Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals

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ABSTRACT

The chapter discusses the meanings of data protection and data exclusivity in the context of the provisions of the Trade-Related Aspects of Intellectual Property Rights agreement. In addition, it outlines the relationship between data exclusivity and patent protection and briefly reviews the possible costs and benefits of introducing data exclusivity laws. Finally, the chapter explains that countries need to consider the costs and benefits when negotiating bilateral trade agreements that might require the introduction of these laws.

1. INTRODUCTION

The development of a new drug or agrochemical, such as a pesticide, usually requires extensive testing, inside the laboratory or in the field, on animals, humans, plants, or the environment, depending on the nature of the drug or chemical.

The way in which these tests are undertaken are, at least in the later stages, governed by rules set by the regulatory authorities. These rules are designed to ensure the safety, quality, and efficacy of products being developed for use by humans or in the environment (in the case of agrochemicals). In the United States, for instance, this regulatory authority is the Food and Drug Administration (FDA) for medicines and vaccines and is the Environmental Protection Agency (EPA) for agrochemicals.

Meeting the requirements, which is necessary for permission to place products on the market, involves a considerable cost. Studies on pharmaceutical industry data, albeit disputed by some, have suggested that the average total development cost of a new drug is on the order of US$800 million, of which about 60% would be incurred in the conduct of trials (a substantial portion of these trials would be required for regulatory approval).[1] In agrochemicals, it has been estimated that the average development cost is more than US$180 million.[2]

Because of the size of the required investment in clinical test data, the pharmaceutical and agrochemical industries argue that the use of such data by third parties (other than the regulatory authority) must be prevented. If the regulator, relying on test data provided by the originator company at great expense, allows an equivalent product to enter the market, originator companies would have no incentive to incur the heavy costs necessary to bring new products to market in the first place. In practical terms, a rule that prevents use of the data by a third party (or the regulator relying on that data to approve a third party's generic product) also has the effect of providing exclusivity to the originator product. This is principally because the cost of replicating the investment in trials to satisfy regulatory requirements would be sufficiently prohibitive to deter a potential competitor. In the case of medicines, even if the cost were not prohibitive, there are also ethical concerns about repeating trials (that

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include an untreated control group) with a drug known to be efficacious.

This chapter seeks to explain the quite complicated issues related to data protection and data exclusivity and how they are treated in different jurisdictions. Particular consideration is given to the position of developing countries who are contemplating, or being obliged to contemplate, data protection or exclusivity regimes.

2. WHAT IS THE DIFFERENCE BETWEEN DATA PROTECTION AND DATA EXCLUSIVITY?

The modern debate about *data protection* and *data exclusivity* largely derives from differing interpretations of what the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) says on the subject.

The relevant article (Article 39(3)) says:

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.

There are unreconciled views on what this paragraph, the subject of protracted discussion when the agreement was negotiated, means in practice.

It is important to note that Article 39, as a whole, constitutes the section of the agreement "protection of undisclosed information" that relates broadly to what are generally known as *trade secrets*. Article 39(2) is a general clause about World Trade Organization (WTO) members' obligations with respect to trade secrets. Article 39(3) covers such obligations in the particular case where such trade secret data are submitted to governments or government agencies as a precondition for obtaining marketing approval.

Article 39(3) essentially imposes three obligations on governments:

1. To protect data on new chemical entities, the collection of which involved considerable effort, against unfair commercial use
2. To protect such data against disclosure, except where necessary to protect the public
3. To protect such data against disclosure, unless steps are taken to ensure that the data is protected against unfair commercial use

The first obligation is simply about protecting data submitted to regulatory agencies against unfair commercial use. No time limit is specified. Examples of unfair commercial use could include, for example, the government itself using the data for a commercial purpose or various kinds of dishonest commercial behavior. The World Intellectual Property Organization (WIPO)[3] provides a set of model provisions on protection against unfair competition.

The second and third obligations concern protecting data against disclosure to third parties, in the case of one or another exception. Although there is some lack of clarity, arising from the generality of the wording, about when disclosure would be justified by the exceptions (particularly in the third case), the essential point is that the obligation creates a presumption that the regulatory authority would not disclose data, without due reason, to a third party. Again, no time limit is specified. The purpose of avoiding disclosure is to avoid unfair commercial use. The third obligation implies, therefore, that disclosure is acceptable provided it can be ensured that disclosure will not lead to unfair commercial use.

Most observers regard what is referred to in TRIPS Article 39 as "data protection," dealing as it does with the protection of undisclosed information or trade secrets. Article 39(3) does not create *new* property rights, nor a right to prevent reliance on the test data submitted by an originator for the marketing approval of an equivalent product by a third party, except where unfair commercial practices are involved. The article is an articulation of widely accepted legal precepts regarding trade secrets and unfair competition, not an invitation to create a new intellectual property right for test data.

However, industry groups and some developed countries, for example, the United States and the European Union, have argued that Article 39(3) requires countries to create a regime of "data exclusivity," a form of time-limited intellectual property right. In the United States and countries in the European Union a data exclusivity regime for both medicines and agrochemicals was adopted prior to the TRIPS agreement (for example, in 1984 in the United States and in 1987 in the European Union, for medicines). For a period of five years from marketing approval of an originator product, no other company may seek regulatory approval in the United States of an equivalent product based on data submitted by the originator company without the latter's approval. During the period of exclusivity, regulators cannot use (rely on) the originator's data to approve a generic product, even if the product is demonstrated to be exactly equivalent in chemical composition and in its behavior within the body.

The European Union now provides more extensive exclusivity, up to 10 years, for medicines. Unlike TRIPS provisions for data protection, data exclusivity regimes often extend beyond new chemical entities. For instance, in the United States only chemical entities never previously approved are entitled to exclusivity for a five-year period, but new uses or indications of an already approved entity are also entitled to exclusivity for three years. In the European Union, exclusivity is provided to new medicinal products, not just new chemical entities. Details of the European Union and United States regimes are described in Sanjuan.[4]

In the United States, agrochemicals have been entitled to a ten-year exclusivity period; the period is five years for medicines. This difference exists because the act that introduced data exclusivity for medicines in 1984 (known as Hatch-Waxman) also introduced a provision allowing for patent extensions of up to five years to compensate for the loss of patent life in meeting regulatory requirements (principally the time lost compiling the test data required by the FDA). Thus the term of data exclusivity for medicines was reduced as a trade-off.

In addition, the United States provisions for agrochemicals allow for a further five years of exclusivity during which the originator data may be relied on to approve a generic product, provided compensation for the use of the data is paid to the originator.

In summary, a data exclusivity regime relates to how long the regulatory agency may be prevented from relying on originator's data to approve the products of potential generic competitors. Data exclusivity does not relate to the question of disclosure to third parties and trade secrets dealt with in TRIPS Article 39(3) (and 39(2)) in which no time limits are specified.

3. DATA EXCLUSIVITY AND PATENTS

If the patent period has expired, or there is no patent on a product, data exclusivity will act independently to delay the entry of any generic companies wishing to enter the market until the period of data exclusivity is over. It should be noted that in most cases the period of data exclusivity may have no material effect if it is within the patent period, because exclusivity is protected by the patent.

However, the data exclusivity right is a much stronger right than a patent because, unlike patent law, there are no exceptions or flexibilities that allow governments to tailor the law to national circumstances. For example, there is no ability for governments to provide the equivalent of a compulsory license, or data exclusivity may act as a barrier to compulsory licensing of a patent on the same product by preventing marketing authorization for a compulsory licensee. Data exclusivity is attractive to originator companies because unlike a patent, data exclusivity is automatic (rather like copyright). No fees are incurred for application or maintenance of the right, and there is more limited scope than exists in patent law for legal challenges, which are expensive to mount and to defend. For these reasons pharmaceutical companies are strong proponents of data exclusivity regimes. Whatever the benefits, which depend on exclusivity extending beyond the patent term, the costs to these companies are very low.

4. COSTS AND BENEFITS

The claimed benefits of data exclusivity relate, to a great extent, to the additional incentives offered to companies in the long and expensive process of pharmaceutical R&D. Data exclusivity gives companies an incentive to extend the original use of the product (for example, to a wider population, by age or geography, or in new indications for therapeutic use) where, for one reason or another, no patent protection is available. Data exclusivity provides an additional opportunity for originator companies to recoup their investments where marketing approval is given late in the patent life, so that the protection afforded extends beyond patent expiry. Experts argue that data exclusivity offers benefits to domestic innovators in developing countries, and, in particular, that it provides incentives for research to identify new uses for existing unpatented products and for originator companies to introduce products into developing countries, since, in effect, exclusivity would protect the companies from generic competition.

On the other hand, in developing countries where there is little or no innovative research capacity, the benefits of data exclusivity are likely to be limited. In those circumstances, data exclusivity would not promote R&D and the benefits to the companies themselves, and a potential addition to the R&D incentive, would be small because of the limited market potential in most developing countries. However, data exclusivity would allow additional periods of exclusivity for originator products, and it therefore would correspondingly delay the onset of generic competition. Specifically, exclusivity would preclude possible reductions in the cost of medicines in the developing country, keeping healthcare costs higher.

Data exclusivity is likely to have the largest effect in countries where, for historical or other reasons, there are many products with no current patent protection that may gain rights to exclusivity. For example, in many developing countries there are numerous medicines that are not patented (even if they *are* patented in developed countries). This is often the case in developing countries where TRIPS-based laws have only recently been introduced (for example, India only introduced TRIPS-compliant laws in 2005 on the expiry of its transitional period allowed under TRIPS). In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents. In that case, the introduction of data exclusivity laws may bring into exclusivity drugs that would otherwise be open to generic competition. The perceived absence of strong patent protection in India, even after the law was revised in 2005, and the presence of a large number of products without patent protection due to the absence of product patent protection before 2005, is a major reason why the international pharmaceutical industry lobbied very hard for a strong data exclusivity regime in India. By contrast, Indian companies focusing principally on generics argued for a weaker data protection regime.[5]

5. BILATERAL TRADE AGREEMENTS

Earlier drafts of the TRIPS agreement, which was in negotiation for nearly a decade before coming into force in 1995, contained, in addition to language closely following the final form of Article 39(3), text reflecting the U.S. five-year data exclusivity regime, which had been enacted in 1984 in the Hatch-Waxman Act. The North American Free Trade Agreement (NAFTA[6]), which was agreed in 1992, contained a close equivalent of Article 39(3) followed by a paragraph preventing the regulator from relying on the originator's data for a reasonable period, normally meaning not less than five years.

From the point of view of supporters of data exclusivity, the TRIPS agreement was, therefore, in this particular respect, something of a backward step. Although supporters of data exclusivity argued that exclusivity, taking account of the negotiating history, was what TRIPS Article 39(3) really meant, most observers have noted that the fact that a specific clause on data exclusivity along the lines of NAFTA was omitted from the final agreement indicated the opposite. If TRIPS had meant to sanction "data exclusivity," it would have done so explicitly, as does NAFTA.

The United States in particular has sought, in post-TRIPS negotiations, to insert the language of NAFTA on data exclusivity, or even stronger provisions, in negotiating bilateral free-trade agreements with developing countries. Countries that have reached such agreements include Bahrain, Jordan, Morocco, Chile, the Dominican Republic, and the countries of Central America. Negotiations are ongoing with Thailand, Ecuador, Peru, and Columbia.

Most United States bilateral treaties involve agreement to the five-year rule as it is followed in the United States. In other cases, such as the Central American Free Trade Agreement (CAFTA), approved in 2005, the five-year rule applies also to a product approved in another party to the agreement—that is, marketing approval in Country A deters generic entry in country B for a period of five years. If the originator seeks marketing approval in Country B within five years, there will be an additional five years of data protection in Country B from the time of obtaining marketing approval, providing a maximum exclusivity of up to 10 years. CAFTA also obliges parties to provide extensions to the patent term on the grounds of unreasonable delays in granting a patent (for example, five years from filing) or unreasonable delays in procuring marketing approval.

Developing countries need to consider the extent to which the demands for data exclusivity in bilateral trade agreements reflect the lobbying of the pharmaceutical industry in developed countries, particularly the United States, where there are close and legally institutionalized links between the industry and negotiators, in particular through the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15). This Committee evaluates successive free trade agreements as to whether or not they meet the objectives of U.S. intellectual property-based industries. The committee's objectives do not include consideration of what measures might be in the best interests of developing countries.

6. CONCLUSIONS

This chapter has sought to explain the meaning of data protection and data exclusivity in the context of pharmaceuticals and agrochemicals. The protection of commercially valuable data held by governments is a duty of government, formalized in the TRIPS agreement, essentially to protect such data against unfair commercial use. Data exclusivity, by contrast, is a time-bound form of intellectual property protection that seeks to allow companies to recoup the cost of investment in producing data required by the regulatory authority. The effect of data exclusivity is to prevent the entry of generic competitors, independent of the patent status of the product in question. The costs and benefits of data exclusivity depend on the particular economic circumstances of countries. In developing countries with little innovative capacity, the benefits may be less obvious than the costs in terms of reduced competition in the market for medicines or agrochemicals. These costs and benefits need to be considered in the context of bilateral trade agreements, particularly with the United States, where data exclusivity is likely to be part of the package of intellectual property measures governments are asked to accept. ■

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