



ANNEX

Intellectual Property 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.

General Approach/Provisions

The objectives on IP in the agreements' general provisions almost exclusively adopt the position of IP holders. This severely limits any interpretation of the treaties that allows for the protection of public health. Furthermore, the European Commission's (EC) proposals limit the ability of the Andean countries to use certain TRIPS flexibilities. For example, the European proposal avoids the reference to the freedom to establish 'the appropriate method of implementing the provisions of this (TRIPS) Agreement within their own legal system and practice'.

The provisions on enforcement of IP rights are particularly rigorous. The EC's pursuit of extended IP provisions in trade agreements impedes the use of flexibilities designed to protect public health. The EC's actions run counter to previous EU commitments to support these flexibilities in multilateral fora.

Data protection

In practice, data protection prolongs the duration of the monopoly of the product owner. The European proposal exports its strict system for the protection of medicines' data, which can extend the exclusivity of the patent holding company by up to eleven years. If the European proposal succeeds, Andean countries would be obliged to enact legislation ensuring that marketing authorisation data would remain undisclosed to third parties for up to eleven years. In contrast, the implementation of the US FTAs by Peru and Colombia grants 5 years while Ecuador does not currently grant any period of exclusivity. The extension of the data protection period would further delay generic competition, as generic manufacturers need access to these test data to be able to register their products.

Extension of Patents/ Supplementary Protection Certificates

The EU proposal foresees additional protection periods for patented medicines that have filed an application for marketing authorisation. The extension will be equal to the time elapsed between the filing of the application for a patent and the date of the first market authorisation, up to a maximum of 5 years. The extension of supplementary data protection represents yet another legal mechanism that delays generic competition.

Enforcement

Provisions on enforcement are a main focus of the chapter on intellectual property.ⁱ The application of the proposed enhanced border measures would create serious constraints. These problems are not only related to the increased budget allocation to customs activities, but they extend to access to medicines. Third parties would be able to temporarily block the entry of generics, even if the allegations were later proved unfounded.¹

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 overreaching 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 CAN 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.

ⁱ In this regard, the EC exports the contents of the European Directive 2004/48/EC and the European Regulation 1383/2003.

¹ Xavier Seuba, Health Protection in the European and Andean Association Agreement, Health Action International (Europe) and Accion Internacional para la Salud (AIS) Latinoamérica & Caribe Paper series; January 2009. <http://www.haiweb.org/23032009/18%20Mar%202009%20Policy%20Paper%20EU-CAN%20Association%20Agreement%20FINAL.pdf>