A Shift in Intellectual Property Policy in US FTAs?

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The revised template for US free trade agreements with developing countries contains a number of important changes that respond to concerns expressed by scholars and civil society actors about the expansion of private rights on intellectual property, particularly in the area of public health.

Since the conclusion of the Uruguay Round negotiations and the adoption of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), the US has pursued new and expanded commitments in the area of intellectual property (IP) with a number of its trade partners. As of 1994, the US has sought such provisions in more than 15 free trade agreements (FTAs) containing standards that go beyond the requirements of the TRIPS Agreement.

One of the major critiques raised against FTAs has been that they impinge upon the flexibilities established in the TRIPS Agreement. The sector most affected has been public health. Specifically, critics have contended that FTAs "upset an important balance between innovation and access by elevating intellectual property at the expense of public health," thus marginalising the Doha Declaration on the TRIPS Agreement and Public Health, which confirms the right of all countries to protect public health and promote access to health for all.[1]

In a substantial departure from past practice, the US recently relaxed several patent-related IP rules in revised versions of its FTAs with Colombia, Panama and Peru. This note examines the main elements of the amended agreements with the three countries, and raises some questions regarding the potential impact of such changes on third-party states where older, more restrictive IP rules have already entered into force.

New Health-related IP Provisions

In early May 2007, US congressional leaders reached a compromise with the Bush administration regarding the country's position on issues related to IP, labour standards and the environment in its trade pacts. As a result of the deal, which was intended to facilitate ratification of pending FTAs, negotiated trade agreements with Colombia, Panama and Peru were required to be amended to reflect newly agreed guidelines.

The original IP chapters of the Colombia, Panama and Peru FTAs included provisions similar to those contained in the agreements that the US had negotiated earlier with Chile, as well as in the Dominican Republic-Central America Free Trade Agreement (DR-CAFTA). With respect to IP and access to medicines, the deal required changes in five areas: data exclusivity, patent extensions, linking drug approval to patent status, as well as special provisions on both public health and economic development.

Data Exclusivity. The exclusive protection of data for 'at least 5 years' has been one of the most controversial TRIPS-plus provisions. The stipulation relates mainly to the regulatory hurdles that generic competitors must overcome before their pharmaceutical products reach the market. More specifically, the protection of test data prevents producers of generic drugs from relying on information provided by the person that submitted the original data to sanitary authorities. This special protection is in addition to the regular protection provided by a patent; the rationale for the additional measure derives from the complexities of bringing a pharmaceutical product to market.

In the case of Peru, for example, the changes introduced include the notion that the protection of undisclosed test or other data should not exceed 'a reasonable period of time'. The relevant provision clarifies that for this purpose, such a timeframe shall normally mean five years, taking into account the nature of the data and the degree of effort and expenditure required to produce it. The provision further clarifies that parties shall be allowed to implement abbreviated approval procedures for such products on the basis of bioequivalence or bioavailability studies. The revised text of the Peru FTA is indeed much more flexible than the original version, which did not condition the five-year protection rule on the quality of the data or the economic investments made in producing it. Contrary to, for example, the DR-CAFTA, the revised text leaves room for a balanced domestic implementation of the norms including, for example, a protection for less than five years when the origination of such data has not involved considerable efforts and costs.

In an another important departure, the text of the revised Peru FTA provides that the reasonable period of exclusive use shall begin when the drug was first approved in the US (a so-called 'concurrent period'), provided that Peru grant its approval of the compound within six months of an application. This new mechanism provides an incentive for rapid marketing approval in exchange for a period of protection that starts in the country where the drug was first approved, generating a shorter period of effective protection. This change responds to a criticism of the original version of the FTA, which allowed for a period of five years within which the innovator could claim exclusivity in the other country. Such a priority right could generate a *de facto* extension of the period of protection of up to 10 years.

Patent Extensions. In the revised version of the FTAs each party 'may' extend the term of a patent for a pharmaceutical product to compensate for unreasonable delays in the patent- or marketing-approval process. In other words, the mandatory obligation to compensate for those delays laid out in the original version of the FTA is transformed into an option for the parties. The revised text gives parties the option to compensate for unreasonable delays in the issuance of a patent for a pharmaceutical product by restoring the patent term or patent rights. In all the above circumstances, however, the parties need to make a best effort to process patent and marketing approval applications expeditiously with a view to avoiding unreasonable delays.

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Linking Drug Approval to Patent Status. Another major controversial provision in the earlier US FTA template is the obligation of the agreements' signatories not to grant marketing approval to any third party prior to the expiration of the patent term without the consent or acquiescence of the right holder. This stipulation has been perceived as an unnecessary burden on sanitary authorities, as it would require them to determine whether a private right exists on a particular pharmaceutical product. Such a requirement would effectively transform the regulatory agencies into patent enforcement authorities. In the case of Colombia, Panama and Peru, the amended FTAs do not include any such 'linkage', and in particular do not require sanitary authorities to withhold approval of a generic until they can certify that no patent would be violated if the generic were marketed.

Instead, the revised FTAs require parties to provide procedures and remedies for adjudicating expeditiously the validity of any patent infringement claim or dispute concerning a product for which marketing approval is sought. The revised texts also require greater transparency in these processes, calling on parties to the FTA to make available (i) an expeditious procedure to challenge the validity or applicability of the patent (so as to break the 'link' in appropriate cases), and (ii) effective rewards for a successful challenge to the validity or applicability of the patent. In other words, the revised FTAs try to balance the rights of patent holders with opportunities for generic producers to challenge patented products that might prevent competing products from entering the market.

Side Letters on Public Health. Most of the FTAs recently negotiated by the US, including the original agreements with Peru, Colombia and Panama, have contained side letters with reference to the health solution of paragraph 6 of the Doha Declaration on TRIPS and Public Health, which allows countries with insufficient or no manufacturing capacity to make effective use of compulsory licenses. The revised FTAs, departing from the earlier ones, call on the parties to affirm their commitments to the declaration, particularly emphasising that the provisions on data exclusivity should be subordinated to the right of a party to take measures to protect public health. The revised texts further oblige the parties to respect existing waivers granted by WTO Members regarding provisions of the TRIPS Agreement. These changes put both the declaration and existing waivers at the same level as other provisions in the FTAs, thus facilitating a pro-public health interpretation of the provisions on regulated products, as well as other sections of the FTA. This change may have a positive interpretative effect on certain TRIPS-plus standards in US free trade agreements, such as those on patents, enforcement and dispute settlement.

Economic Development. An interesting new provision in the revised FTAs calls for a periodic review of the implementation and operation of the IP chapter, and gives parties an opportunity to conduct further negotiations. Such deliberations could serve to incorporate modifications to the agreement in response to an improvement in a party's level of economic development.

Some Conclusions

The recent developments suggest an interesting shift in IP policies in US FTAs. The criticisms related to some aspects of the agreements, particularly those concerning the reduction of TRIPS flexibilities, have produced concrete results. The revised FTAs provide clarifications on a number of obscure aspects of the texts and leave space for innovative implementation of the treaties. Moreover, the amended deals emphasise these flexibilities much more clearly than did the original texts as negotiated by Peru, Panama and Colombia.

This shift is also taking place on the other side of the Atlantic in relation to the Economic Partnership Agreements (EPAs), in which provisions on patent and test data protection have been omitted from recent EU trade proposals to African, Caribbean and Pacific (ACP) countries. Furthermore, the European Parliament has recently adopted two resolutions on the matter, one calling for the EU not to include IP provisions in the EPAs, and the other expressing concern over the incorporation of TRIPS-plus provisions in those agreements.

One lesson that could be drawn here is that developing countries still occupy weak bargaining positions vis-à-vis their more powerful trading partners. Especially in the cases of Colombia and Peru, even competent and well-prepared negotiators were unable to obtain in the original agreements the development-friendly provisions that were eventually incorporated thanks to the intervention of US legislators.

Another lesson is that developing countries continue to face important challenges in complex areas such as IP. In many instances, multilateral negotiations have proven to be better fora for striking deals that take into account broader considerations as illustrated by the TRIPS and Health Declaration. In the past, free trade negotiations have typically been guided by an overly simplistic political and mercantilist rationale. This has been the case in the IP field, where powerful industrial sectors have wielded considerable influence. However, the new template suggests that consumers' and users' rights are starting to be taken into consideration in the crafting of IP rules in FTAs. Nevertheless, the new provisions will clearly generate adjustment and implementation costs for developing country partners, showing again that perhaps nothing in the trade world is free.

Finally, an important issue remains open for debate as we advance in the understanding of this new shift: how will the revised FTAs affect third parties? Could other countries benefit from the revisions the US FTAs with Peru, Colombia and Panama? Could DR-CAFTA countries be exposed to higher obligations in the area of pharmaceutical products than those recently agreed for Peru, Colombia and Panama? Could weaker partners, such as those in DR-CAFTA, request a renegotiation in line with changes made to Colombia, Peru and Panama FTAs? Could countries be exposed to unilateral sanctions for non-compliance with the 'linkage' obligation even when the requirement has been removed from the recent agreements?

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ENDNOTE

[1] Letter dated March 12, 2007 to the US Trade Representative signed by 12 US congressmen.