

## **Role, Perspectives and Challenges of the Generic Pharmaceutical Industry in Latin America**

### **SUMMARY**

The domestic generic pharmaceutical industry has a relevant participation in the LA domestic market.

The access to medicines is a permanent challenge for LA Health Authorities, as the majority of the countries in this region have an important part of their population below the poverty line.

The domestic pharmaceutical industry has adapted to the new rules set by the WTO Agreements since 1995, even if the TRIPS obligations became binding on developing countries only in 2000; and the obligation to grant product patent protection for pharmaceuticals will only commence in 2005. The patent protection for pharmaceutical products generated an unexpected scenario: the indiscriminate granting of trivial patents (polymorphs, isomers, second uses or combination of known products, formulations, etc) to foreign pharmaceutical companies. Patents granted according to a TRIPS-plus system of "pipeline" protection (see below for an explanation) jeopardize or exclude from the market medicines that have been in the public domain and marketed for a long time under the presumption of infringement. In some cases the exclusion is obtained through judicial provisional measures, in many cases without ground. After years of litigation, these law suits some times cannot prove the patent infringement, but serve the purpose of forcing competition out of the market.

The Doha Declaration was an important step in favor of developing countries, and could improve the way that LA countries implemented TRIPS Agreement prescriptions through domestic legislation. But many LA Governments are not taking full advantage of it. They should take into account all the flexibilities that TRIPS and the Doha Declaration recognize and promote, so as to avoid monopoly practices and high prices for medicines.

The bilateral FTA that the US is promoting with many LA countries brought even higher requirements than the intellectual property protection standards initially requested by the WTO.

The FTA standards are probably putting at risk the very existence of the domestic pharmaceutical industry. If this happens, the LA Governments will have increased difficulties to face the access to medicines for the population.

The role of the Health Ministries in the international forums and FTA negotiations, the coordinating position among Developing Countries in WTO; WHO; PAHO; etc, the implementation of Doha Declaration flexibilities in the domestic patent legislation, and the implementation of policies in order to develop domestic industry as a strategic sector, could be some possible measures to preserve the industry and facilitate the access to medicines.

### ***THE ROLE OF THE NATIONAL PHARMACEUTICAL SECTOR***

The Latin American (LA) domestic pharmaceutical industry owned by respective Latin American nationals has had an outstanding role in the last decades. In many LA countries there are laboratories that have existed for almost a century. The majority of their industrial plants respond to WHO - standards.

The domestic industries count around 350 laboratories that supply an average of 60% of the medicines that are consumed in the Region, being also the main supplier for Governments purchases.<sup>1</sup>

The domestic industries were born and developed under a frame of patent legislation that, until the mid 1990's, did not admit patent protection for pharmaceutical products.

The data below illustrates the domestic industries market share in the Region.

	<b>% in unit's</b>	<b>% in revenues</b>
Argentina	60,42	49,34
Brazil	40,00	30,00
Chile	78,00	48,00
Colombia	67,00	61,30
Dominican Rep.	50,00	33,00
Ecuador	47,00	43,39
El Salvador	60,00	40,00
Guatemala	60,00	40,00
Uruguay	58,00	88,00

The generic products significant participation within the total market should be directly attributed to their relatively lower prices.

Some examples of the pricing gap between generics and brand name products are:

	<b>Generics</b>	<b>Brand Names</b>
Argentina	US\$ 3,50	US\$ 6,20
Brazil	US\$ 3,20	US\$ 4,98
Chile	US\$ 2,20	US\$ 5,86
Paraguay	US\$ 2,00	US\$ 6,00
Uruguay	US\$ 1,45	US\$ 6,04

LA countries, as the majority of the developing countries, have an important part of their population below the poverty line. Governments have to face unsatisfied needs of their people. They design different type of assistance policies seeking to support vast masses of people.

Those measures include the participation in international or domestic bids (where pricing is pushed down due to the larger volumes and stiffer competition involved)<sup>2</sup>. In some cases this comes also associated with using the benefit of soft loans granted by International Financing Institutions (e.g.: World Bank, etc)<sup>3</sup>.

<sup>1</sup> In Chile, the national industry supplies 90% of the government purchases (Source: ASILFA 2004). In Mexico, the public sector market is basically dominated by national companies. Government purchases represent 50% of the total market in units and only 17.7% in values, (Source: ANAFAN 2003)

<sup>2</sup> Argentina uses the "Programa Remediar" to purchase medicines by international bids using soft loans from the IDB. Those medicines are then delivered for free to health centers throughout the country. Also, it has a program, financed by the BIRF, to assist HIV patients in the country.

<sup>3</sup> Peru has some kind of public auction mechanism where the Government buys medicines through the Stock Exchange market. That procedure mandates that the laboratories compete against each other by offering their pricing out-loud. This generates more transparency into the system and, at the same time, pushes the prices down due to the open competition and the short time given to each party to make the offer. The Government determines the minimum prices at which the products could be purchased through the auction (Source: ADIFAN, 2004).

Other successful tools used are purchasing pools. These were applied by various LA countries where Governments united forces and economies of scale to join their purchases of medicines for their respective HIV programs. Under such a framework, the Governments<sup>4</sup> convoked national and multinational companies to bid and compete for the supply of the medicines. Programs were aimed to support a system that could enable care, and access to medicines, for HIV patients. The programs were negotiated reducing medicines prices by a range of 60-70%.

Some Governments import finished products; whether there is discrimination either with respect to the origin or to the quality of the imported products depends on a case-by-case analysis. In this context it is worth mentioning that, those Governments at the same time request the pharmaceutical industry established in each country to comply with very high international standards of quality, good manufacturing practices and, in many cases, bio-equivalence and/or bio-availability testing.

LA Health Ministers, in a recent joint public statement, evidenced very clearly the weak sanitary status within the Region. They also expressed concern, and the willingness to promote policies that could ease the access to medicines for everybody, since this represents an essential role in people's health rights.<sup>5</sup>

Reality evidences the absence of enough resources for health care in the Region, and the necessity to adopt measures to remedy that default. However, the Governments measures are, in many cases, not coherent and, as mentioned, even contradictory. They focus more on solving short term emergencies (for example making spot purchases to low cost countries) instead of establishing serious long term policies, which could allow the actual development of pharmaceutical industries within the Region.

### ***THE NATIONAL PHARMACEUTICAL INDUSTRY AS A STRATEGIC SECTOR***

Many policies and measures adopted by the Health Ministries in the Region are possible because there is a national generics industry established in the countries, which offers medicines at lower prices.

In LA, the majority of the countries rely on pharmaceutical laboratories capable to supply an important portion of the domestic demand.<sup>6</sup>

The key strategic importance of having a strong pharmaceutical industry in a country became evident in the Doha Declaration on the TRIPS Agreement and Public Health. There it is strongly recommended to member States to find mechanisms for solving the situation of countries with insufficient or non-existent pharmaceutical manufacturing capacity. The reason for this is that for those countries it becomes almost impossible to make effective use, for example, of compulsory licensing under the TRIPS Agreement. Given that situation, the Council for TRIPS issued, on August 30, 2003,<sup>7</sup> a special procedure of exception to allow countries in the above-mentioned situation to import products through compulsory licenses.

The LA national pharmaceutical industries not only play a decisive role in their own markets, but could also supply many products elsewhere, under the framework of the above-mentioned Council for TRIPS decision.

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<sup>4</sup> Participant countries were: Argentina, Bolivia, Ecuador, Colombia, Mexico, Peru, Paraguay, Uruguay and Venezuela (Resolution XXIV/381 - "Organismo Andino de Salud"- Hipolito Unanue Treaty, Lima, Peru, June 2003).

<sup>5</sup> III Meeting of LA Health Ministries Declaration, Buenos Aires, June 18, 2004.

<sup>6</sup> In Argentina, for example, six companies manufacture around 50 active ingredients. Some companies export a significant percentage of their production.

<sup>7</sup> WT/L/540, Trips: Council for Trips, August 30, 2003.

### **THE PHARMACEUTICAL SECTORS CHALLENGES - THE NEW INTELLECTUAL PROPERTY RULES**

The LA national generic pharmaceutical industry has faced many challenges in the last decade.

The first ones were related to the patents regime reforms introduced at the beginning of the 90's and the new rules imposed by the WTO in the TRIPS Agreement e.g. patent protection in all fields of technology, including pharmaceutical products, the term of protection of twenty years, the burden of proof for process patents).

The change in the rules of the game has been aggravated by the way that the TRIPS Agreement has been implemented in many LA countries. For example, Brazil and Mexico adopted "pipeline" protection for pharmaceutical products instead of the transitional period permitted by the TRIPS art. 65. 4. Under such protection, a country that has not provided patent protection before undertakes to give effect to patents and/or patent applications from another country(s), notwithstanding circumstances that might otherwise have precluded late-patenting within the former's territory. Thus, pipeline protection may constitute an exception to the novelty requirement and the concept of territoriality of patents.

Some countries declined completely to use the transitional period, and all the others, but one (Paraguay) opted for a shorter period than the one authorized under TRIPS. There is a different treatment of patent law infractions in developed countries on the one hand, and developing countries on the other hand. While in the first, the penalties do not go beyond compensatory damages in the second they could involve also imprisonment. Compulsory licensing regimes sometimes are not widely implemented, and in some cases, regimes of national exhaustion exclude parallel imports.

The new intellectual property standards for LA countries have been rigorous. But, if it were not enough, they have also been subject to permanent change.

International Organizations, such as WIPO, are promoting treaties which imply changes ranging from the harmonization of Intellectual Property Offices procedures to substantive patent rights harmonization. Such changes seriously harm present LA countries maneuverability under the Trips Agreement framework, because they restrict the flexibilities to set patentability criteria in national legislations.

Besides, the free trade agreements that the USA negotiates with developing countries, are a phenomenon that is radically changing the scope of the TRIPS Agreement, imposing obligations that have a direct negative impact on the generic pharmaceutical industry (see below for some details).

Obviously, all this will have direct implications on the next round of multilateral trade negotiations. By that time many countries would have already accepted protection standards that largely exceed their original commitments assumed in WTO. They would then have no other option but to accept reforms in the multilateral trade agreements presently in force.

The unequal balance of power between fully developed and developing countries becomes evident when analyzing the non-explicit retroactivity rights imposed on patent protection, even if the TRIPS Agreement doesn't have those retroactive effects, according art. 70. 1 and 2.

This non-explicit retroactivity is facilitated by various mechanisms, to obtain exclusivity rights on pharmaceutical products that are already in the public domain, being commercialized by national and foreign companies as well under free competition rules.

Some means presently used by foreign companies in the Industry to limit free market competition are:

- The use of the patent protection system for negligible innovations, many times requested for products already in the market, or to protect minor, often trivial developments. Most of the patent filings have those characteristics (e.g.: new or secondary uses of known products, therapeutic methods, known products combinations or formulations, a specific dosage form, etc.) while the system was conceived to encourage genuinely “inventive” innovations.<sup>8</sup>
- The intention to get exclusive data protection from the corresponding Health Authorities
- Provisional judicial measures, requested due to presumed patent rights infringement, are easily and quickly granted by domestic tribunals. Usually, they are obtained without a prerequisite of previous technical investigation by a skilled independent expert that could confirm a “prima facie” case of infringement. This forces national industry to withdraw from the market those generic products questioned in the provisional judicial measures. Since final courts rulings<sup>9</sup> could take several years to materialize, this actually represents a way for foreign companies to circumvent free competition. Several cases resolved by tribunals have shown that the so-claimed patent infringement did not actually exist. Although affected domestic companies had the right to claim recovery of damages (e.g.: lost revenue, business interruption, etc.) the potential recoveries never gets even close to actual losses. Those measures have little financial incidence on foreign companies and, of course, they do not contemplate at all the damage imposed to the public, whose rights to access medicines under free competitive rules were impaired for several years. On top and above, once a medicine is removed from the market for a significant time, it becomes very difficult to regain market share in a short period of time. By the time the product gets back to previous levels of market share the domestic company manufacturing the product could even have been forced out of business due to lack of sales.

Since product patent protection legislation started not before the mid 90’, the above-mentioned initiatives to introduce “pipeline protection” have a devastating effect in LA countries, because they affect also products in the public domain.

The situation described above exists although LA countries have relied on a multilateral legal framework that was not seeking such type of effects; this was especially true at the inception of such legislation.

The TRIPS Agreement authorized transition terms to implement its obligations and also transition terms that allowed postponing pharmaceutical product patents until 2005<sup>9</sup>. As we mentioned before, that flexibility could not be used in practice by the majority of the LA countries. Thus, domestic pharmaceutical industries are exposed to the unfair threat of potential patent infringement law-suits related to products that have been already in the market for several years.

Given the undesired practical consequences mentioned above, it has been expected that the Doha Declaration would have corrected errors made through measures such as:

- privileging products that offer to medicines in developing countries at much lower prices,

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<sup>8</sup> See Trends in Drug Patenting. Case Studies. Carlos Correa, Ed. Corregidor, Buenos Aires, 2001.

<sup>9</sup> The transitional period has been adopted by a few LA countries. Only Paraguay postponed the pharmaceutical product protection until 2005. Others adopted shorter periods (Argentina, 2000, Uruguay 2001), and Mexico and Brazil implemented the pipeline protection, as an exception the universal novelty requirements, according to Paris Convention, art. 4.

- introducing in patents legislation all the available TRIPS flexibilities (confirmed in the Doha Declaration) to meet the TRIPS Agreement goals of transfer of technology (art. 7 TRIPS); and
- targeting social and economic welfare to contemplates an adequate balance between rights and obligations.

Nevertheless, the patent laws were not flexibilized. Moreover, through new free trade agreements (FTA's) some developed countries are pushing to limit more and more the participation of domestic industries in the market. This, of course, impedes the market to work under competitive rules (see below).

Intended to implement what the Doha Declaration mandates in its 6<sup>th</sup> paragraph, the latest WTO negotiations focused on finding a mechanism to solve the situation in countries without industry. However, there was not in the WTO agenda a debate about the use of the flexibilities allowed by the Trips Agreements to develop and support the industries already installed in the countries to limit, to the minimum possible extent, the need to recur to the exception mechanisms established by the Council for Trips related to the above-mentioned paragraph 6.<sup>10</sup>

### **FREE TRADE AGREEMENTS (FTA)**

The FTA's that the USA is subscribing with many LA countries reflect the ambitions that the USA was not able to include in the Trips Agreement. The NAFTA (pre-TRIPS) is a clear example of this. The treaty subscribed with Chile is even more favorable to the USA than the NAFTA. And, the CAFTA is, perhaps, the "best model" that the USA got up to now to limit the domestic generic industry development, jeopardizing even its survival.

Some of the tools that would help the multinational pharmaceutical companies prevail in the market over the generic industry competition are:

- The obligation to protect technological sectors that, under Trips art. 27. 3, could be actually excluded from that protection
- Patents life extension due to pretended delays in their concession
- Patents life extension due to pretended delays in granting the sanitary authorization to commercialize the medicines
- Exclusive data protection
- The linkage between the Industrial Property Offices with the Health Authorities

Under those types of agreements:

- The data protection rules abandon the Trips' criteria to constitute a new category of exclusive rights themselves, without patents, forcing and contradicting the unfair competition rules that according to Article 39 TRIPS are the juridical bases for their regulation.
- the clinical studies and tests that support the commercialization of products that are "not new" receive also exclusive protection

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<sup>10</sup> Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Art. 66.2 of the Trips Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for Trips. WT/L/540, 1 September 2003, par. 7.

- the information not required by Health Authorities as mandatory to apply for marketing authorization is, nevertheless, protected with exclusive rights

The CAFTA also has an exclusive protection for the data filed before third countries' Health Authorities. The purpose is to prevent in some Central American countries approval for generic products through abbreviated procedures that would not require the duplication of test data (protection by "similarity"). Under such abbreviated procedure, those products are authorized by the demonstration of pharmaceutical equivalence with other products already approved and already commercialized in the market, without having to file the same data presented by the Innovator.

Finally, under some FTAs, the Health Authorities will not be able to grant authorization to commercialize a product when a patent for that product already exists. This clause will impede, in many cases, the sale of products that are already in the public domain. This is so, because the Health Authorities are not in a position to clearly determine the scope of many already granted patents which, in their vast majority, are referred to new/second uses, compositions, formulations, therapeutic methods, polymorphous, etc. All of them related to products known in the market.

Such obligation imposed on Health Authorities contradicts the nature of intellectual property rights as typical private rights<sup>11</sup>. In addition, it burdens the Government with the obligation to look after those rights when, actually, their owners should be the proper defendants through the juridical and judicial systems existing in each country.

### **Conclusions**

Doha represented an important progress in interpreting the scope of the Trips Agreement, and a powerful tool for the developing countries. However, fully developed countries are trying to elude or deviate its actual utilization.

The best example of that strategy are the FTA that the USA reached with various developing countries, Under the apparent umbrella of becoming a "partner" to the USA, many developing countries, compelled by their high foreign debt and by their relative low participation in the global trade, tend to accept temporal advantages on relieved duties for some products, usually a very limited list, at the expense of de-regulating trade on services and increasing intellectual property protection, among others.

This development reinforces the presence of monopolies and limits even more any possibility to re-create the industrial base that is urgently needed to re-generate growth in the Region. The pharmaceutical industry is a strategic sector that should be prioritized in any design of a sound industrial development policy. Although the regulation of paragraph 6 of the Doha Declaration was intended to help countries without, or with insufficient, pharmaceutical industry, it was nothing but a mechanism to address current shortcomings, seeking to soften claims of governments urged by widespread epidemics, such as HIV. Thus, in general, the multilateral forums as of today do not present or offer solutions to procure the sustainable development of the developing countries and their domestic industries.

The health policies do not target those goals either. As said before, they try to solve emergencies, but they lack long term strategies.

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<sup>11</sup> Trips Agreement introduction "...Recognizing that intellectual property rights are private rights...".

Besides, in some cases the Health Departments/Ministries of a given Government do not participate in trade negotiations, although those negotiations have a direct impact on the medicinal policies.

LA countries Health Authorities, urged by the situation, import finished generic medicinal products assuming that this is “the solution” to cope with the medicines supply of the market at prices affordable by the population.

On the one hand, some of those Health Authorities realize that the pharmaceutical domestic industries will end up being seriously damaged, or reduced to a minimum presence in production capacity, and they then rely on the imports of finished products from third party markets to face that problem. On the other hand, they do not seem to realize the importance of relying on a domestic pharmaceutical sector. Among other things, the generics industry represents a competitive barrier to avoid unrealistically high prices in the market, to promote urgently needed investments within the LA countries and to generate significant employment, etc.

After Doha, the questionable way that LA Governments implemented the Trips Agreements became evident. Doha generates the framework, as well as the opportunity, to limit the power of pharmaceutical monopolies in the market. All this could be achieved by re-formulating the pharmaceutical patents legislation. When doing so, it should be a must to include the August 30<sup>th</sup> 2003 Trips Council Decision within that legislation.

Implementing the above mentioned process could be complex, but there are already various examples within LA that demonstrate the viability of such measures when there are firm political convictions to support them<sup>12</sup>.

There are procedures that Governments can rapidly adopt, without having to modify substantially present legislation. One of them would be to establish clear, strict and transparent criteria for the examination of patents applications, and for the approval process to grant them. This will certainly help to restrict the approval criteria to those cases where novelty, inventive step and industrial applicability of inventions are evident. Those pre-requisites are qualifications established in all LA countries patents legislation. They just need to be enforced through guidelines.

Rigorous and robust criteria to appraise and grant patents would help to avoid current problems such as the granting of patents aimed exclusively at protecting investments made, instead of limiting protection to genuine innovation, which should enjoy exclusive rights during the patent term.

An active role of the LA Governments Health Authorities is essential when defining strategies before the international forums (e.g.: WIPO, WTO, WHO, PHO, FTA). This is also true for the design of an industrial model that could enable the LA population to access medicines at reasonable prices. The domestic generic pharmaceutical industry should be the key instrument to achieve such a purpose.

Finally, the efforts that Governments can make individually should go together with, and be reinforced by, a strong coordination among developing countries in all the international forums where those issues were debated. WIPO and WTO should definitely be the place for the discussion of

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<sup>12</sup> Paraguay in amending its patent law postponed the transitional period for pharmaceutical products, from 2003 to 2005. The Andean Community amended Decision 344 on undisclosed information, replacing the data exclusive protection, by the unfair competition rules according to art. 39. 3 of the Trips Agreement.

matters related to countries' development, and not only be conceived as a means to reach higher and higher protection for patents<sup>13</sup>.

WHO has been sponsoring researches, and the publication of documents, related to the impact of patents in the people's access to medicines in developing countries. Its Declarations in the two last General Assemblies were very clear in this area too<sup>14</sup>.

Thus, WHO's performance in the intellectual property area during the last years demonstrates that it offers an adequate framework where developing countries can coordinate policies, and jointly pursue strategic stances, to assure their people's smooth access to medicines at reasonable prices, enjoying the benefit of a market that allows free competition among suppliers.

Today developing countries are better prepared for a debate on intellectual property in international forums given the experience gained in these approximately ten years since the TRIPS Agreement's new rules entered into force and the Doha Declaration on Public Health was approved.

This legal framework is appropriate and favorable to revise carefully the domestic legislation of each country and to generate a debate where intellectual property is not a cost for the countries without innovation capacity but a tool to promote the transfer of technology and development.

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<sup>13</sup>See, establishing a "Development Agenda" for World Intellectual Property Organization, to be submitted to the 40th, series of Meetings of the Assemblies of the Member Status of WIPO and to the 31th Session of the WIPO General Assembly, September 27- October 5, 2004. Document submitted by Brazil and Argentina.

<sup>14</sup> 56th and 57th WHO General Assembly, May 2003 and May 2004.