ALIFAR
Asociación Latinoamericana de Industrias Farmacéuticas

COMMENTS BY THE LATIN AMERICAN ASSOCIATION OF PHARMACEUTICAL INDUSTRIES (ALIFAR) ON DOCUMENTS SCP/16/7 SUBMITTED BY THE SOUTH AFRICAN DELEGATION, AND SCP/17/11 SUBMITTED BY THE UNITED STATES OF AMERICA, RELATED TO "PATENTS AND HEALTH"

1. The WIPO Development Agenda requires that the patent system should be consistent with fundamental public policy priorities and, in particular, with the promotion and protection of public health, as rightfully stated in the Proposal by the Delegation of South Africa (document SCP/16/7).

The patent system, and the intellectual property as a whole, are not ends in themselves that should be blindly maximized; instead, they represent one more of the diverse political, economic and legal tools aimed at promoting development and, therefore, they should be assessed and applied taking into account the characteristics of each country.

In particular, it is necessary to emphasize that patent laws should seek to achieve an adequate balance with public health interests and policies, and ensure the population's right to health and, specially, their access to essential medicines.

Failure to make use of the flexibilities provided for in the TRIPS Agreement, and the adoption of a more rigorous patent system that includes, for instance, the extension of the patent protection term, the increase of patentable subject matter, the adoption of border measures in respect of patents, or the introduction of exclusive rights on test data submitted to the regulatory authorities, will necessarily convey negative consequences on public health.

A more strict patent system will bring about a deep restriction in the pharmaceutical market, as well as an increase in the prices of medicines and in government and social public health costs, which shall hinder any action aimed at ensuring public health and access to medicines.

2. Having in mind the goal of achieving a balance between the patent system and the promotion of public health, ALIFAR could not share the proposal submitted by the delegation of the United States of America concerning patents and health (document SCP/17/11).

First, ALIFAR must point out that it is not correct to state that "the lack of effective patent protection is one factor which prevents the appropriate medicines from reaching the neediest patients in DC and LDCs". Conversely, there is wide international consensus on the negative implications that the adoption of laws that tend to maximize the strictness of the patent system may have on public health.

This has been emphasized in the WTO Ministerial Declaration on the TRIPS Agreement and Public Health, adopted on November 14th 2001. The Doha Declaration recognizes the gravity of the public health problems experienced by many developing and least developed countries (paragraph 1), stresses the need for the TRIPS Agreement to be part of the wider national and international efforts to address such problems (paragraph 2), recognizes the concerns on the intellectual property effects on medicine prices (paragraph 3), and states that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health and promote access to medicines for all (paragraph 4), while reaffirming the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose (paragraph 4).

In line with this analytical perspective, the WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), in its report entitled "Public Health, Innovation and Intellectual Property Rights", analyzed the diverse effects of intellectual property rights on upstream research, the subsequent development of medical products and the possibility of ensuring access to them in developing countries, and included, as well, a wide range of recommendations related to compulsory licenses, exceptions to patent rights, pro-competitive measures and access to medicines[1].

[1] Cfr. Commission on Intellectual Property, Innovation and Public Health (CIPIH): *Intellectual Property, Innovation and Public Health,* World Health Organization, Geneva, 2006. See, *inter alia,* recommendations 2.7,

It is to be noted that the report of the Commission on Intellectual Property Rights, Innovation and Public Health of the World Health Organization was expressly acknowledged and adopted by the World Health Assembly in May of 2006[2].

Second, ALIFAR considers that it is not correct to state that "weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets (…) leads manufacturers to keep already developed medicines out of those markets" and that "more goods become available in developing countries when IP rights are strengthened there".

In this regard, ALIFAR is compelled to point out that the problem of access to medicines in DC and LDCs is not based on the availability or lack of medicines, but in the fact that, when medicines are available, their prices must be affordable for the public and for the national public health budgets.

In this regard, the 14th edition of the report "Untangling the Web of Antiretroviral Price Reductions", published by the well-known international humanitarian organization Medècins Sans Frontières in July 2011, clearly shows that, in the case of antiretroviral medicines, patents work as strong barriers to medicine access, while the promotion of competitiveness for generic drugs and policies that tend to flexibilize pharmaceutical patent rights has a positive and direct effect on market prices and, therefore, on the extension and strengthening of more and improved public health programs[3].

2.9, 2.10, 4.10, 4.13, 4.14, 4.16, 4.18, 4.19, 4.20, 4.23, 4.24, 4.25, 4.26, 4.27, on the need to promote further flexibilities on exceptions and limitations of patent rights and compulsory licenses, and to adopt measures to benefit access to medicines and technology transfer, among other aspects.

[2] See WHA 59.24. For a further analysis on the resolutions adopted by the World Health Assembly regarding the relationship between the TRIPS Agreement and Public Healthm see WHA52.19, WHA53.14, WHA56.27, WHA57.14, and WHA60.30. See, also, the institutional website of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) http://www.who.int/phi/igwg/en/index.html#

[3] Available at http://www.doctorswithoutborders.org/publications/article.cfm?id=5448&cat=special-report

Third, ALIFAR considers that the proposal submitted by the Delegation of the United States of America presents a misconception in its attempt to make the expressions "weakening patent protection" and "greater use of flexibilities" equal concepts.

In fact, proposals that seek to make a connection between patents and public health – and development as a whole-, which emphasize the flexibilities of the international patent system, do not attempt, by any means, to make patents "weak"; instead, they emphasize the idea that more patent protection not always implies better and improved patents as well as more innovation and development; instead, they seek to prevent patent protection strictness from increasing out of proportion, which would affect competitiveness and public policies.

Similarly, such proposals intend to guarantee DC and LDCs the widest scope of freedom to outline their own intellectual property systems, as developed countries have always done in the past and continue doing at present.

Fourth, regarding the alleged positive effects of the patent systems in terms of encouraging research and development to create innovative drugs, ALIFAR notes that such incentives have been clearly insufficient to treat a wide variety of diseases that affect DC and LDCs, which leads to the problem of neglected diseases. This only proves that public health, innovation and development policies of the different WTO member countries should not be restricted to proposing a stricter patent system, expecting that such unilateral legislative reforms automatically improve population's health.

Fifth, ALIFAR considers that it is inadequate to analyze the "other factors external to patent protection" that "are at play in limiting the availability of medicines". Such "other factors" exceed the SCP's and WIPO's goals and mandates. The problems of access to medicines not related to intellectual property are analyzed more deeply and exhaustively in other fora. However, WIPO does have the authority and obligation to analyze the relationship between patents and public health. WIPO is naturally linked to the patent system and, by virtue of such connection, it must focus on that relationship. However, this does not imply that WIPO should analyze public health matters in general, if these are unrelated to patents.

Sixth, ALIFAR believes it is necessary to emphasize that measures to promote a more active use of flexibilities are, in fact, useful to improve the availability of medicines.

Compulsory licenses, for instance, have proved their effectiveness to reduce the price of patented drugs and, the mere fact that there is a possibility of using them has led to more fruitful negotiations between countries and patentees.[4] Similarly, the adoption of strict provisions on patentable subject matter by WTO member countries has proved that it is possible to implement policies aimed at preventing *patent evergreening* and patents on minor innovations that only affect competitiveness in a negative way[5].

Seventh, regarding the alternative approaches proposed by the Delegation of the United States of America to improve the availability of medicines, ALIFAR considers that it is not possible to affirm that those approaches are "more useful" than the use of the flexibilities at an international level. Instead, it is only possible to affirm that they are just "useful" and that they can be used as a complement to other public policy tools.

Without prejudice thereof, ALIFAR needs to address the implementation problems that some of the above mentioned "alternative approaches" present. In fact, patent pools prove to be limited since they strongly depend on the patentees' will, which has not been positive in all the cases. This is the case of Johnson & Johnson, a corporation that has recently announced its refusal to enter into negotiations with the Medicine Patents Pool created by UNITAID, which decision will affect the access to three key antiretroviral drugs[6]. At the same time, the tiered pricing program also depends too much on the patentee's will, with the

[4] For example, since 2001, Brazil has resorted to compulsory licenses on several occasions to obtain price reductions on antiretroviral medicines. See Shadlen, Kenneth C. (2009) "The politics of patents and drugs in Brazil and Mexico: the industrial bases of health policies", *Comparative politics*, 42 (1). pp. 41-58.

[5] E.g., article 3 (d) of India's patent law.

[6] http://www.ip-watch.org/2012/01/12/johnson-johnson-denies-patent-pool-licences-for-hiv-medicines-for-the-poor/

difficulties that this implies. In this regard, the policies of certain pharmaceutical companies to exclude developing countries from their tiered pricing programs are widely known[7].

3. The proposal submitted by the delegation of the U.S.A. also includes, in their enforcement section, the subject of the trade of falsified and substandard drugs, which quality is below the standards of health regulations. The national member associations of ALIFAR and their associated laboratories have been supporting the efforts undertaken by the national authorities of their respective countries to eliminate this true scourge. Also, ALIFAR has been actively involved in all the actions and efforts promoted by the Pan American Network for Drug Regulatory Harmonization / WG – Combat Counterfeit Medicines.

Without prejudice of the above, ALIFAR considers that the topic of trade of counterfeit and substandard medicines widely exceeds the authority vested in SCP and WIPO and, also, is absolutely unrelated to patents and the enforcement thereof. In fact, we should remember that "a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, with insufficient active ingredient or with fake packaging"[8]. Therefore, by definition, the problems with counterfeit and substandard medicines affect both patented drugs as well as medicines in the public domain. For such purposes, fighting counterfeit drugs does not demand the enforcement of intellectual property regulations but, instead, the strict enforcement of laws and regulations on manufacturing and marketing of drugs, including criminal rules, if existing in the local legislations.

On the other hand, ALIFAR warns about the dangers of assimilating an eventual drug patent infringement under the legal concept of counterfeit or substandard drugs trading

[7] Regarding antiretroviral drugs, the discriminations included in the tiered pricing policies are explained in the report by Medicinès Sans Frontières "Untangling the Web of Antiretroviral Price Reductions", above mentioned.

[8] WHO, Department of Essential Drugs and Other Medicines, *Counterfeit Drugs – Guidelines for the development of measures to combat counterfeit drugs,* Geneva, 1999, p. 8.

which underlies in the U.S.A. proposal. An important cornerstone of the patent system in the area of public health is the role of competitors in seeking non-infringing alternatives to a drug patent or a patent being declared invalid in order to offer consumers alternatives with the same therapeutic efficacy and without paying monopoly prices. This policy is incorporated in the legal systems of many WIPO members and has been particularly promoted by the United States[9] with significant success in terms of having access to medicines before the expiration of their patent term, and of savings for consumers and governments[10].

The fact of including medicines authorized by the competent health authority under the category of "counterfeit drugs", which challenge the validity or infringement of a patent, would seriously endanger the use of policies such as the ones described above, which have been successfully implemented by many countries of the international community, including U.S.A.

4. Among the wide spectrum of issues that link patents to public health, ALIFAR is particularly concerned about the extension of patenting practices usually known as "*evergreening*" and, in particular, about the proliferation of pharmaceutical patents, generally obvious, awarded on minor modifications on drugs or on drugs manufacturing processes. We consider that such phenomenon seriously affects competition and, as a direct consequence thereof, it has negative effects on the access to medicines and on public health policies.

Therefore, ALIFAR considers it necessary that SCP makes progress in the approval of the work program proposed by the South African Delegation, on behalf of the African Group and the Development Agenda Group (document SCP/16/7), without subscribing the proposal of the Delegation of the United States of America (document SCP/17/11).

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[9] See *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585h

[10]See FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 15 (2002), p. 9, available at http://www.ftc.gov/reports/index.shtm#2002; and CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998) p. 28, available at http://www.cbo.gov/publication/10938.

In the same sense, ALIFAR agrees with the inclusion of the preventions and activities proposed by The Third World Network (document SCP/17/INF/3, paragraphs 55 through 57) in the SCP work program.

Also, with a view to strengthening and collaborating with the SCP work program proposed by the Delegation of South Africa, ALIFAR emphasizes that the frame study to be designed by eminent independent experts, within the frame of the so-called "Element I", should also cover an analysis on costs and benefits to public health and practices on the admissibility of the following types of claims and/or pharmaceutical patents[11]:

i) Selection patents.

ii) Methods of treatment

iii) Use claims and second pharmaceutical indications

iv) Pharmaceutical formulations and compositions.

v) Combinations of active principles.

vi) Dosage forms.

vii) Salts, ethers and esters.

viii) Polymorphs.

ix) Analogy processes

x) Enantiomers

xi) Active metabolites and prodrugs.

[11] The work paper entitled "Guidelines for the Examination of Pharmaceutical Patents. Developing a Public Health Perspective", by Carlos Correa, sponsored by the WHO, ICTSD and UNCTAD, 2006, has addressed the analysis of the topics mentioned in these comments. We understand that the SCP is an adequate frame to continue and intensify such analysis.