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# Papers

## New US trade policy: A turning point?

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**Abstract** Trade agreements on intellectual property (IP) became a useful tool for patent holders to increase their exclusive marketing rights around the world. Bilateral agreements have gradually increased the standards of protection beyond those of the TRIPS agreement creating a growing imbalance between the rights of IP holders on one side and those of consumers and the generic industry, on the other. After the Democratic Party became the majority party in the US Congress in January 2007, the new leadership of the Ways and Means Committee of the House of Representatives forced the US Trade Representative to reopen the Free Trade Agreements (FTAs) with Peru, Panama and Colombia, the ratification of which was pending, and introduced substantial changes to the final texts to reduce the negative effects on access to medicines posed by the original agreements. This seems to mark a significant turning point but all will depend on how these governments implement the FTAs into their national laws and on whether they actually take advantage of this opportunity. Will other governments follow the leadership shown by the Ways and Means Committee?

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### TRADE AGREEMENTS AS TOOLS TO INCREASE INTELLECTUAL PROPERTY PROTECTION AROUND THE WORLD

The conclusion of the Uruguay Round of GATT (General Agreement on Trade and Tariffs) and the adoption of the first global intellectual property (IP) agreement (Agreement on Trade Related Aspects of Intellectual Property Rights — TRIPS)

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marked a substantial change for access to medicines throughout the world. The TRIPS agreement established the international standard of IP that all members of the World Trade Organization (WTO) must respect. Although most countries thought that this agreement would be the new standard under which they would operate for years to come, they soon learned that it marked only the beginning of new pressures to gradually increase IP protection. Driven by the lobbying efforts of the innovative pharmaceutical industry, the US launched a tri-dimensional strategy of global, regional and bilateral IP negotiations — all of them aimed at strengthening IPR (intellectual property rights). Each new agreement set new standards that were the basis for the following ones. As

discussed in articles previously published in this Journal,<sup>1,2</sup> this trend is clearly evident when one analyses the bilateral trade agreements negotiated by the US between 2002 and 2007. The other side of this increasing protection was the delay of generic competition and consumers' access to affordable medicines.

On 10th May, 2007, the Ways and Means Committee of the US House of Representatives and the USTR (US Trade Representative) announced a new trade policy, which essentially introduces changes in three areas: labour, environment and *pharmaceuticals*. The text of the amended Peruvian FTA (Free Trade Agreement) was released on 25 June, and the others were released a few days later. With regards to pharmaceuticals, the text introduces changes on three issues that were clearly TRIPS-plus: (a) patent extensions which, although they were not part of the TRIPS agreement, were included in all recent FTAs; (b) data exclusivity — again, the TRIPS does not require the adoption of data exclusivity periods but all FTAs signed under the Trade Promotion Authority (TPA) Section of the Trade Act of 2002, included periods of 'at least five years' and (c) linkage between the patent office and the sanitary approval office (also not part of the TRIPS but included in all recent FTAs). Specifically, these three sections include the following changes.

### PATENT EXTENSIONS

The requirement to grant patent extensions included in the original text was eliminated for pharmaceuticals. Specifically, the amended text has a new reference only for pharmaceuticals according to which countries 'may' instead of 'shall' make available a restoration of the patent term, both for delays in the marketing approval process and in the issuance of a patent (Art. 16.9.6 (b) and (c)). Therefore, there is no longer an obligation to grant such extensions.

In an effort to have a fair provision, the new agreement says that 'Each Party shall make best efforts to process patent applications and marketing approval

applications expeditiously with a view to avoiding unreasonable delays'.

### DATA EXCLUSIVITY

Data exclusivity is a newer type of monopoly in the area of pharmaceuticals, which is rapidly becoming increasingly complex. Innovative pharmaceutical companies have made major efforts to obtain exclusive rights over the data they submit to demonstrate the safety and efficacy of a drug. Although Art. 39.3 of the TRIPS agreement requires that data not be disclosed to prevent unfair competition, during the negotiation of the agreement there was no consensus regarding the adoption of a period of exclusivity and the proposal was rejected. Nevertheless, all recent FTAs established a period of exclusivity.

In the new text, a new section has also been introduced just for pharmaceuticals with regards to data exclusivity.

The changes include:

- *Grace period*: Elimination of the grace period for the registration of a product's data exclusivity. The old text granted a grace period of up to five years from its registration in the US in addition to the actual exclusivity period thus potentially making generic (more affordable) versions of such products unavailable for a period of ten years.
- *Period of protection*: The periods of protection would be concurrent in both countries as long as Panama/Peru/Colombia recognise the US registration and the court in question granted approval within six months of the filing of a complete application in the court. This sets an important precedent for countries such as Israel and Chile, which have been under a great deal of pressure under the Annual Special 301 Review of the USTR to adopt periods longer than five years (or in the case of Israel longer than 5.5 years of data exclusivity).
- *Scope of the protection*
  - *Limits the protection to New Chemical Entities*: The protection is no longer

for 'new pharmaceutical products' but limited to 'new chemical entities'.

- *Limits the protection to 'required' data:* Only the required data to demonstrate the safety and efficacy of a drug can be protected. Under the old text, the protection was potentially broader since it was granted to information 'required or permitted'.
- *Limits the scope to 'undisclosed' data:* The old text for Peru and Colombia had dropped the word 'undisclosed' so any information could have been granted exclusivity. The new text reincorporates the word 'undisclosed' thus limiting the scope of what can receive such exclusivity.
- *Eliminates the protection for 'information':* The FTA with Peru referred to 'the submission of information concerning safety or efficacy of the product', the new text limits such protection to 'the submission of undisclosed text or other data'. Again, this elimination narrows the scope of the protection.
- *Eliminates the words 'at least' five years:* The new text says 'a reasonable period shall normally mean 5 years'. This represents a very significant change. If this is properly implemented, it will no longer mean that there is an open-ended exclusivity period but one that has clear limits as it is in the US, a real turning point.
- *Reduces the protection: It actually may be less than five years:* The text says 'a reasonable period shall normally mean five years'. Therefore, in some cases the protection could be less than five years.
- *Eliminates the words 'same and similar':* It eliminates these two words which is a significant improvement since the word similar could be a barrier for the authorisation of a therapeutic family of medicines and also of biogeneric/biosimilar drugs.
- *Incorporates strong language so that data exclusivity will not limit the approval of generic drugs through bioequivalence or*

*bioavailability:* This means that it would allow the indirect reliance on the data for the registration of products as Canada used to have until 2006.

- *Establishes data exclusivity exceptions:* The protection may not be enforced to protect public health according to the Doha Declaration on the TRIPS agreement and public health, TRIPS waivers or amendments.

## LINKAGE

Linkage is a provision under which regulatory offices cannot approve a generic drug if there is a patent in force covering the original drug. Although at first glance it seems reasonable, linkage has been very problematic since it has opened the door to many abuses. Linkage was first established in the US and Canada due to the pressure of patent holders and is related to several other issues, including the evergreening or the improper filing of patents (frivolous lawsuits), and the misuse or abuse of patents by right holders. According to this regulation, in the US and Canada no generic drug can be approved until any claim of alleged patent infringement is decided in court or for a certain period of time (30 months in the US and 24 in Canada), whichever comes first. In the US once a patent has been granted, a company can register it in the Orange Book at the Food and Drug Administration (FDA), but not every patent can be registered. The only patents that can be listed are those that claim to be (1) a drug substance (active ingredient), (2) a drug product (formulation and composition) and (3) a method of use.<sup>3</sup>

Although not part of the TRIPS agreement, the inclusion of linkage has been one of the consistent demands of the USTR when negotiating bilateral trade agreements under the current TPA. The way it has been included goes beyond US standards as, for example, there are no restrictions on the patents that could be subject to linkage. In fact, in its 2007 Special 301 submission to the USTR, PhRMA criticises Mexico, Chile and others for their restricted implementation of linkage.

Furthermore, linkage shifts the responsibility for protecting private property from the patent holder to the government.

According to the new language of the three agreements, each party shall provide procedures or remedies for the expeditious adjudication of disputes concerning the validity or infringement of a patent with respect to patent claims that cover an approved pharmaceutical product or its method of use. Therefore, it does not *per se* establish the linkage but the 'procedures or remedies' to address disputes over the validity of patents.

The new text states that governments must grant a transparent system to provide notice to the patent holder that another person is '*seeking to market*' an approved pharmaceutical product during the term of a patent. The Chilean Government has implemented this by creating a website where this information is available.

In addition, the reference to an 'approved pharmaceutical product' clearly indicates that the patent holder would not need to know which companies are seeking to market a product until the marketing approval for the product has been granted.

Also, parties shall allow sufficient time and opportunity for a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies for an infringing product. This only allows the patent holder to 'seek' remedies for an allegedly infringing product. Therefore it puts the responsibility back on the patent holder so that he/she has to act if he/she considers that a patent may be infringed. The original agreement did not require the patent holder to do anything and it granted full protection.

Furthermore, the new text allows for the challenging of the validity or applicability of a patent, something that was missing from the original agreement. In addition, it contemplates providing effective rewards for the successful challenge of a patent. This opens the way to obtaining benefits in other countries such as the 180 days of exclusivity for the company that successfully challenges the validity of a patent, similar to what is in

force in the US. This is a new concept for many countries so its implementation will depend on their governments. Without doubt, it represents a very good opportunity both for the generic industry and consumers.

## CONCLUSION

The New Trade Policy announced by the Ways and Means Committee and the USTR was the result of the new leadership in the US Congress, which took a stand to stop the trend of increasing IP standards in trade agreements at the expense of access to medicines and the generic industry. Therefore, this new policy tries to restore a balance between promoting innovation and protecting consumers, between innovative and generic companies.

The new texts of the FTAs with Peru, Panama and Colombia show that the type of leadership makes a difference, that countries should negotiate harder with the US, that the USTR has represented more the side of IP holders, but that they do not reflect the views of all the US Government.

FTAs can be good but countries need to work harder to get better agreements.

Furthermore, the new texts show that access to medicines can be something governments should fight for. We will see whether the governments responsible for implementing the new texts of the FTAs follow the Ways and Means leadership and take full advantage of this opportunity, or whether they will let interest groups take over again at the expense of their citizens' access to more affordable medicines.

## References

1. Jorge, M. J. (2004). TRIPS-plus provisions in trade agreements and their potential adverse effects on public health. *J Generic Med* 1(3), 199–211.
2. Jorge, M. F. (2007). Trade agreements and public health: Are US trade negotiations building an intellectual property platform against the generic industry? Are they raising the standards to go beyond the US law? *J Generic Med* 4(3), 169–179.
3. 'Generación y protección del conocimiento. Propiedad intelectual, innovación y desarrollo económico', Jorge Maria Martínez, Pira Coordinator, Libro de la Cepal, México DF, 2007, forthcoming.