United Nations High Level Panel on Access to Medicines

Call for Contributions – February 2016

Submission by Nicolás Hermida, Vanesa Lowenstein and Pablo Wegbrait

In our former presentation, we had proposed to work on the text of the TRIPs Agreement, resorting to its "flexibilities", expressing that TRIPs not only includes minimum, but also maximum standards[1], proposing to define -at the international level- some terms such as "technology transfer". The main goal of the foregoing was to achieve enforceability of Sections 7 and 8 of TRIPs.

Nowadays, the international scenario has changed significantly: the proliferation of commercial agreements (TPP and TIPP, among others), and the quantity of fora considering themselves competent to participate in matters concerning patents, public health and access to medicines, call for the necessity of other measures, which may be tackled through independent agreements, or as chapters additional to free trade agreements being negotiated or to be negotiated in the future.

In light of the above, we propose the following measures to facilitate access to medicines:

1- Measures related to Free Trade Agreements (FTAs):

- *Antitrust Agreements*. The topic is usually addressed cursorily in sections concerning cooperation between the parties for institution-building for developing countries. Antitrust issues should be introduced as chapters in FTAs as a substantive matter, or eventually within an intellectual property chapter. This could prevent the use of patent trolls, patent thickets and sham litigation, among other practices, whose effect is no other than increasing prices and give rise to regulatory, legal and commercial monopolies. Currently, national offices, including those in developing countries, lack the capacity (whether resulting from lack of human or financial resources, lack of information or unequal powers between the parties), to investigate and punish anticompetitive practices. The inclusion of these measures in FTAs would enable having the capacity to institute proceedings, gather information and eventually sanction, through an international mechanism, those parties who give rise to practices preventing or hampering competition, generating barriers in access to medicines for society at large. Contrary to the prevailing scheme, Antitrust provisions should be subject to FTAs' dispute settlement mechanisms[2].

---

[1] Lowenstein, Vanesa - "Estándares mínimos y máximos en el Acuerdo sobre los ADPIC ¿Pisos y Techos?" in Revista Puentes entre el Comercio y el Desarrollo Sustentable. Vol. VIII No. 4. September, 2007.

[2] For example, the Free Trade Agreement between the European Union and Central America (EU-CAFTA), whose Section I, Antitrust and Merges, Article 7 sets forth: *Dispute Settlement. Neither party may call upon a dispute settlement procedure under this Agreement for any matter arising from this Chapter.* This is the

- *Cooperation Chapter*. The majority of FTAs include cooperation chapters which are usually not subject to the dispute settlement mechanisms of the agreements including them. In other words, they are not enforceable. Moreover, the provisions on technology transfer usually included in IP Chapters are at the last minute of negotiations moved over to the cooperation chapter. The proposal is therefore to revert this situation. That is, in new agreements, not only to incorporate the provisions of cooperation chapters in the FTAs' dispute settlement mechanisms, but also to include a "trigger" clause establishing that, in case of failure to comply with the cooperation agreement, the State who is refused cooperation may refuse to comply with any other chapter, without becoming bound to the dispute settlement mechanism. It would be like an escape clause: State A does not provide institution-building mechanisms, training, financing and technology transfer, among other aspects, to State B, so the latter may refuse to comply with the IP Chapter or patent or trial-data provisions concerning State A, and these matters may not be brought forth to the dispute settlement mechanisms.

2- Independent Treaties:

- In our former presentation we mentioned the possibility of implementing a mechanism similar to the one included in the International Treaty on Plant Genetic Resources for Food and Agriculture, but for viruses, for example. The idea would be to generate a platform facilitating the exchange of material, information, access and use, avoiding at the same time the possibility of third-party appropriation or exclusion of knowledge and use of the material. The regulatory framework enabling that mechanism would be a treaty within the framework of the World Health Organization, together with a standard material transfer agreement.
- Patent pools concerning specific diseases[3]. The idea is to generate a mechanism, through an international treaty, or a less ambitious forum, for example a commission in an institution such as the WHO, WIPO or a non-governmental organization, where patent holders and holders of free sale certificates share their property titles or license the use thereof. The goal is for these pools to function as accelerators allowing innovation to mature more rapidly and collaboratively facilitating the arrival of technologies to the market. The platform would enable to share capabilities, facilitate cross-licensing, and make a more efficient use of resources, decreasing in turn transaction costs.

---

scheme which we propose to change, enabling parties to resort to dispute settlement mechanisms on Antitrust issues.

[3] Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties. Often, patent pools are associated with complex technologies that require complementary patents in order to provide efficient technical solutions. Generally, these patent pools cover mature technologies. Pools also frequently represent the basis for industry standards that supply firms with the necessary technologies to develop compatible products and services. In that case, they rather concern technologies that are yet to be fully developed. Source: http://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf

3- Creation of international mechanisms for information, monitoring and presentation of observations against patent applications.

- This mechanism may function as an addition to the cooperation pool on patents over specific diseases, mentioned in the preceding section, or independently. The proposal is to generate an early-alert mechanism enabling the identification of health-related technologies around which research is being conducted or which are being patented. This would enable several actions, namely: a) presenting observations to patents not meeting the patentability requirements, thus avoiding subsequent judicial challenges with all the costs and time frame associated therewith, b) facilitating the presentation of oppositions or assistance in litigation for local parties, c) becoming aware of the latest state of technology being developed, and d) in case of the grant of a patent, there would be enough time to generate an alternative solution outside of the patent system, a substitute permitting an alternative to combat the disease.

All of the foregoing should be analyzed against the backdrop of the latest trends within the United Nations system, which tend to strike a balance between Intellectual Property and Human Rights. In this regard, the Committee on Economic, Social and Cultural Rights has expressed that States parties have a duty to prevent unreasonably high costs for access to essential medicines, plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education[4].

[4] Committee on Economic, Social and Cultural Rights Thirty - Fifth session, Geneva, 7 - 25 November 2005, General Comment No. 17 (2005) – The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the Covenant on Social, Economic and Cultural Rights).