

Data Exclusivity Provisions in India: Impact on Public Health

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One of the contentious issues of intellectual property rights is related to data exclusivity. Data exclusivity relates to protection of data generated by the innovator from disclosure to third party in order to prevent 'unfair commercial use'. The debate has serious implications for pharmaceutical companies where substantial amount of data is generated during discovery and development of a new drug. The data is in the form of clinical trials data, reports of pharmacological and toxicological profile of drug, its use and indications etc. This data which is submitted to regulatory authorities of concerned countries for marketing approval is generally referred by regulatory authorities for approval of generic medicine. Multinational companies based in developed countries argue that this data generated during drug discovery and development needs to be protected in the form of 'data exclusivity' which is mandated under Article 39.3 of TRIPS Agreement. Developing countries state that 'data exclusivity' is not mandatory according to TRIPS Agreement. So far India has not provided for 'data exclusivity'. India's position on 'data exclusivity' with respect to other countries of the world is subject to recommendations and suggestions of the committee set up by the Government of India to look into issue of 'data exclusivity' which is discussed in this article.

Keywords: Data Exclusivity, TRIPS Agreement, Article 39.3 of TRIPS

Data exclusivity refers to the time period after approval of a new drug before a competitor can rely on data submitted in the original approval process for its own filing to the FDA.¹ Data exclusivity is a protection instrument for pharmaceutical companies' independent of any other form of intellectual property right (IPR). Unlike market exclusivity, it does not directly prevent from launching a drug on the market, but prevents a drug agency from approving an application of subsequent applicants (generic companies) based on the data submitted by a first applicant (innovator company).² Data exclusivity is currently the most debatable issue of pharmaceutical

intellectual property. Data exclusivity is becoming an additional form of IP protection for research based pharmaceutical companies. Companies involved in research and development (R&D) spend a considerable amount of time and money on the discovery of new products. It is estimated that around \$897USD are required for the development of a new molecule and major share of research and development expenditure is on generation of pre-clinical and clinical trial data for approval of new drug.³ The data thus generated is submitted to Drug Regulatory Authorities as a pre-requisite for marketing approval of the (NCE). This entire process may take about 12-13 years. Hence effective patent life is about 7-8 years or even less. The research data or test data which is generated during R&D process of new drug is proprietary to innovator.

Patents and Data Exclusivity

While data exclusivity and patents are the two most critical and, hence, relevant IPR for the pharmaceutical industry, they are distinct forms of protection; protection of one right is neither dependent on the other nor linked to the other in any intrinsic way and any linkage between the two contravenes TRIPS.⁴ In view of Pugatch⁵, 'the

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underlying logic of data exclusivity suggests that it is an expression of trade secrets and, as such, should be independent of patents'. The logic that data exclusivity is an expression of trade secret is not plausible as data exclusivity is submitted to the regulatory authorities for approval to market a product whereas underlying concept behind trade secret is that information regarding invention or discovery is not known to any other person than the innovator. Hence, it is important to note that patents and data exclusivity are independent of each other.

Article 39.3 of TRIPS Agreement

Article 39.3 of TRIPS reads as 'Members when requiring, as a condition of approving marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, 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.'⁶ Article 39.3 aims to protect and safeguard pharmaceutical registration test data which is submitted to regulatory authorities for marketing approval of new medicine. But ambiguous nature of Article 39.3 of TRIPS Agreement has created confusion with reference to the interpretation of Article 39.3 in the context of data exclusivity or Data protection. Correa⁷ has identified five points with reference to Article 39.3 of TRIPS agreement. In his analysis Correa has stated that the inclusion of test data in the TRIPS Agreement as a category of 'intellectual property' does not determine the nature of the protection conferred. According to Correa, the Article 39.3 conditions for protection are:

Data Necessary for Marketing Approval

The first sentence of Article 39.3 of TRIPS states 'Members, when requiring, as a condition of approving the marketing of...' means the obligation of data protection arises only when the regulatory authorities of member countries require submission of test data for market approval of new drug molecule or new chemical entity. Data submitted voluntarily or in excess by the innovator does not fall under Article 39.3.

Protected Data

Article 39.3 protects the written data which details the results of safety and efficacy testing of drugs and

agrochemicals which pertain to human, animals and plant health. These 'other' data may include manufacturing, conservation and packaging methods and conditions but to the extent that submission of this information is necessary for marketing approval of new drug.

Undisclosed Data

To qualify for protection under Article 39.3, the pertinent information must be 'undisclosed'. The information which is in public domain does not fall under Article 39.3 of TRIPS. While a substantial part of the information on tests relating to safety and efficacy of approved drugs becomes publicly available – because the information is published in scientific journals, or made public by the health authority.

New Chemical Entities

The data submitted to drug regulatory authorities must correspond to a new chemical entity to be eligible for protection under Article 39.3 of TRIPS Agreement. The Agreement does not define the term 'new'. Article 39.3 does not clarify either whether newness should be absolute (universal) or relative (local), that is, whether 'new' would mean the first application in the world or in the Member country where it was filed.

Considerable Effort Investment

The text is vague about the type of effort involved (technical, economic?) and also with respect to its magnitude (when would it be deemed 'considerable'?).

Data Exclusivity for Developing Countries

Dhar and Gopakumar⁸ argue that protection of data against unfair commercial use does not prevent the government or its agencies from relying on the originator's data to provide the subsequent marketing approval. Such reliance on the data by government or its agencies cannot be termed as commercial use, let alone it being unfair commercial use because purpose of such reliance is in the public interest to ensure access to safe and quality medicines. They also argue that introduction of data exclusivity could encourage the 'evergreening' of patents. Developed countries like the US and the EU insist that providing 'data exclusivity' is mandatory according to TRIPS requirements. Data exclusivity implies that the data submitted to the authority for obtaining market authorization for a new product or compound, should

not be used, or, relied upon any other party or third parties, for a limited period.⁹ In a position paper released by European Generic Association in July 2000¹⁰, it stated 'Clearly, no parts of Article 39, including Article 39.3, create a 'property' in information nor create 'exclusive rights' of any kind, as is the case with EU and US data exclusivity laws.' What Article 39.3 requires is that the data submitted is either protected against disclosure or protected against 'unfair commercial use'. On the other hand developing countries opposed the provisions of data exclusivity as it would enforce additional requirements, which are outside the purview of TRIPS Agreement or what is often referred to as TRIPS plus requirement. Instead, the provisions of TRIPS Agreement allow the member countries enough flexibility to enact and enforce appropriate laws for protecting test data. In a significant development, The Doha Declaration on TRIPS Agreement and Public Health¹¹ affirmed that 'TRIPS should be interpreted and implemented in a manner supportive of WTO members right to protect public health and, in particular, to promote access to medicines for all'.¹² Clift¹³ has stated that the provisions of data exclusivity are of little benefit to countries where there is little or no innovative research. In these countries data exclusivity would not promote R&D or any other benefits to the companies. Any potential addition to the R&D incentive would be small because of the limited market potential in most developing countries. On the other hand, Grabowski¹⁴ contests that without a data exclusivity period, there would be little incentive to invest in developing and marketing new product candidates with few remaining years of patent protection or with uncertain forms of protection. As pharmaceutical firms do have some years of patent protection after marketing approval, it is possible to recover the cost of development of drugs. Karin Timmermans¹⁵ of World Health Organization (WHO) has stated that data exclusivity—the granting of exclusive rights to commercial companies over clinical and preclinical trial data—could jeopardize efforts to create generic versions of life-saving medicines and harm public health. It is thus evident that the issue of data exclusivity has created much debate and the world is divided with respect to granting of data exclusivity. Developed countries are of the opinion that granting data exclusivity is within the ambit of Article 39.3 of TRIPS Agreement whereas developing countries feel

that Article 39.3 does not mandate granting of data exclusivity but insist on protecting data 'against unfair commercial use'.

Data Exclusivity Laws in Some Countries

United States

In 1984, the US became the first country to enact data exclusivity legislation. Under the Hatch-Waxman Act, applications for approval of new drugs receive 5 years of data exclusivity. Applications for the approval of new indications for an existing drug receive 3 years of data exclusivity.¹⁶

New Zealand

In New Zealand period for data exclusivity is for 5 years. New Zealand does not provide data exclusivity for new uses or formulations of old active ingredients.¹⁷

Japan

A formal data exclusivity regime is not in place in Japan. Instead Japan has a system of 're-examination' system under Article 14-4 of the Pharmaceutical Affairs Law which is similar to data exclusivity.¹⁸ In Japan, the system of 're-examination' grants exclusivity for new drugs for 8 years, 4-6 years for new indication or routes of drug and 10 years for orphan drugs.¹⁹

China

Under Article 35 of the Implementing Regulations of the Drug Administration Law of 4 August 2002, China provides 6 years of data exclusivity as from the date of marketing approval.²⁰

Australia

Australia provides for 5 years data exclusivity for NCE only.²¹

European Union

In the EU, Directive 65/65 provides a period of data protection of either 6 or 10 years depending on the Member State at issue. The larger Member States provide 10 years, while the smaller provide only 6 years. However, for products which are approved through the centralized procedure, Regulation 2309/93 provides a 10 year period of data protection.²² The 6 to 10 year range for national registrations reflects differences between the national regulatory regimes of the EU members. The EU is considering harmonizing protection to 10 years for all

national registrations under 8+2+1 formula, which has 8 years of data exclusivity with 2 years of marketing exclusivity that can be further extended by an additional one year, if during the first 8 years of those ten years, the innovator obtains authorization for one or more therapeutic indication.²³

Brazil

Brazil grants exclusivity for five years.²⁴

Mexico

Data exclusivity rights are mentioned in Articles 82 and 86 bis of the Mexican Industrial Property Law (MIPL) and in Numeral 167 bis of the Health Supplies Regulations (HSR).²⁵ Mexico provides for 5 years of data exclusivity.²⁶

Data Exclusivity and Benefits to Innovator: An Example

In certain exceptional cases it is observed that 'data exclusivity' helps innovator companies to recover investments made on discovering and developing a new drug. An example is Aventis's innovative drug Leflunomide (Arava[®]) for Rheumatoid Arthritis, which took 17 years from discovery to commercialization. In the absence of data exclusivity, the investment cost would have to be recovered in 3 years.²⁷ Long timelag - from development to commercialization - may not be the case with every medicine or company. Hence, it would not be prudent to say that data exclusivity provisions are required.

Data Exclusivity in India

It is argued that provisions of data exclusivity would jeopardize availability of generic medicines to millions of poor in developing countries. According to Gopakumar Nair²⁸ introduction of data exclusivity in pharma field, would adversely affect at least partially, the hitherto proven capabilities of Indian generic industry. Consequently, there will undoubtedly be a short term monopoly and adverse pricing scenario impacting public health interests. At present, India does not recognize data exclusivity provisions. It is said that data exclusivity provisions, if added to the Indian Drugs and Cosmetic Act, will prevent India's drug regulatory agency from referencing or otherwise relying on registration data previously filed by innovator drug companies in order to gain regulatory approval for therapeutically equivalent generic versions.²⁹ On the other hand, Organization of Pharmaceutical Producers of India

(OPPI) had suggested for 5 years data protection provision from the date of marketing approval in India.³⁰ In order to assist the Department of Chemicals and Petrochemicals (Ministry of Chemicals and Fertilizers), Government of India constituted an Inter-Ministerial Consultative Committee on 19 February 2004 to study data protection provisions as outlined in Article 39.3 of TRIPS. The committee was entrusted with the task to submit its recommendations related to data protection provisions in India. The committee headed by Mrs Satwant Reddy, Secretary to Government of India had looked into the matter of granting data protection for pharmaceutical products. After deliberations and consultations with several stakeholders such as representatives of concerned departments and experts in the field, various groups/ delegations from industry, non-government bodies and other interested persons the committee has recommended for 5 years of data protection in India for pharmaceutical products.³¹ The Committee has also suggested for several safeguards with respect to data protection for pharmaceutical products. One of the noteworthy exemptions is related to drugs used for life threatening diseases such as HIV/AIDS. The exemption states, Drugs for life threatening diseases like HIV/AIDS may be exempted from the provisions of fixed period data protection. The Committee has also suggested for 'transitional period' for upgradation of physical infrastructure and technical skills with respect to providing data protection but the duration of the period is not stated.

Conclusion

The issue of data exclusivity is quite debatable as several issues are attached to it. These issues are concerned with availability of generic medicines especially in developing countries particularly those having high population of patients with HIV/AIDS. The debate revolves around the interpretation of Article 39.3 of TRIPS Agreement and whether the said article obliges for data exclusivity or not. Developed countries like the US and the EU try to enforce provisions of data exclusivity in the form of Free Trade Agreements with developing countries. Doha Declaration on TRIPS and Public Health has ascertained the rights of member countries to enact legislations that help them to protect public health. Developing countries need to maximize benefits of this flexibility accorded to them and put patients rights of access to economical healthcare ahead of economic rights of patents. India is now regarded as a

global supplier of quality generic medicines. Thus India must take a more liberal view of data exclusivity provisions and ensure that flexibilities in TRIPS Agreement are utilized fully.

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