Data Exclusivity: Implications for Developing Countries

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The protection of pharmaceutical test data is rapidly becoming a global North–South issue as the US and the EU expand their web of trade agreements with developing countries. This article looks into the potential implications of the EU's data exclusivity provisions.

Data exclusivity is one of the most interesting issues in the current discussion on pharmaceutical intellectual property policy-making globally. It is aimed at protecting and safeguarding pharmaceutical registration files, i.e. the data submitted by companies to regulatory authorities, such as the US Food and Drug Administration and the European Agency for Evaluation of Medicinal Products, for the purpose of obtaining marketing approval for new drugs.

Recognised internationally for the first time in the mid-1990s in Article 1711 of the North American Free Trade Agreement (NAFTA) and Article 39.3 of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), data exclusivity is a relatively new form of intellectual property.

The underlying logic of data exclusivity suggests that it is an expression of trade secrets and, as such, should be independent of patents. Compared with patents, the market power of data exclusivity is in theory less restrictive, mainly because it does not legally prevent other companies from generating their own registration data. In other words, data exclusivity protection does not apply to cases where the second (generic) comer provides its own test data. In such cases, the originator may not prevent marketing approval from generic 'new-comers'. Rather, the marketing of the generic product may only be prevented if there is a valid patent on the relevant substance. However, in practice, the vast financial resources and extended time required for gathering and generating pharmaceutical registration data for a new drug create a market barrier that is too high for generic-based companies.

Data exclusivity is also rapidly becoming a global North-South issue, as it is now being fiercely advocated by the United States and to some extent the EU vis-à-vis developing countries, such as Guatemala, Israel, Taiwan, India and Thailand.

The EU's '8+2+1' formula

EU data exclusivity legislation is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). The new Directive was finalised in December 2003 and came into effect in May 2004.[1]

EU legislation can be divided into two periods: 2001 to December 2003, in which data exclusivity legislation was not harmonised between EU members and varied between six and ten years, and the period thereafter, in which the term of protection was harmonised according to the 8+2+1 formula, as discussed below.

In order to better understand the new format of the EU's data exclusivity legislation it is important to provide a brief background to the main reasons underlying the 2003 amendments.

Prior to December 2003, Article 10(1)(a)(iii) of Directive 2001/83/EC stated that, for the purpose of obtaining authorisation for market use, six years must elapse before the generic drug could rely on the registration dossiers of an original product that had been authorised for use within the Community. The Directive also stated that the six-year period of market exclusivity would be extended to ten years in the case of high-technology medicinal products, and that member states could extend the period of exclusivity to ten years to all medicinal products.[2]

One also has to bear in mind that prior to the December 2003 resolution, the period of data exclusivity at the national level varied between the member countries (and EU candidates at the time). For example, Germany, France, the UK and the Netherlands granted a ten-year period of data exclusivity, while Austria, Greece, Spain, Estonia and Latvia allowed only six years.

The December 2003 amendments to the EU's data exclusivity legislation were part of a wide 'package' of proposed changes aimed at substantially modifying the regulatory framework governing the pharmaceutical industry in Europe. The calls for changing the current state of affairs in the European pharmaceutical industry were based on two major factors:

- the urgent need to harmonise the European pharmaceutical market following the expansion of the EU, and
- the fact that the European pharmaceutical industry had become much less competitive vis-à-vis that of the US.

This is why the European Commission established, on 26 March 2001, a High Level Group on Innovation and the Provision of Medicines. The Group's mandate was to propose a new agenda to improve the framework for competitiveness in the pharmaceutical industry and to harness its power to deliver on Europe's health care goals.

Based on the Group's recommendations, the Commission proposed in July 2003 a mandatory data exclusivity period of ten years for all new pharmaceutical products registered under the pan-European 'centralised procedure'.[3] The Commission also proposed granting an extra year of protection for new indications of original medicines (this is usually referred to as the 10+1 formula). Finally, the Commission recommended that generic companies be legally entitled to make commercial experiments in patented pharmaceutical drugs as part of the process of obtaining marketing approval for generic substitutes (so called 'Bolar' provisions).[4]

In December 2003, the European Parliament adopted a compromise, known as the '8+2+1' formula.[5] According to this formula, new pharmaceutical products would be entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic companies would be allowed to rely on the data of the original product, i.e. sub-

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mit bio-equivalence tests, but not yet to market their generic substitute) and an additional year of protection for new indications of existing products. As stated in paragraph 8 of Directive 2004/27/EC:

" *By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the (generic) applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community. A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.*

The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies."

Article 10(6) of the Directive also allows generic companies to engage in Bolar-type activities for the purpose of registering and approving their products for market use.

Implications for Developing Countries

The debate over the scope and term of data exclusivity is rapidly spilling over to other countries, particularly advanced developing countries with established research and development capabilities.

There is growing evidence suggesting that regional and bilateral trade agreements – between the US and EU on the one hand and developing countries on the other – are based on TRIPS-plus provisions, including those in the field of data exclusivity.[6]

In the case of data exclusivity, the US is the *demandeur* in the sense that bilateral and regional free trade agreements (FTAs) between the US and developing countries are based on the data exclusivity standards of the former. Generally speaking, the US-led FTAs require the establishment of data exclusivity legislation, consisting of a minimum five-year protection period, including cases in which marketing authorisation was granted to a third party in another country.[7]

In this context, the main question is what will be the data exclusivity requirements of the EU-led FTAs that are in the pipeline. In other words, will the EU's FTAs require developing countries to adopt a data exclusivity legislation according to the 8+2+1 formula discussed above?

Compared to the US, the IP provisions of the new-generation FTAs (so-called 'association agreements') between the EU and developing countries (Jordan, Israel and Chile) are more general and less issue-specific. These provisions usually refer to the need to provide "adequate and effective protection of the highest international standards including effective means of enforcing such rights".[8] Not surprisingly, this language provokes considerable debate about what the highest international standards are, and to what period these standards refer.

There are specific cases in which the EU has gone beyond the above pattern to demand a higher level of IP protection from its trading partners, based on the EU standard (meaning the EU's data exclusivity formula of 8+2+1). For example, the 1998 Partnership and Co-operation Agreement between the EU and Ukraine requires the latter to implement IP protection standards similar to that existing in the EU by the end of 2003.

We do not yet know where the EU is heading with its IP demands in regional or bilateral FTAs involving developing countries. The big question is: if the EU does decide to adopt a more hawkish approach, demanding developing countries to implement its data exclusivity standard, are we likely to enter a new phase of 'TRIPS-double-plus' or 'TRIPS-max' trade agreements?

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ENDNOTES

[1] *Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use*, Official Journal of the European Communities, (30 April 2004), L 136/34.
[2] Directive 2001/83/EC, Article 10.
[3] European Commission, July 2003, p. 14. The 'centralised procedure' refers to product registration with the European Agency for Evaluation of Medicinal Products.
[4] For a discussion on Bolar provision see; Pugatch (2004), pp. 180-186.
[5] European Parliament resolution, Amendment 14, Article 1, Point 8 (17 December 2003); This resolution is based on the recommendations of the European Parliament Committee on the Environment, Public Health and Consumer Policy. *Draft Recommendation for Second Reading on the Council amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use* (28 November 2003) A5-0425/2003.
[6] OECD-Trade Directorate. *Regional Trade Agreements and the Multilateral Trading System* (Paris: 20 November 2002), TD/TC(2002)8/FINAL. See also: Abbott, F. M. *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements* (Quaker United Nations Office: 14 April 2004) Occasional Paper; Vivas-Eugui, D. 'Regional and Bilateral Agreements and a TRIPS-Plus World: the Free Trade Area of the Americas (FTAA)', *TRIPS Issue Papers 1* Geneva (Quaker United Nations Office: 2003).
[7] For an analysis of the different components of data exclusivity legislation in US-led FTAs see: Pugatch M.P. *Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access*, prepared for the International Centre for Trade and Sustainable Development: the Third Bellagio Dialogue on Development and Intellectual Property (Geneva: UNCTAD- ICTSD: October 2004). An expanded paper will be available in late 2005.
[8] A reference for this language can be found in the EU-Israel Association Agreement (2000), Chapter 4 - Intellectual, Industrial and Commercial Property; EU-Jordan Association Agreement (2002), Article 65; EU-Chile Association Agreement (2002), Title VI - Intellectual Property, Article 168.