



ANNEX

Intellectual property rights: TRIPS, Bilateral Agreements and Public Health

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), concluded at the World Trade Organization in 1994, contains strong intellectual property (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 by allowing certain policy space for developing countries to protect public health through the so-called “TRIPS flexibilities”.

Some definitions

TRIPS plus: legal provisions that go beyond the TRIPS Agreement regarding subjects already regulated in the TRIPS.

TRIPS extra: legal provisions that go beyond the TRIPS Agreement regarding subjects and legal institutions not considered in the TRIPS.

EC extra: legal provisions that go beyond European legislation on intellectual property

Nonetheless, bilateral free trade agreements negotiated by both the United States and the European Union with third parties have frequently been used to set higher standards of IP protection, ignoring the progress made in multilateral forums. The so-called TRIPS plus and TRIPS extra standards that the pharmaceutical industry failed to obtain in multilateral platforms consolidate and extend monopolies for brand name pharmaceuticals, allowing companies to maintain high prices and reap huge revenues.

General Approach/Provisions

The general provisions objectives on IP in the agreements almost exclusively adopt the position of IP holders. This severely limits any interpretation of the treaty that allows for the protection of public health. Furthermore, the European Commission's (EC) proposals limit the ability of the Andean (CAN) countries to use certain TRIPS flexibilities. For example, the European proposal avoids 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’.

The provisions on enforcement of IP rights are particularly rigorous. A reference is made to the Doha declaration, but only in the article referring to patents, not to IP in general, omitting important issues such as data protection, technology transfer and, monitoring and enforcement.ⁱ The EC's pursuit of extended IP provisions in their trade agreements obstruct the use of flexibilities designed to protect public health that they have previously committed to supporting in multilateral fora.

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.

Enforcement

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

Furthermore, 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 pharmaceutical products by alleging reasons that, even if they are later proven unfounded, would delay the entry of generic competitors into the market.

Technology transfer

The EU has made no commitment regarding technology transfer or i) guaranteeing access to innovative products, ii) fostering technological development in the CAN countries and iii) prioritising the higher social good, such as human health and technology dissemination.^{iv}

Global Strategy & Plan of Action on Public Health, Innovation and Intellectual Property (GSPA)

In May 2008, the EC committed itself to the GSPA, adopted by the World Health Assembly. 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. Government delegations were brought together for over two years to revise and apply concepts into a global strategy and plan of action. In adopting the GSPA, the EC committed to the protection of public health over commercial interests.

Doha Declaration

The Doha Declaration signed by WTO Members, including the European Commission, in 2001 reaffirmed the importance of upholding TRIPS flexibilities to protect public health. While quoting the Doha Declaration, the EC proposals to the CAN countries fail to meet the spirit of the text and, in fact, the EC's proposals establish several barriers for public health protection mandated by the Doha Declaration.

It is particularly worrying that the EC is attempting to limit the effect of the Doha Declaration by applying it only in the article relating to patents rather than to all the intellectual property provisions.

Recommendations of the European Parliament in its 2006 and 2007 Resolution

The following recommendations feature in resolutions given to the EC by the EP:^v

- i) Using negotiating guidelines on development cooperation designed to achieve the Millennium Development Goals, including the protection of public health,
- ii) ensuring 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.

As recently as 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 A good reference to improve the EC text is point 36.5.2 of the WHO Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property (WHA 62.21)

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

ⁱⁱⁱ The TRIPS Agreement, in article 41.5, states that it “does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.”

^{iv} Xavier Seuba; The Protection of Health in the New Association Agreement between the CAN and the EU in the light of Intellectual Property Rights. 2008.

^v P6_TA(2007)0080, <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0080+0+DOC+XML+V0//EN&language=EN>