Chile and the US Priority Watch List: Some Considerations

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In January 2007, the United States Trade Representative decided to add Chile to the Priority Watch List of countries considered to have serious shortcomings in the protection or enforcement of intellectual property rights.

The announcement came as a surprise to many observers of Latin American economic and political developments. Since the restoration of democracy in 1990, Chile has often been acclaimed as an example of modernisation and economic liberalisation in the Western hemisphere. The move did not, however, surprise those familiar with developments in the field of intellectual property (IP) and the strategies the US government uses to advance its policies in favour of strengthened IP protection around the world.

US IP Protection Policies

Section 182 of the United States Trade Act of 1974 introduced a link between respect for intellectual property rights (IPRs) and preferential market access. This seminal concept of 'trade-relatedness' was subsequently integrated into the multilateral trading system during the Uruguay Round negotiations on the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). The 1974 US Trade Act was later amended and under the current Special 301 provisions, USTR annually reviews the 'adequacy and effectiveness' of IPR protection in nearly 90 countries, which are placed in three different categories.

Countries on the Priority Watch List (PWL) are characterised as those that "do not provide an adequate level of IPR protection or enforcement, or market access for persons relying on IP protection." They are the focus of increased bilateral attention concerning the problem areas. A number of nations – for example, Argentina, Brazil, China, India, Israel, Kuwait, the Republic of Korea, Taiwan and EU member countries – have been placed on the list over the years.

In parallel to its strong battery of domestic instruments, such as Special 301, the US has been a strong advocate for strengthening multilateral IP disciplines. The adoption of the TRIPS Agreement with its minimum standards of protection was at the time perceived by many as a step towards the 'multilateralisation' of trade disputes over IPR issues. A new generation of free trade agreements (FTAs) championed by the US – including one with Chile – have made IP obligations even stricter and more robust than those required by TRIPS.

How Has Chile Allegedly Misbehaved?

The major bone of contention between the US and Chile relates to the protection of undisclosed information related to the safety and efficacy of pharmaceutical products and the so-called 'linkage issue', according to which no marketing approval may be given to third parties prior to the expiration of the patent, unless by consent or acquiescence of the patent owner. According to the US, "Chile remains unwilling to address the concerns of patent holders, who report that Chile has authorised the marketing of patent-infringing pharmaceutical products." In addition, the US contends that "Chile relied inappropriately on undisclosed test and other data submitted in connection with the approval of innovative drug products in order to approve generic versions of these drugs."

The US also complains that Chile's "commitment to the vigorous enforcement and prosecution on intellectual property theft of copyrighted goods appears to be diminishing significantly […] the political will and a comprehensive government strategy for reversing recent trends towards higher levels of infringements appears to be lacking."

In brief, according to the US, Chile has not done enough to protect and enforce IPRs held by foreigners. Other trading partners that have entered into FTAs with Chile (notably the EU and Switzerland through EFTA) have also informed the Chilean government of their dissatisfaction with its IP enforcement policies. The EU, for instance, has complained that Chile, as of January 2007, has not acceded nor ensured an adequate and effective implementation of obligations arising from the WIPO Patent Co-operation Treaty. Switzerland has made complaints in the area of pharmaceutical products similar to those of the US.

Chile and the International IP Architecture

In order to understand Chile's actions, it is useful to review briefly the evolution and status of IP protection in the country.

First, Chile is not a major player in terms of patent registration. An average of 2,500 applications are made yearly, mostly by foreign firms. These figures are not of the same order of magnitude as those of Argentina, Brazil or Mexico. Brazil, for example, receives an average of 6,000 patent applications per year and Argentina 8,000. Conversely, in the area of trademarks, Chile appears to have more relevance. Thirty thousand applications are made yearly. This is a globally significant figure.

Second, Chile started to modernise its IP regimes long before the entry into force of the TRIPS Agreement. In 1970 it promulgated a new copyright law (amended in 2004) and in 1991 was the first Latin American country to recognise patenting for pharmaceutical products. It should be recalled that the TRIPS Agreement granted developing countries such as Chile until the year 2000 to meet the minimum standard of non-discrimination in the fields of technology under patent protection (and – with some conditions – until 2005 for countries that, unlike Chile, had not already offered patent protection for pharmaceutical and chemical products). Countries such as Switzerland, with a technologically advanced pharmaceutical sector, had introduced full patent protection only 14 years earlier.

Chile continued enhancing its IP system through a number of reforms, first in 2004 and later in 2005. More recently in January 2007, Chile further fine-tuned its system to meet commitments undertaken in the context of FTAs, particularly with respect to the protection of undisclosed information and invigorated enforcement policies.

Third, Chile is a member of most major international conventions on IP. For instance, the country has subscribed to ten out of the 25 treaties administered by WIPO (the US is party to 14 of those treaties). While it is true that Chile subscribed to the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works – the two pillars of the international IP system administered by WIPO – relatively recently, it is worth noting that the US itself only became party to the Berne Convention in 1989 (the delay was due to the view that it was not consistent with US interests). Through its FTAs, Chile has also assumed further commitments to subscribe to, or comply with, other international treaties, including the Patent Co-operation Treaty of 1970.

Finally, over the last decade, Chile has entered into FTAs with robust IP chapters with the EU, EFTA, the US, Canada, New Zealand, Singapore and the Republic of Korea. It has also concluded an FTA with China and negotiations with Japan are almost finalised.

What Lessons to Draw?

The US classification of Chile – one of the best-performing countries in terms of economic policies and democratisation – as a seriously 'non-performing' country in the world of IP calls for a critical reflection on the evolution and gaps of the international system.

A first issue concerns the possible distortions that bilateral approaches introduce into the multilateral system of IP protection. When the Uruguay Round was concluded, the inclusion of TRIPS as part of the Final Act of the Marrakesh Agreement was accompanied by considerable concern from developing countries about the projected costs of its implementation. Importantly, however, governments were hopeful that the new agreement would promote a multilateral response to alleged lack of compliance with IP rules rather than unilateral acts or trade sanctions. Moreover, under the TRIPS Agreement, parties retain the freedom to determine the appropriate method of implementing its provisions within their own legal systems and practices.

Chile provides a striking example of a country that has gone further than the TRIPS Agreement by willingly accepting further IP obligations, including the protection of undisclosed information concerning the safety and efficacy of a pharmaceutical product, and enforcement measures more generally. Under FTAs, countries such as Chile appear to have lost their freedom to determine how best to implement IP provisions. However, the United States makes clear that it preserves the discretion to determine how the FTAs are implemented under its standard FTA implementation legislation which states, *inter alia*, that:

(1) No provision of the Agreement, nor the application of any such provision to any person or circumstance, which is inconsistent with any law of the United States shall have effect.
(2) Nothing in this Act shall be construed
  (A) to amend or modify any law of the United States, or
  (B) to limit any authority conferred under any law of the United States, unless specifically provided for in this Act.[1]

A second challenge in the international IP system is the lack of clear procedures and criteria for assessing the degree of IP protection in countries and the extent to which they meet international obligations – whether bilateral or multilateral. This gap is particularly worrisome because it leaves countries vulnerable to a wide range of allegations of misbehaviour – which in turn can cause considerable damage to their international reputation – whether or not deserved. The TRIPS Agreement and the FTAs that Chile has entered into underline the importance of transparency and due process of law. Unfortunately, these fundamental principles of the trading system do not prevail in the decision-making process of classifying a country as a major transgressor of international rules.

The allegations made by Chile's major trading partners that it does not enforce IP rules according to their expectations are not based on hard evidence or data, nor on transgressions that have been authoritatively established by judicial or administrative bodies. The EU's conclusions on Chile are based on surveys or guesses of selected firms operating in the country, while the conclusions reached by USTR are based on reports prepared by interested firms that use diplomatic and media channels to pursue their claims. In fact, for several years powerful industry coalitions of major companies, such as the International Intellectual Property Alliance and the Pharmaceutical Research and Manufacturers of America, have repeatedly called on USTR to add Chile to the Priority Watch List.

Where the US and the EU do have genuine concerns and complaints about the interpretation given by Chile to the implementation of some of its IP commitments, these should be resolved through dialogue and finally by Chile in conformity with its international obligations and under its legal system and practice. This could be the case, for example, with respect to the 'linkage issue' that might require more efforts by Chile to ensure transparency and legal security to those holding valid patents, as well as to third parties wishing to market a new product.

Meanwhile, the potential harm caused to Chile by these unilateral actions is not compatible with its efforts to liberalise the economy, to reinforce fair competition and to modernise domestic institutions, including those related to the protection and enforcement of IPRs. Unilateral actions targeting Chile as a 'non-performing' country contradict the spirit of the FTAs signed by the parties and undermine the purported commitment in those agreements to the fundamental principles of the multilateral trading system and to their own dispute settlement mechanisms.

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ENDNOTE

[1] Section 102 of the US-Chile FTA Implementation Bill.