allow for a reduction of purchase prices for such products.

Studies have shown that the pharmaceutical industry has also received government subsidies in many countries, particularly in response to official healthcare programmes during the 1970s and 1980s involving welfare policies aimed at providing essential public services and supporting research and manufacturing platforms wholly financed from government resources. In many countries, the situation evolved simultaneously with the awarding of patents for drugs developed almost exclusively by subsidized companies but which were marketed at prices that were practically inaccessible to most people. While governments came under pressure to increase access to healthcare by subsidizing specific branches of the drugs industry, it also paved the way to a future unsustainable situation.<sup>38</sup>

According to OECD data, pharmaceutical sector was the most profitable in recent decades. In 24 out of 32 years between 1960 and 1991, the pharmaceutical industry occupied first and second position in the *Fortune* magazine ranking, which lists the most profitable industries in the United States and the rest of the world. The situation arose from the return on investment and the yield achieved by shareholders in the pharmaceutical companies (dividends and receipts from the sale of shares). In 1998, the pharmaceutical industry was the most profitable industrial sector and also with respect to positive, accountable and share balances, was only followed by the telecommunications industry occupying second place on the list. It is also worth noting the concentration of the industry. In relative values market share in European countries such as Germany, the United Kingdom and France is the largest in the world especially when the brands of the drugs actually consumed are taken into account.<sup>39</sup>

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<sup>38</sup> See D. HENRY e J. LEXCHIN, *The pharmaceutical industry as a medicines provider* cit, pp. 1592-1593.

<sup>39</sup> The five most important drugs produced in these countries in each category are the following: medicines for treating cardiovascular problems (80 different brands produced in the United Kingdom, 67 in Germany and 60 in France), high blood pressure (16 Germany and 60 in France), analgesics (36 in the United Kingdom, 36 in Germany and 75 in France), tranquillizers (36 in the United Kingdom, 68 in Germany and 70 in France), anti-rheumatism drugs (65 in the United Kingdom, 60 in Germany and 15 in France, antibiotics (43 in the United Kingdom, 26 in Germany and 25 in France), and anti-asthmatic drugs (77 in the United Kingdom, 41 in Germany), diuretics (69 in the United Kingdom, 70 in Germany and 79 in France). For details on the structure of the drug market, see OECD *Competition and regulation issues in the pharmaceutical industry*, Committee on Competition Law and Policy, Directorate for Financial, Fiscal and Enterprise Affairs, February 06, 2001

In the United States, the effectiveness of *march-in rights* as applied to the drug sector has also been questioned. In its practical effects this mechanism heralded the possibility of government authorities licensing patents for alternative companies unless the patent holders agreed to market their drugs at reasonable prices ('fair prices', plentiful availability etc). Criticism was not raised against the practice as such. From the point of view of intellectual property protection this has emerged in various countries under the guise of compulsory licensing - for example in the case of Brazil. But the problem has basically been the reluctance of the US authorities to employ these exceptions to accepted practice in order to facilitate access to essential medicines. This has proved to be the case over the past few years regarding the US approach to commercial questions involving the pharmaceutical industry and patents.<sup>40</sup> The same kind of inaction has occurred with respect to direct negotiation with the major drug companies, since the lack of competition in certain segments has made it difficult to find solutions for purchasing drugs at more accessible prices for needy population groups.<sup>41</sup>

The accountability of domestic public health systems is also in at the crossroad. Overall costs related to anti-retroviral treatment for HIV/AIDS patients in developing countries are expensive and show how dramatic the situation may turn in the near future. The retail prices for the drugs concerning the ARV's amount between \$10,000 and \$16,000 per year. In Central America, for instance countries have only been able to negotiate with pharmaceutical industry an average price equivalent to \$7,000 per patient/year for few drugs of the ARV's (e.g. the case of Costa Rica). Although this appears to be on the first impressions less expensive than the retail prices in most developed countries, it still represents nearly 3 times Central American countries' per capita income.<sup>42</sup> Countries such as Brazil, India and South Africa which have been experiencing so far a large number of AIDS cases still must afford for patients' treatment a considerable quantity of the drugs that they may consume an overwhelming proportion of the country's health budget. Brazilian

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<sup>40</sup> Id.p.1593. This demonstrates that the issue of essential drugs and access to health is not confined to developing countries. It is, as has been seen, also an issue in the United States. The problem refers particularly to the group of countries where most of the population live beneath the poverty line, i.e a significant number of developing countries and all the least-developed countries are in this situation.

<sup>41</sup> D. HENRY e J. LEXCHIN, *The pharmaceutical industry as a medicines provider* cit., p. 1593.

<sup>42</sup> For a overview of the debate on the costs of ARV's, see K.FLOYD, C.GILKS, "Costing and Financing Aspects of Providing Antiretroviral Therapy" in *The implications of antiretroviral treatments*, Geneva: World Health Organization; April 1997, pp.63-78; Steven S.FORSYTHE, *The Affordability Of Antiretroviral Therapy In Developing Countries*, in *Anti-Retroviral (ARV) Treatment in Developing Countries: Questions of Economics, Equity and Ethics*, UNAIDS/The World Bank, available in [www.worldbank.org/aids-econ/ar](http://www.worldbank.org/aids-econ/ar); and MSF, *Untangling the web of price reductions: a pricing guide for the purchase of ARV's for developing countries*, Campaign for Essential Medicines, January 2005..

Ministry of Health for instance distributes 15 ARV drugs for treatment of HIV/AIDS patients. Four of them are imported from US and Europe, amounting about 57,18 % of overall ARV's expenditure (US\$ 223 million estimated in 2005).<sup>43</sup>

Negative and positive outcomes generated by intellectual property rights systems are to be assessed in any analysis concerning this field. It is worth noting that the mere existence of the patent protection as such is not in question, since this would just throw the effectiveness of a global system for intellectual property protection into discredit.<sup>44</sup> The plausible major criticism revolved around the effects flowing from the abuse of patent rights, not only with regard to drugs but also involving various other industrial sectors in which both competition and consumption protection were being undermined by the abuse of such rights (especially in the areas of biochemistry, electronics and information technology). Awareness of the sensitive issues involved in pricing and the final purchase costs of patented products was to be one of the first signs of the total breakdown of monopolies based upon patents. This was easily detectable at the end of the economic cycle, especially when the predicament of end-consumers was taken into consideration.

In fact, public reactions to abuse of intellectual property rights (including noncompliance with their original functions and objectives) especially in the field of patent protection, proved to be determining factors for creating widespread awareness about the measures that needed to be taken to promote healthcare in developing and least-developed countries.<sup>45</sup> The quest for better distribution of

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<sup>43</sup> For instance Efavirenz (Merck, Sharp & Dome) represents a cost amounting US\$ 1,575/tablet, and US\$ 574.8 per patient/year. Nelfinavir (Roche) costs US\$ 0.468/tablet, and US\$ 1,537 per patient/year. Lopinavir/Ritonavir (Abbott), US\$ 1.30/capsule and US\$ 2,847 per patient/year. Tenofovir (Gilead Sciences), US\$ 7.68/capsule and US\$ 2.803 per patient/year. See Pan-American Health Organization, "Fact Sheets on HIV/AIDS Care and Treatment", available at <http://www.paho.org>; Brazilian Ministry of Health-National STD/AIDS Programme, *The Brazilian Strategies and Expectancies on Access to HIV/AIDS Inputs*, 1st Round of the HIV/AIDS Technological Network, 25 - 28 January 2005, Rio de Janeiro, Brazil.

<sup>44</sup> The basic reference point is the enforcement of the rules of a international system for protection of intellectual property, postulated since the Conventions of Paris in 1883 and Berne in 1886 (the *Unions*), the creation of the WIPO in 1967, and the insertion of the subject into the trade negotiations between member countries of the WTO according to the provisions of the final Act of the 1994 Uruguay Round. This is fundamentally a system of institutional guarantees relating to the application of intellectual property protection policies in an international context, to be observed by the member countries. For a specific analysis of the issue, see M. BASSO, *O Direito Internacional da Propriedade Intelectual*, Porto Alegre, Livraria do Advogado, 2000, pp. 159 et seq.

<sup>45</sup> In general the abuse of patent rights exists when the patent holder chooses to adopt an approach which is not in line with the function of the patent right or rights by availing itself of the exclusivity provided by the rights that have been acknowledged and conferred upon the firm as the legitimate patent holder in order to achieve undesirable effects from the legal point of view such as the violation of consumer rights and those related to competition and intellectual property (especially when the aim would appear to be to expand opportunistically and indiscriminately the scope of the

essential medicines such as those for the treatment of infectious- contagious and endemic diseases was closely associated with the balance between two factors: patent protection applied to drugs and the level of effectiveness of access to healthcare. It was a question of either (i) subsisting side-by-side or (ii) one of these factors falling by the wayside in order to allow the other to prosper. Once the term protection for certain products had elapsed, many countries began to formulate strategies to encourage the manufacture of generic medicines- effectively representing a major step forward, replacing previously patented drugs owned by large pharmaceutical companies.<sup>46</sup>

In the case of the generics industry, it is believed that the same benefits provided by drugs manufactured by patent-holding companies can be achieved. In the second half of the 1990s, Brazil benefited from such an approach, especially as regards the question of price reductions on essential medicines that were no longer exclusive to a particular drugs company, but which are now available for distribution for the treatment of many different diseases.<sup>47</sup> As will be explained below, a number of

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exclusivity conferred by the patent). In its Article 65, for example, the Canadian *Patent Act of 1985* establishes broad hypotheses about the abuse of rights conferred by patent such as (i) the failure on the part of the patent holder to meet demand for the patented product in an appropriate way and in accordance with deadlines and reasonable conditions; (ii) the refusal to license, manufacture or distribute the patented products; or (iii) if an individual or a class of individuals were to be harmed by the conditions arising from exclusivity or if the product or patent process were used by the patent holder to undermine the manufacturing and marketing activities of other products. On the subject of abuse of patent rights, see studies such as those by E. T. SULLIVAN, *The Confluence of Antitrust and Intellectual Property at the New Century*, in the *Minnesota Intellectual Property Review*, n 1, 2000. pp. 1 and ss; and D. J. GIFFORD, *The Antitrust/Intellectual Property Interface: An Emerging Solution to An Intractable Problem*, in the *Hofstra Law Review*, n. 31, 2003, pp. 363 and ss.

<sup>46</sup> Domestic patent offices and public health authorities could also make joint efforts to bolster programmes for enhancing industrial and public health policies, specially focused on innovation and access to essential medicines. This could well be done by providing incentives for ensuring control over the basic objective of the drug patent, i.e ensuring that it is used for appropriate purposes (treatment of diseases), as well as taking a census of drugs which are not under patent. The WHO estimates that in the overwhelming number of least-developed countries, fewer than 20% of the essential medicines are protected by patent. Many of the drugs are in fact in the public domain, but generic versions have not been developed and manufactured. Hence such drugs are extremely expensive since they are purchased through direct importation from developed countries. The prices also reflect foreign currency exchange increases and monetary devaluation (e.g. in the case of the US dollar and the European currencies) which have substantially raised the price of such drugs in the consumer markets of poor and developing countries.

<sup>47</sup> In Brazil, the definition of a generic drug was given in Law n° 9.787 of 10 February 1999 ("Brazilian Generics Act"), which modified the provisions of Law n° 6.360 of 23 September 1976 regulating national health surveillance. In Article 3, XXI, the Act establishes that a generic drug is "a drug that is similar to a reference or innovative product and which sets out to be interchangeable with the latter, and is generally manufactured after patent protection or other exclusive rights have either expired or been rescinded, providing its efficiency, security and quality are proved". According to estimates, over the last few years 39.170 thousand (2001), 75 .650 thousand (2002) and 79.161 thousand (2003) units were produced, with a significant increase of almost 492% between 2001 and 2002. These were marketed at prices that were almost 40% less than trademarked medicines. Some numbers provided by the Brazilian

solutions have been studied with respect to the unilateral initiative of the pharmaceutical industry and the government-inspired negotiations concerning differential pricing negotiations.<sup>48</sup>

### *3.2.1 Differential pricing policies: specifically related to antitrust law and patent exceptions*

Recent studies have shown that certain instruments related to intellectual property protection can be employed for achieving a differential pricing policy, either by reducing the prices for drugs or by providing the stimulus for parallel importations of cheaper products. The same is applicable to competition instruments, since applying a differential pricing policy for essential drugs would in itself amount to discrimination. The target products are marketed/supplied for consumers at reduced prices although, theoretically, they should be made available to all for the same end-price.<sup>49</sup>

The key question arising is therefore to determine to what extent the fixing and feasibility of differential prices for essential medicines can also comply with the objectives contained in intellectual property and antitrust rights. Various alternatives have been put forward in legal and economic studies focused on healthcare access policies. These studies reveal concern to retain a balance between competition/intellectual property protection systems and mechanisms which would allow for poor and developing countries just and equitable access to essential drugs.<sup>50</sup>

The following are some other options. Compulsory reduction of purchase prices of the drugs, followed by a policy of control would be more drastic and less desirable solution from the point of view of competition and the credibility of economic policies adopted by governments. The patent owner would remain the exclusive

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Association for Generics Industry (<http://www.progenericos.org.br>) indicate that 83 of these kinds of drugs were registered in 2001, and 1124 in 2004.

<sup>48</sup> Cf. item 3.3.

<sup>49</sup> It is believed that from the point of view of industrial organization, segmentation of the market based on variety and the composition of the drug products could favour differential pricing policies. This policy depends on robust governmental action and negotiation with the drug companies in order to generate distributive effects. Two price bands for essential drugs for poor and developed countries with efficient public health systems can therefore be created. Equally, according to the World Health Organization experience of price indicators, essential drug prices can only be achieved when a reasonable number of manufacturers operates in competitive markets.

<sup>50</sup> see basically J. HUDSON, *Generic Take-up in the Pharmaceutical Market Following Patent Expiry: A Multi-Country Study*, in the *International Review of Law and Economics*, vol.20, 2000, pp.205-221. Also the empirical data in K. BALASUBRAMANIAM, *Equitable Pricing, Affordability and Access to Essential Drugs in Developing Countries: Consumers Perspective*, WHO/WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, April 8-11, 2001.

manufacturer of the essential drugs and would begin charging minimum prices (fixed or listed by regulatory authorities) for the products. Although, in the final analysis, the aim of this measure would be to fulfill accessibility criteria facilitating access by low-income consumers, it would in our view contain a degree of anti-competition bias. Control, together with price-fixing, would be undesirable in the essential drugs markets given that these mechanisms would reinforce and strengthen lobbying by the pharmaceutical industry before government authorities in an effort to secure given prices and would in reality serve only to encourage abuses of patent rights. In short, compulsory reduction of prices would not achieve the objective of obtaining accessible prices for consumers of essential drugs.<sup>51</sup>

Another measure would be the adoption of an official government-led policy to encourage the signing of accumulated licensing agreements involving transfer of technology and the payment of differential royalties to the companies owning the various patents. The non-exclusivity involved in this mechanism would be to provide stimulus for competition in the market in the production and distribution of essential drugs. It would also involve the transfer of technology - a development that would be fully consistent with patent protection in the majority of the countries concerned and accord with the safeguards under TRIPS. Control in this case would also be needed in order to ensure that they licensees did not produce, directly or indirectly, the drugs in non-target markets. The aim of such a license would be to facilitate the supply of essential medicines according to a differential pricing regime (extending also to tiered *royalties*) for developing and least-developed countries, while taking appropriate steps to avoid the products leaking back to consumer markets in developed countries (in a kind of reverse effect).

A further more effective option (as yet little employed) is the implementation of compulsory licensing. This arrangement is in line with the provisions established under TRIPS and is one of the most common methods employed for local production of essential drugs.<sup>52</sup> In Brazil, the Industrial Property Code of 1996 (Law No 9.279/96) explicitly covers the possibility of granting compulsory licences in cases where local production cannot meet demand or in cases where patent holders

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<sup>51</sup> WHO /WTO, *More equitable pricing for essential drugs*, Workshop on Differential Pricing and Financing of Essential Drugs, Hosbjor, Norway, April 8-11, 2001, especially Part B

<sup>52</sup> For this specific case of compulsory licensing, TRIPS provides for the patent holder to receive reasonable royalties for the license, taking account of the circumstances and the economic value of a particular license (cf. Article 31 of TRIPS). In the various sectors of the pharmaceutical industry, royalties often do not exceed a rate within the range of 2% to 8%, depending on the type and aim of the license in relation to the product itself or in relation to the 'inventive process'. See the rates applicable to royalties in D. M. MC.GAVOCK, *Licensing practices, business strategy and factors affecting*

abuse the rights conferred by the patent.<sup>53</sup> In practice, this approach has not been adopted, but could in the future be subject to (more) effective regulation in order to facilitate, rather than impede, the grant of compulsory licences where drug patents are concerned.

Given the different alternatives, we are inclined to support the alternative that predicates improved *closer liaison* between governments of low-income countries interested in differential-pricing programmes and the pharmaceutical industry itself, providing the principles of legality and transparency are respected.<sup>54</sup> Brazil's experience shows that essential drugs can be acquired for differential prices on the basis of advantageous negotiations and centralised auctions and bulk purchases and thereafter distributed to the consumers.<sup>55</sup>

As for antitrust policies, although substantial differences still exist between the prices charged for essential medicines in the markets of both developed and developing countries, it would not be correct to regard the supplying company as if it were an agent anxious to partake in anticompetitive practices. When pricing products, companies generally sell their products at different prices (reduced or high) to a range of consumers who theoretically have the same conditions and purchasing power to acquire the products. Different prices themselves do not imply discriminatory practices.<sup>56</sup>

The case of differential pricing for essential medicines clearly illustrates the situation: on the one side, the drugs industry and on the other governments of developing or least-developed countries (and their low-income consumers). More

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*royalty rates*, in the *Licence Law and Business Report*, n. 205, 1991, and CPTech Page on Royalties on patents for health care inventions, available at <http://www.cptech.org/ip/health/royalties/>

<sup>53</sup> Subsequently, Decree No 3.201/99 was enacted, regulating compulsory licensing in Brazil for cases related to national emergency and public interest. More recently, this Decree was modified by Decree No. 4.830 of 4 September 2003, which incorporated in Brazil the principles of the *Doha Declaration on TRIPS and Public Health*

<sup>54</sup> This is justified by the need to strike and ensure an appropriate balance between the mechanisms set forth in intellectual property statutes as far as the grant of compulsory licences is concerned in the case of drug patents, and also the public policies dealing with access to health and the maintenance of efficient public health services. The principle of transparency aims to avoid member states from abandoning the objectives of public policies of access to health despite making exclusive use of pressure on the drug companies through compulsory licensing. It is absolutely vital that the State should be aware of the fact that people look to it to promote social welfare and ensure the delivery of public health

<sup>55</sup> Concerning these strategies in particular, see item 3.3

<sup>56</sup> This has been so far made clear by antitrust approaches: different prices can be justified on the basis of objective criteria (for example: discounts, length of negotiations etc.) and by consumer preferences and circumstances. See for instance R. BORK, *The Antitrust Paradox: A Policy War with Itself*, New York, The Free Press, 1993, pp. 382 and ss.

accessible drug prices can apply for the latter and according to the debate raised by WHO they have been seen to be fair, so in effect price discrimination which would be condemned from the competition standpoint is not an issue. Two factors are evident from this brief analysis: the importance of the purchasing power of consumers and the ease of access to products, in this case to medical drugs.

Equally, both WHO and WTO have at least reaffirmed that the hoped-for objective is to give concrete expression to differential pricing policies for essential medicines as a 'a point of equilibrium' between health access, effectiveness of patent protection and the instruments designed to preserve free competition in the markets.<sup>57</sup> The basic reasons for this are that the initial concern that differential pricing is indeed justified by the priority need for access to drugs in developing and least-developed countries.<sup>58</sup> The resistance put up by developed countries with regard to this particular topic does not revolve only around their concern with the supposed threat to drug patent protection arising from the implementation of differential pricing policies. These countries are concerned about the negative impact of differential pricing on the performance of their internal markets, following the logic that lower prices for drugs in developing and least-developed countries would in practice impact negatively on their own domestic health budgets.

Overall, the role of the interested sectors in publicizing and advocating the benefits of differential pricing policies for essential medicines appeared to be a key component for the success of a common agenda for the improvement of public health access at an international level. In addition, a fair pricing policy for developing and least-developed countries would not prove to be a hardship for the pharmaceutical industry, which is indeed currently well-developed on a global scale.

### *3.3 Strategies of the pharmaceutical industry, access to essential drugs and differential pricing: donation programmes, bulk purchasing and drug procurement auctions*

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<sup>57</sup> see WHO/WTO, *Report of the Workshop on Differential Pricing*, cit., item 3.6 et seq.

<sup>58</sup> Some believe in the existence of the risks of price interdependence in the markets, enhanced by the effects of the implementation of differential pricing in the consumer markets of poor and developing countries on the level of drugs supply in developed countries. Regulating such prices would be conditioned precisely by the comparison between values on an international basis, given that the target countries for price differential policies (for example, almost all the countries located in the southern hemisphere) have already been adopted in the course of negotiations with the manufacturers. What appears to have happened over the last few years has been the creation of an institutional network of price comparisons at international level - a development which can influence from time to time the core aspects of the negotiations between pharmaceutical industry and governments.

As mentioned before, a number of problems arise from the concentration of the pharmaceutical industry in developed countries, which tends to focus concern about patent protection for products made for the consumer markets in the developing world. Even in countries where local production of drugs (including drugs falling outside patent protection) exists, high prices have been charged, making the products unaffordable for considerable part of the population.<sup>59</sup>

It has also been recognised that the pharmaceutical industry globally has made efforts to advertise and encourage policies involving donations, drug purchasing auctions and high-level negotiations with governments. More favourable conditions for procuring medicines have indeed been established (which in themselves could herald differential prices). An effective quality standard for drug production is also in place and at stake in that debate. A great deal of publicity has also been devoted to the initiatives taken by governments and international organizations related to centralised purchasing of essential medicines by means of auctions, a process widely used for acquiring vaccines, contraceptives and certain medicines for specifically treating tuberculosis.<sup>60</sup>

*Corporate donation programmes* could be a more generous initiative than many others conducted by government healthcare institutions, since these are directly linked to enhancing the distribution mechanisms for essential drugs.<sup>61</sup> Normally with the aim of compensating the drug companies involved, various kinds of incentives are offered, such as physical exemptions, income tax deductions and other benefits which are clear symbols that the ‘social burden’ is being shared between the public and private sectors.<sup>62</sup>

Other arrangements involve voluntary price reduction for drugs such as those contained in the antiretroviral cocktail for treating diseases associated with HIV/AIDS. Price reductions would at first sight appear to be the result of governmental policies responding to international and public opinion pressure to

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<sup>59</sup> See for instance the outcomes of the research by MSF, *Fatal Imbalance: the crisis of research and development on drugs for neglected diseases*, Campaign for Access to Essential Drugs and the Working Group on Drugs for Neglected Diseases, September 2001

<sup>60</sup> UNICEF runs programs concerned with the purchase of drugs on the basis of public auctions and drug purchases financed with regional funds such as those of the *Gulf Co-operation Council* and ACAME (*African Association of Central Medical Stores*). Price reductions have been negotiated on a differential basis of 30% for the majority of essential drugs. In the United States, this programme is largely associated with the procurement of contraceptives, where reductions of around 90% have been achieved over the normal market price.

<sup>61</sup> See the examples provided by J. WATAL, *Differential Pricing and Financial of Essential Drugs* cit., especially item 2 and ss.

<sup>62</sup> J.WATAL, *Differential Pricing and Financial of Essential Drugs* cit., p. 10.

deal with domestic emergencies or demands for increased drug distribution networks. They can also result from drug companies interested in contributing to social responsibility programs. In other cases, regulatory policies designed to stimulate competition in these sectors could be involved, particularly policies that embrace specific rules to avoid supply retention in the market of developed countries.

Corporate donation programmes by the pharmaceutical industry are useful, but they are not wide-reaching enough to cover all the needs of poor and developing countries with respect to health access. These programmes can involve discrimination mechanisms by the pharmaceutical industry in different markets and short-lived distributive effects as far as the consumers are concerned. Furthermore, governments in these countries find it difficult to leverage the real costs of the donation programmes, especially with respect to control and infrastructure building, to enable such programmes to function properly (e.g: registry procedures, drawing up lists of essential medicines for procurement, using selective distribution criteria and conducting census counts of consumers in greatest need etc).<sup>63</sup>

It has been seen that is impossible to rely upon corporate donation programmes lasting, since they are always run on a voluntary basis and call for aggressive incentive and regulation policies. Differential pricing would be a much more secure way forward for developing countries on account of (i) the fact that institutions are involved and (ii) that differential pricing is closely associated with the economic process (production-distribution-consumption) and tends to reflect the real 'economic burden' faced by governments of the relevant countries as well as by consumers and patients who have no bargaining power in individual negotiations.<sup>64</sup>

The donation and auction approach is also often confined to developed countries, especially those in which many of the drug companies holding patents on essential drugs are located. These techniques are liable to divert companies from their core activities (such as discovery and development of new drugs) into efforts to build up more effective marketing and advertising schemes for the products that they already sell to the markets, in order to maintain or increase profits.<sup>65</sup> Furthermore, R&D efforts by the companies would not necessarily be geared to addressing the majority

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<sup>63</sup> see for instance P. J. HAMMER, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health* cit. pp. 889 and ss.

<sup>64</sup> This can be explained why it is impossible to the State to depend wholly on *donation programmes* as a way of acquiring essential medicines for needy populations. This road does not provide the best alternative for overcoming the difficulties involved in public health access policies.

<sup>65</sup> D.HENRY and J.LEXCHIN, *The pharmaceutical industry* cit., p. 1593

of diseases which affect many people throughout the world: these would effectively remain focused on the industrial production of drugs for treating diseases typical of developed countries.<sup>66</sup>

The latter observation is highly relevant. Some studies have pointed out that research strategies in the pharmaceutical industry are not always linked to research on drugs for treating diseases that affect populations in developing or least-developed countries. Rather, research tends to be focused on the kind of diseases that occur in developed countries, such as those related to ageing populations (cholesterol, depression, motor-related disorders, sclerosis etc). It is precisely in the developed countries where the return on R&D investment is likely to be the highest. Decisions favouring a particular drug, whether essential or not, are generally associated with length of research time, development of the formula and successful planning. For this reason, the drug companies operating in those countries most in need of health care policies are not always prepared to develop over short periods of time essential drugs for local consumption aimed at treating the most commonly-occurring diseases.<sup>67</sup> Furthermore, all patent policies applied to the pharmaceutical industry in developing and least-developed countries need to be kept under constant review. From the standpoint of the protection conferred by intellectual property rights it would be undesirable for the principles embodied in such rights to be improperly manipulated, responding to narrow and unwarranted interests.

These are some of the reasons to explain why the opportunity for access to essential drugs in developing and least-developed countries has been increasingly limited. The local pharmaceutical industry could well have recourse to donation or price reduction programmes more to comply with social responsibility targets in reaction to not-inconsiderable public pressure than impelled by their own or government initiative.<sup>68</sup>

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<sup>66</sup> See also the conclusions contained in the document issued by Médecins sans Frontières, *Desequilíbrio Fatal: A Crise de Pesquisa e Desenvolvimento de Drogas para Doenças Negligenciadas*, Campanha de Acesso a Medicamentos Essenciais e Grupo de Trabalho de Drogas para Doenças Negligenciadas (*Fatal Imbalance: the crisis of research and development on drugs for neglected diseases*, Campaign for Access to Essential Drugs and the Working Group on Drugs for Neglected Diseases), September 2001.

<sup>67</sup> D.HENRY and J.LEXCHIN, p. 1592; also see Médecins sans Frontières, *Desequilíbrio Fatal* cit, especially pp. 16 and ss, with regard to the exclusionist research in the pharmaceutical industry

<sup>68</sup> In developing countries the policy of differential pricing of essential medicines much concern accessible prices. Many authors question the reach and effectiveness of the initiatives taken by the pharmaceutical industry, considering the lack of public policies to ensure systematic provision of drugs and to provide incentives for the continuation of donation programmes and drug auctions. On this it is worth taking account the critical views put forward by C. PEREZ-CASAS e N FORD, pp. 960 et seq. who reckoned that the donation programmes could not be employed as a replacement expedient for differential prices, since these referred to policies needing to be implemented,

The WHO seemed to show reticence with regards to the scope of such programmes, observing that corporate donations are undermined by the prospect of non-sustainability. Such programmes exist for a short period of time and depend on the balance of negotiating power between governments and the pharmaceutical industry. Situations certainly exist in which a given medicine that has been offered at a reduced price turns out to be expensive for end-consumers in developing and least-developed countries. For the pharmaceutical industry, it would appear to be more attractive to employ corporate donation programmes rather than to undertake negotiations with governments on price reduction policies which could take the drugs (product supplied) to secure access levels (differential pricing policy), but which would at the same time call for well-conceived legislative and institutional reforms.<sup>69</sup>

It is to be hoped that different ways can be reached to improve the effectiveness of corporate donation programmes and buying auctions related to essential medicines. As mentioned above, planning at international level can assist, such as (i) making public price differential policies viable for consumer markets situated in developing and least-developed countries; (ii) standardisation of purchases in accordance with guaranteed volume supplied, continuity and appropriate regulation; (iii) the maintenance of high standards of competition at the supply level; (iv) control of the monopsonic power of governments in order to avoid this being exercised unduly; (v) principles of transparency and efficiency applied to government purchasing and (vi) a closer relationship to be forged between the social responsibilities of the pharmaceutical industry and public policies.<sup>70</sup> By means the implementation of such policies, governments would ensure access to health, enhance treatment conditions for the population and be better placed to develop more efficient systems of emergency and preventive care.

#### **4. Access to health and the World Trade Organization: trends in the debate on differential pricing policies**

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whereas donations are voluntary and not always systematic, depending substantially upon the willingness of the pharmaceutical industry to engage in such programmes.

<sup>69</sup> See WHO/WTO, *Differential Pricing and Financing of Essential Drugs* cit. especially item 3.2.

<sup>70</sup> This concern is shown by the WHO, especially because there is a more technically and economically viable policy of differential pricing for essential drugs. Attempting to meet access deficits through *donation programmes* is not enough, given the various drawbacks involved in this kind of expedient. Even minimum affirmative action targeted on implementing a system of differential pricing by governmental entities in developing countries would be much more promising. See WHO-WTO, *Differential Pricing and Financing of Essential Drugs* cit., especially item 3.2.

#### 4.1 The Doha Declaration on TRIPS and Access to Health, and the policy of differential pricing

Following the consensus reached at the Doha Ministerial Conference in 2001, the experience within the World Trade Organization has exposed difficulties within the international debate concerning access to essential medicines. Familiarity with the issue had already been indirectly revealed in the course of the confrontation between the US and South Africa in which the first questioned South African patent legislation with respect to the granting of compulsory licences for drug patents on grounds of national emergency and protection of public health. The US government claimed that the South African measures were incompatible with the obligations assumed before WTO/TRIPS, as well as with minimum standards of patent protection.<sup>71</sup>

At the Conference, issues relating to levels of patent protection provided by TRIPS were discussed. One of the prime concerns was to seek an alignment between the conflicting interests of member countries (on the one hand the EU-US block, and on the other the Group of 21) especially concerning the greater or lesser expansion of the models of protection applying to intellectual property. This led to member countries drawing up and issuing the *Declaration of Doha on TRIPS and Public Health*.<sup>72</sup>

The Declaration emphasizes in a number of clauses that TRIPS shall not be interpreted in such a way as to prevent WTO Members from adopting domestic measures aimed at protecting public health and that its provisions must be directed to supporting improvements in public health systems and to promoting access to appropriate drugs.<sup>73</sup> A minimum consensus was reached, basically expressed in a

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<sup>71</sup> South Africa passed the legislation establishing compulsory licensing on the basis of a decree issued by the Ministry of Health precisely aimed at facilitating access to medicines to control and treat HIV/AIDS, as well as for securing price reductions on essential medicines (see provisions of *Medicines and Related Substances Control Amendment Act of 1997* and *South African Medicines and Related Substances Control Act of 1965*). This initiative was heavily attacked by the pharmaceutical industry in United States on account of the supposed violation of the minimum standards of intellectual property protection provided by TRIPS provisions. This country disagreed with the altruistic purposes of the new South African legislation whose intention was to promote public health and access to drugs - a posture which in reality was a reflection of the lobbying exerted by the pharmaceutical industry on the US government. There would still appear to exist a great deal of confusion in the US government agencies concerning the enforcement of compulsory licensing rules and *march-in rights*. This conflict was later resolved through successive bilateral negotiations (flexible isolation of trade policy in view of the recognition of special circumstances surrounding the control of epidemics in the case of AIDS).

<sup>72</sup> see *WTO Ministerial Conference, Fourth Session, Doha, 9-14 November 2001* (WT/MIN (01)/DEC/2, 20 November 2001)

<sup>73</sup> Conversely, the wording would be much clearer if it were established that TRIPS were to allow the member countries to take the necessary measures for protecting domestic public health. The

broad, generic formula: “*intellectual property rights cannot be used to prevent member countries from taking the necessary measures to protect public health*”.<sup>74</sup>

According to this definition, those countries that are not capable of producing essential medicines domestically could take advantage of compulsory licensing for local production as well as taking measures to bolster parallel importation. This concept henceforth tended to guide subsequent discussions regarding drug patents within the logic of international trade, precisely on account of the specific emphasis conferred upon it by the Doha Declaration.<sup>75</sup>

The Doha meeting also clearly showed the difficulties of reaching a consensus on the interpretation of the TRIPS measures related to patent protection and the exceptions and safeguards established therein. The Agreements’ flexibilities tended to pave the way for a confrontation between “techniques” of interpretation which varied according to the different approaches of WTO Members: on the one hand, more restrictive approaches reflecting the views of developed countries and, on the other, the more permissive approaches adopted by developing countries.<sup>76 77</sup> It became apparent that with respect to drugs sector-related patent protection and to domestic compulsory licensing policies, a gap had opened up in the international

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criticism of J. H. REICHMANN are worth noting in *Taking the Medicine with Angst: An Economist’s View of the TRIPS Agreement*, in the *Journal of International Economic Law*, n.4, 2001, pp. 795 et seq

<sup>74</sup> See §4° of the Declaration: “*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*”.

<sup>75</sup> At Doha, pressure was applied by many other members for the exclusion of the application of this clause as applied to South Africa, Brazil and the Philippines, precisely because they were countries with large populations and high levels of disease which made them extremely profitable consumer markets for the pharmaceutical industry-especially the US and European companies

<sup>76</sup> The most important flexibilities of the Agreement referred to the exceptions to patent protection in accordance with the provisions established in Articles 27 and ss of TRIPS, with respect to the possibility of parallel importation and compulsory patent licensing.

<sup>77</sup> This occurs with regards to Article 31 of TRIPS and its specific conditions of enforcement in accordance with the different conceptions held by Members. In her study, S. Ford, *Compulsory Licensing Provisions under the TRIPS Agreement*: cit., especially pp. 963 and ss., defines the need for developing countries to forge a common interpretation regarding the TRIPS exceptions and compulsory licensing. The author refers to the enhancing interpretation which could be given to the provision under reference in order to delimit the application of licences within the minimum standard conceived by TRIPS (enhancing interpretation equally in accordance with the Agreement). This effectively means that in the standpoint of developing countries, emphasis could be placed on the open clauses such as “morality”, “public interest”, “national emergency” etc, as interpretative criteria. On the basis of these, governmental authorities would be in a better position to give more careful consideration to the opportunistic performance of certain pharmaceutical companies with respect to the abusive exercise of the patent rights, and thus to identify protection of the public interest in accordance with that set forth by the Agreement.

trading order: basically, the interests of the developed countries and those of developing and least-developed countries were in opposing camps.

Over the past few years, affirmative action has been sought by Members to implement TRIPS in such a way that its measures could be applied positively and compliant with public health policies. This has been the case with respect to the implementation of domestic legal provisions related to compulsory licensing and the parallel importation, although both of these have been on a small-scale when contrasted with the real needs of the consumer markets of the countries concerned. Efforts need to be made to encourage price reduction and to guarantee better distribution of essential medicines in consumer markets. Once again, an alignment of national legislation with the TRIPS flexibilities at international level would be a highly recommendable step in this direction, especially in view of the possibility of securing a favorable interpretation of the TRIPS measures within the negotiations at WTO level.<sup>78</sup>

At the core of the Doha Declaration, emphasis was given to "the rights" of member states to use the "flexibilities" that the TRIPS mechanism establishes, especially in accordance with the interpretation of paragraph 5, clauses "b" and "c":

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

*(b) Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.*

*(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 first clause is very important because it enables a positive interpretation to be made with respect to compulsory licences. This recourse is open to countries to enable them to overcome on the domestic level a disadvantageous situation arising from international trade relations in conflict with their public interest. It would also

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<sup>78</sup> In this respect, see the observations of C. PÉREZ-CASAS and N. FORD, *Pricing of drugs and donations: options for sustainable equity pricing*, cit., pp. 963 and ss. This deals with a favorable interpretation of the TRIPS rules regarding the implementation of policies aimed at access to health and the experience of countries with regard to parallel importation of essential and a generic drugs, as well as the award of compulsory licences.

enable them to achieve a balance between the rights and obligations of the holder of a particular drug patent. Clause (c) can also be interpreted in the sense of emphasising the autonomous power of a Member with regards to the decision concerning the criteria for granting compulsory licences in the event of national emergency.<sup>79</sup>

With respect to Paragraph 6 of the Declaration, it is reckoned that the member countries that do not have a drug manufacturing base or which have a shortage of manufacturing capacity, face difficulties in implementing the measures related to compulsory licensing. The wording of this provision basically suggests that future negotiations regarding disputes over drug patents must take into consideration the situation of different countries, i.e., the majority of developing countries and all the least-developed countries. It is easy to imagine what would happen if at each attempt to implement a compulsory licence the interested country were to demand adjudication by the WTO disputes settlement mechanism.

Once it has been acknowledged that least-developed countries find it difficult to implement compulsory licensing, or if the latter are of limited significance in view of the shortage of absence of production facilities for drugs in the domestic market, finding alternative mechanisms such as parallel importation and buying products at differential prices becomes necessary.<sup>80</sup>

The issue of patent protection related to pharmaceutical products and the TRIPS enforcement by WTO Members has led to voluminous debate, especially concerning public health goals, establishment of incentives for research and development and the development of new drugs, preferably those that could be

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<sup>79</sup> *see* S. STERCKX, *Patents and Access to Drugs in Developing Countries* cit. p. 71. The author draws attention to the fact that the United States was the only country to oppose the memorandum of the Council. Most of the Members were against limiting or listing diseases for the treatment of which given medicines might or might not be subject to compulsory licences or importations. The specific subject could be the subject of negotiation within the context of the WTO. The WHO for its turn, using its mandate in a manner to formulate guidelines for access to health in the international constitutional order, would be in position to rule on essential drugs and adopt the definition to be considered at international level and acceptable to the United Nations Members. This would be beyond the scope of the negotiations on TRIPS in the WTO. The countries agree at least on one point: that the Doha declaration was able to establish a common task requiring member states to implement the obligations of TRIPS in order to permit access for all, without distinction, to the drugs needed for the treatment of diseases. Regarding the importance of TRIPS flexibilities, A. LACAYO (*Seeking a balance* cit., p. 304) has the following comment: "*This flexibility is the result of the efforts of the developing countries and least developed countries to incorporate their concerns into the debate following the creation of the WTO and about the growth of trade initiatives. From the contention that requiring countries to strictly enforce pharmaceutical patents enables drug companies in the developing world to charge exorbitant prices that the poor cannot afford, follows the push for flexibility in enacting intellectual property laws.*"

<sup>80</sup> *see* S. STERCKX, *Patents and Access to Drugs in Developing Countries*, cit. p. 72.

made more accessible to “WTO’s citizens”. The Doha Ministerial Conference, from which the Declaration on TRIPS and Public Health emerged, opened up the discussion about the implementation of differential pricing policies and in the event served to counterbalance the patent protection measures related to essential medicines.

It is well settled that WTO/TRIPS provides flexibilisation instruments and transitional periods for countries possessing no prior experience regarding patent protection in pharmaceutical field<sup>81</sup>, to adjust to the protection levels set down in the Agreement revolving around compulsory licensing, exclusive governmental use, protection measures for free competition and exhaustion. TRIPS also recognises the deployment by member states of measures and objectives unrelated to the field of intellectual property centered on resolving questions of access to essential medicines. However, the efficiency of this group of instruments is linked to the ability of WTO Members to press their claims in the face of those whose principal interests lies in maximum protection for pharmaceutical patents.<sup>82</sup>

There is no doubt that the transitional periods ensured by TRIPS/WTO represent an important instrument for the enforcement of pharmaceutical patent protection and related measures. The Agreement established the period of 10 (ten) years for least-developed countries to implement patent protection for pharmaceutical products. This was extended to 2016 by the Doha Declaration on TRIPS and Public Health.<sup>83</sup> For developing and least-developed countries, the measures set out in Articles 65.4 and 66.1 of the Agreement are a fundamental guarantee in the adjustment between domestic patent policies and access to essential medicines.<sup>84</sup>

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<sup>81</sup> *see*, for instance, Articles 65.2 and 65.3 of TRIPS establishing transitional arrangements for developing countries and Article 66 concerning periods for implementation of patent protection and waivers by least-developed countries.

<sup>82</sup> See J.WATAL, *Differential Pricing and Financial of Essential Drugs* cit., especially item 1.4.

<sup>83</sup> *Doha Declaration on TRIPS and PublicHealth*, paragraph 7.

<sup>84</sup> *"Article 65 -Transitional Arrangements*

*(...) 4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years."*

*"Article 66 - Least-Developed Country Members*

*1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period."*

#### 4.2 Outcomes of the Doha Declaration – a scenario favouring differential pricing policies for essential drugs

The domestic institutional framework of developing countries presents a number of drawbacks regarding, for example, public sector deficits, dysfunctional planning, health systems that fail to provide universal care for populations etc. It is reckoned that without improvements in the institutional performance of developing and least-developed countries, the majority of WTO Members will be unable to satisfy demand for essential drugs, even when availing themselves of the exceptions contained in the TRIPS Agreement such as compulsory licensing and parallel importations.<sup>85</sup> With these issues in view, the Doha Declaration has effectively spurred a re-opening of the debate about differential pricing and its relevance as an effective mechanism for supplying essential drugs in the context of a transparent programme of access to health, applicable worldwide.<sup>86</sup>

The controversial issue of *drugs selectivity*, which might be used for parallel importation, is still open for debate. The discussions about public health and access to drugs in the Doha Declaration should not be seen as applying exclusively to treatment for HIV/AIDS, malaria or tuberculosis. The United States failed to agree at the time with the plan put forward by the TRIPS Council, highlighting the controversy about non-taxability of drugs that would be potential targets for the TRIPS safeguards in the drug patent area in least-developed countries. The negotiations were postponed and the question is still pending. Representing a ‘utilitarian approach’ in the discussions on access to drugs, drug patents and differential pricing, the United States continues to present arguments about the *erosion* of intellectual property rights and depleted incentives for the drugs industry (eg: reduced potential for research and development etc.).<sup>87</sup> Nevertheless, with regard to an appropriate policy of differential pricing for essential medicines, such arguments are found wanting, particularly when compared with the positive effects that could flow from the generics industry as the result of opening and transparent negotiations between government and drugs industry, and from the effective increase in production in the beneficiary countries. The latter of course would

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<sup>85</sup> For the medical community, for example, it is maybe too early to consider that the Doha negotiations have been effective regarding the granting of compulsory licensing for protected essential medicines. The problem is precisely in the field of treatment for infectious and contagious diseases in poor countries, especially with respect to the prices demanded for existing drugs and the cost of implanting public health policies. See H. BROW, *WTO drug-access agreement will not solve oncology problems*, in *The Lancet* vol. 4, October 2003, pp.586 et seq.

<sup>86</sup> See R. LOPERT et alli, *Differential pricing of drugs: a role for cost-effectiveness analysis*, in *The Lancet*, vol.360, 16 November, 2002, p. 1590.

<sup>87</sup> See, basically, S. STERCKX, *Patents and Access to Drugs in Developing Countries*, cit. p. 72.

require new research and development platforms and clear competition standards in the markets of pharmaceutical products, including the adoption of repressive measures against anti-competitive practices carried out by firms.

Since significant numbers of drug suppliers (around 90%) happen to be concentrated on North America, Europe and Japan, it could be in the interests of these countries to attempt to sideline debate in the WTO negotiations about differential pricing and safeguards within the field of intellectual property rights as far as drug patents are concerned. Their main concern, highlighted during the negotiations inspired by the United States, is that the implementation of the exceptions provisions established by TRIPS agreement would remove positive incentives from the domestic pharmaceutical industry.<sup>88</sup> This argument might well be acceptable according to such countries standpoints, but it cannot be sustained with regard to the accepted practice observed in the pharmaceutical industry in an international context. Many of the financing resources directed to R&D in the developed countries do not in fact rely upon receipts generated in the developing and least-developed markets.

On the other hand, most European countries, Japan and United States tend to adopt a restrictive interpretation of Article 31 of the WTO/TRIPS in an effort to enumerate situations in which compulsory licenses and parallel exportation could be used in the pharmaceuticals markets. Equally, this block of countries views with considerable reserve the clauses in the Agreement referring to "national emergency" and "public interest" as interpreted by developing countries (especially Thailand, Brazil, India and South Africa group), believing that these could be used to justify the creation of a so-called "compulsory licenses market" which could undermine the profits of their domestic pharmaceutical industry. This position has already been adopted by the United States in the dispute with South Africa referring to the adoption by the latter of a permissive patent legislation covering the granting of compulsory licensing for the manufacture of essential medicines in order to deal with situations of national emergency and protection of public health on the home front.<sup>89</sup> However, the hoped-for success of this approach did not in fact succeed,

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<sup>88</sup> The performance of the United States and European countries by diplomatic agents and individuals linked to their respective governments abroad does not necessarily reflect the opinions in domestic academic circles. It is worth noting that scientific production has been considerable in this area and there would appear to exist a common approach about the possibility of access to drugs in developing and least- developed countries without this undermining the pharmaceutical industry in developed countries

<sup>89</sup> See S. FORD, *Compulsory Licensing Provisions under the TRIPs Agreement*: cit., especially pp. 966-967. While the United States possesses patent legislation which also covers the granting of compulsory licensing in exceptional circumstances in the case of abuse of the rights conferred by the patents,

particularly in the subsequent discussions over a wider consensus regarding the Doha Declaration.

The Declaration has nevertheless proved to be extremely useful. In addition to laying the appropriate foundation for a favorable interpretation of the measures related to flexibility foreseen in the TRIPS Agreement, it also ensured a balance between (i) the rights and obligations set forth in the Agreement and (ii) the policies of access to health in developing and least-developed countries. In the same way, as relevant studies have shown<sup>90</sup>, the same legitimately-held concern needs to be extended to differential pricing, thereby broadening the mechanisms for bolstering production of essential medicines and enhancing their effective distribution in the consumer markets of the developing and least-developed countries. While this will be a difficult task to achieve in present scenario, it is to be hoped that future discussion on the issue will bear fruit.

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when these have been financed by the authorities (the case of *March-in rights*), the same posture has not been noted in the course of the negotiations on TRIPS at the WTO. In this forum, the main concern of the developed countries has been to retain the standards of maximum protection for intellectual property rights, according to the restrictive interpretation which they give to *enforcement* of the rules set out under the agreement.

<sup>90</sup> See for instance S. STERCKX, *Patents and Access to Drugs in Developing Countries* cit., p. 74, highlighting the importance of the issue: “Indeed, the Doha Declaration should be implemented to the fullest extent without delay, in order to establish a fairer balance between the rights and obligations of patent holders and between the interests of patients and those of patents owners. Given the basic nature of health needs, patent rules should not prevent countries from adopting policies that protect public health and promote access to drugs.” See also S. FORD, *Compulsory Licensing Provisions under the TRIPs Agreement*: cit., especially pp. 967-968. Before Doha, the author referred to the need to strike a balance in the scope of application of TRIPS, between broad moral interests and strictly protectionist interests, in order to justify restoration of relations between countries within the context of the international negotiations. Such approach we strong support.

## 5. Conclusions

Public policies concerning differential pricing for essential drugs involve taking important steps to attenuate conflicts between patent protection policies and access to health in developing and least-developed countries. We have pointed out that markets in those countries can derive direct benefit from positive differential pricing policies.

Brazil, on account of its expertise in the generics industry, should focus more on effective policies regarding health access, and on creating a transparent environment in which concrete negotiations can take place with the pharmaceutical industry and on the correct application of patent legislation, especially as regards observing the legal provisions related to compulsory licensing and parallel importation. Effective differential pricing policies for essential medicines may contribute to guaranteeing the levels of protection ensured by intellectual property rights while underscoring the appropriate use of these by the pharmaceutical industry.

This same conciliatory and prospective approach should be adopted by Brazil in future trade negotiations involving the TRIPS/WTO. This indeed would be decisive for guaranteeing the correct observance of the Agreement at the domestic level. As we have seen, it is important to work towards a *favorable interpretation* of the provisions of the Agreement in accordance with the Doha Declaration on TRIPS and Public Health, as well as to implement the contents of the Declaration at national level. In future multilateral negotiations concerning TRIPS and the WTO, and on policies embracing the observance of intellectual property rights, Brazil would be in an effective position to assume a *coordination role*, bringing issues concerning patent protection for drug inputs into compliance with public health access goals in developing and least-developed countries.

Eventual difficulties with the implementation of TRIPS flexibilities in developing countries could be avoided by the use of effective and suitable instruments for the protection of intellectual property rights. This is why the importance of implementing differential pricing policies for essential medicines has been strongly emphasised in the present paper. Institutional pressure by the government, such as the possibility of using compulsory licenses and parallel importation, can strongly influence the pharmaceutical industry to undertake reduced drug price policies in developing and least-developed countries. Given the need to enhance effective access to essential medicines, it is likely that closer consideration will be given in

future to appropriate enforcement of intellectual property rights, especially regarding the pharmaceutical industry.

Sufficiently effective government policies must be agreed in the area of health access. They also involve enhanced institutional performance by governmental agencies. The economic impact of balanced patent laws (ie: to guarantee the inventive potential of the interested industry and to impose sanctions in the case of abuse by the patent holders) can impact positively on domestic markets. In Brazil, the instrument *par excellence* has been found in the application of norms related to compulsory licensing and parallel importation (e.g: Decree No. 3.201/99.)

There is no doubt that access to health and essential drugs are fundamental topics for discussion at international level. Various choices are available for developing and least-developed countries to assist them to achieve the fundamental right of access to health. From this point of view, emphasis should be placed upon those choices that involve a shifting structure of the economic process (production-distribution-consumption) related to essential drug products and their function of providing adequate treatment for the diseases that affect humanity. Within the scope of possible alternatives, differential pricing of essential drugs represents a viable, efficient and efficacious option for underpinning public policies with respect to access to health.

Affirmative policies such as reducing the prices of drugs for developing countries lower the "cost of health" which is for many countries an obstacle to achieving people's fundamental right to access to health and, indeed, their right to health as such.

The success of an international policy of differential pricing calls for a transparent and efficient mechanism for evaluating the scope of drug distribution (*need vs. economic viability*). Differential prices can pose important issues, such as rational use of the patent of drugs themselves, boost accessibility, create forms a sustainable financing and assist in the revival of ailing public health systems.

As mentioned before, developing and least-developed countries face significant obstacles to people getting access to health: high drug prices, inappropriate and disproportionate taxation on certain categories of drugs, weak drug distribution networks run by public health services, together with problems attributed to the pharmaceutical industry itself. Through differential pricing policies it is possible to

achieve a fair mechanism for access to health and equally enforce fundamental rights ensured by international instruments.

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