Towards a Law on Data Exclusivity

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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. In most countries, innovative drugs are required to undergo lengthy examination procedures before receiving marketing approval, directed to ensure that they are effective and safe for public use. The information provided to the regulatory authority during the examination is the result of experiments and clinical trials spanning many years and costing significant amounts of money. The entire drug development process from discovery to marketing is said to take as long as fifteen years and cost, on average, $500 million in industrialized countries.

A generic version of the innovative drug, on the other hand, would need to undergo a considerably less exhaustive examination before the regulatory authorities. Currently, when manufacturers of generics apply for approval of their drug, they claim "bioequivalence" to the originator's product without conducting clinical trials by themselves. Permitting a generic applicant to use the information provided during the innovative drug's examination, instead of presenting independent clinical trials, would give the generic drug manufacturer a significant springboard to obtain fast and cheap marketing approval.

Many countries have established a complementary mechanism of data exclusivity provisions, which are aimed exactly at preventing such fast lane approaches. These provisions provide an exclusivity period of usually between five to ten years. The US was the first to enact such legislation. In 1984, it enacted the Hatch-Waxman Act, which provides a five-year data exclusivity for new molecular entities (NMEs). The Act provides for a period of exclusivity such that once an NME is approved, a generic version cannot be approved for five years. That generally is referred to as "data exclusivity." The Act also calls for a three-year data exclusivity period for supplements requiring clinical trials. Other countries have similar durations - 6 years in China, up to 10 years amongst European Union members, 5 years in Australia, 4 to 10 years in Japan, and 5 years in New Zealand. During this time applicants seeking marketing approval for generic drugs may not rely on information provided to regulatory authorities during examination of the innovative drug.

In some cases, however, particularly when patent protection is not available, data exclusivity may be the sole protection for the innovative drug manufacturer. It should be emphasized that data exclusivity protects only the information provided during examination of the innovative drug and does not, in any way, limit the generic applicant's right to provide information originating from any other source.

The core concept of data exclusivity became part of the 1994 multinational Agreement on Trade-Related (Aspects of) Intellectual Property Rights (TRIPS Agreement), in which Article 39(3) reads as follows:

"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."

Thus, if in respect of pharmaceutical or agricultural chemical products which utilize a 'new chemical entity' (NCE), the regulatory authority of a member country requires submission of 'undisclosed clinical and test data' for granting marketing approval it is under obligation to protect the data against 'unfair commercial use' and protect the data against 'disclosure'

Internationally, three distinct trends may be seen in the way countries apply this Article.

1) One set of countries denies that the article mandates data exclusivity application.

Countries such as Australia, Canada and New Zealand have 5 years only for NCEs.

In the United States, data exclusivity provisions consist of the following:

- ?5-year data exclusivity period is granted to the NCE.
- ?3-year data exclusivity period for any new indications.
- 6-month data exclusivity period for paediatric indications.

2) Another set of countries does not restrict data exclusivity to NCE. Notably, EU countries do not make such a distinction.

3) A third set of countries denies that the TRIPs mandate "data exclusivity" legislation per se. India is a member of this third group.

The Indian pharmaceutical industry is one of the most advanced among those of the developing countries. The ranking of the industry in the global market is fourth in volume (eight percent share in world market) and thirteenth in terms of value (1 percent share in the world market). The industry exports products worth rupees 141 billion to over 65 countries. The annual turnover is rupees 226 billion. Besides all the above, India has the largest number of US Food and Drug Administration (FDA) approved manufacturing facilities outside US. The number of Drug Master Files (DMFs) filed with the US FDA is twenty six per cent higher then Spain, Italy, China and Israel.

While multinational (MNC) pharma companies in the country are making a strong case for data exclusivity, the domestic sector has views ranging from supporting the MNC position to that of others like the Indian Pharmaceutical Alliance (IPA), which is against government conceding any demand for data exclusivity, including market exclusivity.

The IPA is concerned that granting this right would lead to ever greening of patents. This implies that if data exclusivity in the country is allowed for say, five years, and a patented drug is introduced in the 17th year of the 20-year patent life, it could effectively extend the patent to 17 plus five equaling 22 years. This has prompted many interested parties to advocate that Data exclusivity rights, if promulgated, must be done subject to the condition that they run concurrently with the term of the patent.

Data exclusivity protection is often charged of being a superfluous form of protection and many arguments are advanced against data exclusivity, that it undermines genuine innovation as it encourages originator companies to focus their activities in changes in the product rather than focus on developing new innovative and beneficial product. The patents are increasingly being granted for new uses, indications, dosages and change in formulations. Data exclusivity period is granted without originator having to demonstrate any of the basic principles of novelty or inventiveness.

The Indian government has consistently taken the line that Article 39(3) does not oblige member states to introduce data exclusivity legislation in the country. The Government of India has constituted a high-level inter-ministerial committee to consider steps that are to be taken in conformity with the mandate of Article 39.3. However the nature of the obligations itself remain nebulous.

There are several burning questions that come to the forefront with regard to the issue of data exclusivity one of which is whether Article 39.3 of the TRIPs agreement mandate 'data exclusivity' or mere 'data protection'?

Although TRIPs refrains from defining the practices that would constitute 'unfair commercial use', thus allowing the several interpretations to creep in. The term 'unfair competition' has been defined in article 10BIS of Paris Convention but that does not aid in identifying the practices that would fall within the gamut of the 'unfair commercial use. Reference may also be made here of the WIPO

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model provision on protection against unfair competition (1996). Article 6 of the model provisions lays down the acts that would amount to unfair competition in respect of Secret Information. It reads as follows:

Applying it to pharmaceutical products utilizing new chemical entity, when the undisclosed data is submitted to the Drug Regulatory authority, it becomes the trustee of that data and the originator remains the person lawfully in control of the data or 'the rightful holder'. The authority thus not being the 'rightful holder' cannot use the data for any purpose other than for which it is submitted without the consent of the 'rightful holder'. The sole purpose for which the data is submitted by the originator is to enable the authority to evaluate the data for ascertaining the safety and efficacy of the drug before granting marketing approval. Therefore the regulatory authority should not be allowed to rely on that data without the consent of the originator for testing the safety and efficacy of the subsequent applications.

Further where considerable cost is incurred by the originator in order to earn reward for his investment, it would be unjust to deprive him of the legitimate and reasonable profits by allowing the other persons to avoid the cost of undertaking the similar procedure and rolling out the same drug at much lower price. Thus compelling a person to suffer loss would tantamount to acting in a manner contrary to honest commercial practices.

Under Special 301 of the U.S. Trade Act of 1974 India has been put on the 'Priority Watch List' of USTR (United States Trade Representative) for failing to provide an adequate level of protection or enforcement and market access for persons relying on intellectual property protection. The absence of 'data exclusivity' legislation inter alia forms the reason for India's inclusion in the list. Special 301' is a part of the US Trade Law that requires the USTR to identify countries that deny adequate protection for Intellectual Property Rights or that deny fair equitable market access for the US persons who rely on IP protection. 'Priority Watch List' is the countries or trading partners that have very serious problems in terms of scope and/or impact on US commerce requiring the focus of increased bilateral attention on the problem areas.

In the light of the above development, it seems likely that India will soon put together a law on data-exclusivity. ◆

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