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Intellectual Property and Access to Medicines: The European Union- Andean Community Trade Agreements

Intellectual Property (IP) Rights: TRIPS, Bilateral Agreements and Public Health

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), concluded in 1994 at the World Trade Organization, contains strong IP regulation, which has posed difficulties when formulating public health policies related to access to medicines in many developing countries. However, this multilateral agreement also recognises public health needs and allows certain policy space for developing countries to protect public health (through the so-called *TRIPS flexibilities*). Bilateral Free trade agreements (FTAs) negotiated by the US and the European Union (EU) are frequently used to set higher standards of IP protection, ignoring progress made in multilateral forums. These *TRIPS plus* and *TRIPS extra* standards that the pharmaceutical industry failed to obtain in multilateral platforms, consolidate and extend monopolies for brand name pharmaceuticals, maintaining high prices and reaping huge revenues for the originator companies.

The EU-CAN Trade Agreements: Problems with the text

General Approach/Provisions-The objectives in the general approach almost exclusively adopt the position of IP rights holders, severely limiting any interpretation of the text from the public health protection perspective. Furthermore, the EC's proposal also limits the ability of the Andean countries to use certain TRIPS flexibilities. For example, the European proposal omits the TRIPS reference to the freedom to establish "the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

Despite this, there has been one extremely important achievement on the application of the Doha Declaration in the text following the recommendations made in the joint HAI Europe and HAI Latin America publication by Professor Xavier Seuba, *Health Protection in the New Association Agreement between the Andean Community and the European Community*. In the original text, the Doha Declaration applied only to the article referring to patents, not to IP in general, omitting important issues such as data protection, technology transfer and, monitoring and enforcement. In the February 2009 negotiation rounds it was agreed, following Colombia's review of Professor Seuba's paper, that the text the application of the Doha Declaration would be broadened to the entire IP chapter.

Patents- The article on patents (article 9) extends obligations to comply with international treaties that were not foreseen in the TRIPS Agreement. Also, the proposal obliges ratification of an amendment of the TRIPS Agreement on compulsory licences, which cuts off the path to other options (though it is not the strongest mechanism). In five years, the compulsory licences mechanism has only been used once (Canada-Rwanda, a very controversial case) and has proved to be a failure as it is not operational.

Data protection- In practice, data protection prolongs the duration of the monopoly of the product owner. As there is no clarity yet on the exact content of this provision in the EC proposal, there is a danger that, based on recent EU treaties, the very high EU standards (TRIPS extra) or similarly strict US standards, could be introduced.

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IP Provisions in EC proposals and Access to Medicines

Enforcement- Provisions on enforcement are the main focus of the chapter on intellectual property, reflecting the main priority of the European Commission. Not only does the proposal go beyond TRIPS, relinquishing the flexibility on enforcement, but even beyond current Community law *(EU Plus)*. The EC proposes to extend criminal sanctions to all IP infringements, something that the EU Parliament rejected in the IPRED2 proposal.

Furthermore, the application of the proposed enhanced border measures would create serious drawbacks in the enforcement of pharmaceutical patents. These problems are not only related to the increased budget allocations necessary for customs activities, but they extend to access to medicines. Third parties would be able to temporarily block the entry of pharmaceutical products by alleging reasons that, even if they are later proven unfounded, would delay the entry of generic competitors into the market. The recent case of the Dutch seizure of generic medicines in transit from India to Brazil is a dire warning of things to come if these enforcement provisions are allowed to remain in the final treaty text.

Technology transfer- The EU has made no commitment regarding technology transfer on either guaranteeing access to innovative products, fostering technological development in the CAN countries or prioritising higher social goods, such as public health and technology dissemination.

A lack of coherence on multiple fronts

Global Strategy & Plan of Action on Public Health, Innovation and Intellectual Property (GSPA)
In May 2008, the European Commission committed the EU to the GSPA, adopted by the World Health Assembly. Government delegations were brought together for over two years to revise and apply concepts into a global strategy and plan of action. The GSPA, devotes considerable attention to IPRs and their impact on public health, singling out the worrying practice of over-reaching IPR protection clauses negotiated in bilateral free trade agreements. In adopting the GSPA, the EU committed to the protection of public health over commercial interests.

Doha Declaration
The 2001 Doha Declaration signed by WTO Members, including the European Union, reaffirmed the importance of upholding TRIPS flexibilities to protect public health. While quoting the Doha Declaration, the EC proposal to the Andean Community countries fails to fully match the spirit of the text.

Recommendations of the Parliament in its 2006 and 2007 Resolution
The following recommendations featured in resolutions given to the EC by the Parliament yet they seem to have been disregarded in the negotiation process: i) Using negotiating guidelines on development cooperation designed to achieve the Millennium Development Goals, including the protection of public health, ii) ensuring the coherence of development policies in line with the principle enshrined in Article 178 of the EC Treaty, iii) granting high priority for greater access to education and health, iv) fostering regional integration by negotiating block by block.

And finally, on July 12th, 2007, there was the European Parliament resolution on the TRIPS Agreement and access to medicines (P6_TA(2007)0353), urging the EC not to demand for TRIPS plus provisions in bilateral agreements.

Executive Agency for Health and Consumers

This arises from the Developing Rational Use of Medicines in Europe project, which has received funding from the European Union, in the framework of the Health programme