

IP Standards in the US–Peru FTA: Health and Environment

Peru signed a bilateral free trade agreement with the US on 7 December 2005. The fact that it acquiesced to some controversial US demands on intellectual property has provoked criticism within and outside the region.

The US–Peru FTA is the first agreement reached in the context of the US–Andean Free Trade Area (AFTA) that is also to include Colombia, Ecuador and, probably at a later stage, Bolivia. Negotiations began in May 2004 after Washington announced that it would not renew the Andean Trade Preferences and Drug Eradication Act scheduled to expire in December 2006. For all the Andean parties, US intellectual property protection demands have been a major factor holding back the conclusion of the talks.

An Unhealthy Outcome? CAFTA-plus IP Provisions

At the outset of the negotiations, Colombia, Ecuador and Peru had pushed for the inclusion of some form of public health safeguards in the actual text of the agreement, such as a direct reference to the flexibilities that exist under the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). Instead of such a reference, Peru signed a separate Understanding Regarding Certain Health Measures with the US. While this understanding does emphasise that the obligations set out in the FTA's IP chapter "do not affect a Party's ability to take necessary measures to protect public health," the legal value of such side letters as opposed to their integration in the actual text of an agreement, remains uncertain.

A greater source of concern, however, is new language included in the chapter's provisions on 'data exclusivity', i.e. the period that clinical test data must be protected for brandname pharmaceuticals. Manufacturers of generics often use data submitted by brandname drug companies seeking marketing approval for a new medicine to prove the safety and efficacy of their generic copies. If the test data, which is expensive and time-consuming to produce, is kept confidential for lengthy periods, the introduction of generics is likely to be delayed.

All recent US trade agreements include data protection periods, in spite of consistent criticism by many health groups. However, while past FTAs, such as the Central American Free Trade Agreement (CAFTA), have required the protection of 'undisclosed' information, the US–Peru FTA covers all safety and efficacy information submitted by firms. This is significant as this language could potentially include information on clinical trials that has already been made public, either by the government or through scientific publications, and could also set a precedent for future US FTAs. The FTA does include a separate letter specifically clarifying that the 'understanding' on public health measures applies to the provisions on data protection, something that has not appeared in previous FTAs. While Peru views this as a considerable negotiating success, it does not provide any further indication about the legal value of such side letters and understandings.

However, the US did not get its way with regard to 'second-use patents'. Peru appears to have successfully argued that protection for new uses of existing inventions could lead to an effective extension of the term of protection, which could further delay the entry of generic competition in the market. Furthermore, the Peruvian negotiators avoided the incorporation of a US proposal to allow the patentability of therapeutic methods, such as particular medical procedures.

Nevertheless, civil society organisations, academics and government officials have criticised the IP provisions in the US–Peru FTA for going beyond WTO requirements. An economic assessment by the Peruvian Office on Intellectual Property and Competition has also predicted that the protection of test data could significantly raise the price of medicines in Peru.

Controversy over Biodiversity and Traditional Knowledge

The US–Peru FTA may also prove to have considerable implications for national biodiversity and conservation policies. Links between trade and biodiversity can be found in the IP

chapter, the environment chapter and a separate 'understanding' outside the agreement's text (see related article on page 18).

In the IP chapter, three new obligations will affect policies aimed at the sustainable use of biodiversity. The first is the obligation to ratify UPOV 1991, a treaty that requires the protection of new plant varieties through patent or breeders' rights as opposed to other possible options. The second obligation relates to 'best efforts' to make patent protection available for plants, potentially paving the way for the patentability of biotechnological inventions that have not fulfilled the access and benefit-sharing criteria set out in the Convention on Biological Diversity (CBD). The third obligation is an expansion of the scope of what is patentable in Peru today to include methods, as opposed to inventions alone.

During the negotiations, Peru took a very active stand on trade and biodiversity matters in other fora, namely the WTO, the World Intellectual Property Organisation and the CBD. This raised the conservation community's hopes that biodiversity concerns would be part of the Andean FTA.

Article 18.8 of the environment chapter emphasises the parties' commitment to the conservation and sustainable use of biodiversity and preservation of traditional knowledge (TK). The US–Peru FTA also includes for the first time an additional understanding on biodiversity and traditional knowledge (see box on page 19). The fact that the text specifically mentions contracts as a way to address access to, and benefit-sharing from, genetic resources and traditional knowledge corresponds to the US negotiating position at the World Intellectual Property Organisation and the WTO.

Neither the environment chapter nor the related 'understanding' contain mandatory obligations, but only a set of best-endeavour clauses encouraging information shar-

Continued on page 18

ing on biodiversity co-operation programmes and for the purpose of evaluating the existence of ‘prior art’ in inventions related to TK. Thus, critics argue that the biodiversity provisions in the FTA do not improve the status quo to effectively tackle concerns over misappropriation of biodiversity and TK. Others counter that the very fact that the US has agreed to the inclusion in an FTA of a series of concepts regarding biodiversity and traditional knowledge is already an achievement, particularly given that the US has never ratified the CBD.

Colombia Finalises Deal

The US and Colombia announced the conclusion of a comprehensive bilateral free trade agreement on 27 February. The accord covers goods and services, intellectual property rights, investment, government procurement, and environmental and labour protection.

The negotiations had stalled late last year amid strong opposition from Colombian farmers, who feared that cheap US imports would displace their products in the domestic market and drive more farmers to cultivating illegal drugs. The primary obstacle in the last round of talks was Colombia’s desire to retain a measure of permanent protection for corn, rice and poultry farmers. In the end, however, Bogota agreed to phase out all tariffs on US farm exports over the next 15 to 19 years, with the longest transition time accorded to rice, its most sensitive product. The US will continue to restrict sugar imports from Colombia, but will phase out all other tariffs. To minimise other market access barrier, Colombia tried to ensure that its agricultural goods would not be subject to unreasonable sanitary and phyto-sanitary (SPS) standards. According to the USTR, there is a ‘consultative mechanism’ that Colombia can use to help its producers move through the maze of US SPS regulations.

Like their counterparts in other Andean countries, Colombian opponents to the FTA continue to denounce the agreement’s intellectual property provisions. In December 2004, an advisor to the Colombian IP negotiating team resigned citing fears that his government would bow to US pressure, with highly negative consequences on public health. Like Peru, Colombia ended by accepting the five-year clinical test data protection period, as well as other standard US patent protection requirements in FTAs. In addition, Colombia agreed to establish a system to prevent the marketing of pharmaceutical products that infringe patents in force. Nevertheless, it was expressly spelled out that Colombia would retain the right to “take necessary measures to protect public health by promoting access to medicines for all, particularly in circumstances of extreme urgency or national emergency.”

The Not-So-Bad US–Peru Side Letter on Biodiversity

Manuel Ruiz

The biodiversity ‘side letter’ of the recently concluded US – Peru Free Trade Agreement is an important milestone in addressing concerns related to genetic resources and traditional knowledge in the context of international trade.

In the Understanding Regarding Biodiversity and Traditional Knowledge, to give the side letter its official title, Peru and the US agreed to a common interpretation of a series of concepts related to biodiversity and traditional knowledge. While the text contains no obligations *per se*, its contents reflect the importance and relevance that both governments accord to these issues.

What Does the Side Letter Mean for Peru?

The side letter represents the very first time that the US has accepted to include in a bilateral trade instrument – if not in the actual text, still as an integral part of the overall agreement – explicit reference to biodiversity and traditional knowledge in more than general terms. As these concepts have been historically problematic for US foreign policy, their inclusion, consideration and acceptance during negotiations of the free trade agreement (FTA) were a positive development for Peru. Furthermore, Chapter 18 (on the environment) incor-

porates a series of provisions regarding biodiversity and traditional knowledge. This is an important achievement in itself.

Politically, the side letter means that Peru acted consistently with its original commitment to ensure that biodiversity and traditional knowledge were fully recognised and explicitly mentioned in the FTA. And, as part of treaty’s co-operation obligations, possibilities to consolidate these commitments grow considerably.

The Side Letter in Detail

In more specific terms, the side letter places biodiversity and traditional knowledge as key components of potential social, economic, cultural development. It also recognises the importance of:

- prior informed consent as the mechanism under which genetic resources should be accessed;
- equitable sharing of benefits derived from access to traditional knowledge and genetic resources; and, most relevantly;
- quality patent examinations to ensure that patents granted to inventions involving biodiversity or traditional knowledge are legally valid.

Although the word ‘recognise’ raises legitimate questions as to its precise legal status, read as a whole the text of the side letter will serve to inform future national measures, policies and, hopefully, laws that elaborate and build upon the basic principles agreed upon.

Paragraph three of the side letter seems to have generated most of the negative reactions from a number of sources, some of whom have voiced concerns about Peru’s proposals and its overall negotiating position regarding disclosure of origin and legal provenance requirements during