



Data exclusivity in international trade agreements: What consequences for access to medicines?

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“Data exclusivity” is a term covering measures some governments, especially the US, are seeking to include in bilateral and regional trade agreements. The implications of such measures need to be understood, because they could have far-reaching ramifications for access to medicines.

Data exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine. Data exclusivity is completely separate from patents. In fact, the strongest impact may be felt in a country where there is no patent for a medicine - if data exclusivity is granted this will provide a monopoly for a set period (e.g. five years).

This short briefing paper outlines the consequences of data exclusivity for access to medicines and explains why countries are not obliged to agree to it.

What kind of data are we talking about?

“Data exclusivity” refers to test and other data that a pharmaceutical company must provide to a drug regulatory authority (DRA) in order to get first-time registration for any new medicine it wishes to market in a country. This test data is necessary to demonstrate the efficacy and safety of the drug. Registration - or marketing approval - by the DRA is needed before a medicine can be marketed in a country.

When generic manufacturers later apply to register another version of an already-registered medicine, they only have to demonstrate that their product is therapeutically equivalent to the original. To fulfil the efficacy and safety requirements, the drug regulatory authority relies on the registration file of the original manufacturer.

So what kind of exclusivity is it?

In order to delay competition from generic manufacturers, multinational companies have been pushing hard to obtain exclusive rights over their test data. During this period of “data exclusivity”, the DRA is not authorised to

rely on information in the originator dossier to approve/register generic versions of a medicine. This period of exclusivity may vary from five years in the US to eight-10 years in the EU and can be found in developed countries mostly in medicines legislation. Such legislation also exists in a limited number of developing countries.

Practically, data exclusivity prevents DRAs from registering generic versions of a medicine during a limited period, unless the generic manufacturer independently carries out its own tests showing the safety and efficacy of the medicine.

What are the consequences of data exclusivity for access to generic medicines?

The biggest impact of data exclusivity is on medicines that are not patented in some countries, as a result of pre-TRIPS patent laws excluding pharmaceutical patents. This is the case of most antiretroviral medicines in Guatemala for instance¹, where generic manufacturers will now have to wait five years from the date of approval of the original medicine in Guatemala before obtaining registration of their own version of the medicine². In other words, even when a medicine is not protected by any patent, multinational pharmaceutical companies are assured a minimum period of monopoly in countries that provide data exclusivity. This is clearly going beyond the TRIPS Agreement (see further below).

In other situations, where a medicine is protected by patents, data exclusivity may constitute a barrier to the use of compulsory licenses. If a generic manufacturer is granted a compulsory license to overcome the patent, it will not be able to make effective use of the license if it has to wait for the expiry of data exclusivity before it can get its generic version approved by DRA and put on the market. Therefore, countries will need to ensure that the use of compulsory licences are not restricted by data exclusivity.

Data exclusivity is a means of impeding generic competition, and maintaining artificially high prices, thereby restricting access to medicines. Moreover, it could be considered unethical to require generic manufacturers to conduct their own safety and efficacy trials with proven effective compounds. Clinical trials could expose patients to sub-optimal treatment. Proof of therapeutic equivalence should be sufficient.

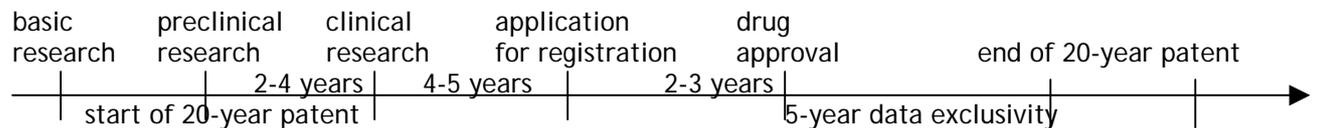
¹ This is because Guatemala only introduced patent protection for pharmaceuticals in November 2000. Consequently, all medicines which were applied for patent protection before this date cannot be patented in Guatemala (except for new improved versions that meet the patentability criteria). See MSF report *Drug patents under the spotlight - Sharing practical knowledge about pharmaceutical patents*, May 2003.

² In accordance with Decree 09-2003, and the recently signed Central America Free Trade Agreement (CAFTA) with the United States.

What is the relationship between data exclusivity and patents?

Patent application is made well before the application for drug registration, at the stage of basic research, but since patents now last for 20 years, they usually expire after the data exclusivity period.

The schematic graph below illustrates the interference of patents and data exclusivity.



Is data exclusivity another kind of intellectual property right?

Compared to more traditional intellectual property rights such as patents and copyrights, data exclusivity is very unusual since it does not require any inventive activity for it to be granted. Data exclusivity protection is instead only based on the fact that an investment has been made by the originator in carrying out the necessary tests to demonstrate the safety and efficacy of their new medicine. Although the TRIPS Agreement now requires some protection for this sort of data, it does not require that exclusive rights be granted in the same way as patents or copyright.

What does TRIPS say about test data?

Developed countries pushed very hard during the TRIPS negotiations to have data exclusivity included in the TRIPS Agreement as a new kind of IPR. They succeeded *in part*, as test data are mentioned in Section 7 of the TRIPS Agreement, but *not entirely*, as TRIPS does not talk about "exclusivity" as such.

There is only one article in the TRIPS Agreement that talks about test data: Article 39.3, which states that

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

In simple words, what TRIPS says is that WTO Members should protect "undisclosed test or other data" against "unfair commercial use" and "disclosure". Nowhere does TRIPS state that countries should provide *exclusive* rights to the originator of the data for a *given* period. Rather, TRIPS simply refers generally to the need for "data protection", without answering the question of how such protection should occur.

As for other forms of IP, Article 39.3 of the TRIPS Agreement only provides a minimum international standard for the protection of the submitted undisclosed information required for market approval of a pharmaceutical product. Since the wording of Article 39.3 is very general, Members maintain substantial flexibility when determining how submitted test data should be protected. WTO Members do *not* have an obligation under Art. 39.3 to confer exclusive rights to test data, whether it is for three years, five years, or 10 years, as pointed out by many experts³.

Data exclusivity is no more than “TRIPS-plus” and is designed to delay the introduction of generic competition, creating a barrier to access of medicines, in particular where there are no patent barriers.

What will be the effect of data exclusivity in bilateral and/or regional trade agreements given TRIPS flexibility?

Countries that are members of the WTO do *not* have to grant data exclusivity, as specified under TRIPS Article 39.3. However, if they agree to grant data exclusivity in a trade agreement signed after the TRIPS Agreement, they are bound by the later agreement, in accordance with the rules of international law, and will have to implement this obligation at national level.

Countries that have agreed to data exclusivity provisions in free trade agreements with the US include: Chile, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua and Singapore.

³ See Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, South Centre 2002. Available at <http://www.southcentre.org/publications/pubindex.htm#books>
See also the Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, London, September 2002, pp.50-51 and 163.