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DATA EXCLUSIVITY AND INDIAN LAW*

INTRODUCTION

The concept of protecting undisclosed data having high commercial value has gained momentum to be protected as exclusive data or information under the TRIPS agreement in recent times. Data Exclusivity is a transitional concept of protection of exclusive test data in the form of publicly undisclosed information which is in between the protection of the data in the form of trade secrets based on the principles of equity and good faith and the domain of patent protection which requires invention to be new, having an inventive step and capable of industrial application. Thus while, every new invention is protected by patent, the need arises to evaluate the situation in developing countries where a generic drug manufacturer may develop drug at a cheaper prices by proving its bioequivalence with the drug of an innovator company[1]. Considering the fact that various interest groups are seeking amendments in Indian law to introduce data exclusivity provisions, the issue is a crucial one. Since India is a signatory to World Trade Organisation, there is a compulsion on India to incorporate data exclusivity in its national legislation in order to comply with the Trade- Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

WHAT IS DATA EXCLUSIVITY?

Data Exclusivity (DE) or exclusivity of registration data is the period of non-reliance and non-disclosure that is provided to new chemical entities, pharmaceutical compositions, and agrochemical registration data or *test data*. It is for a limited period of time when the drug regulatory authorities do not allow the test data of the originator to be used to register the generic version[2]. Data exclusivity provides the originator with rights to preclude third parties from relying on the data to obtain marketing approval for a specific period of time. However, it does not prevent third parties from generating their own data. Generic manufacturers can also apply for marketing approval provided that they conduct their own tests to prove the efficacy and safety of their product.

DATA EXCLUSIVITY AS A SEPARATE INTELLECTUAL PROPERTY RIGHT

Data exclusivity is often considered to be an extension of the rights under a patent. However, it is important to note the distinction between the two rights, as data exclusivity

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[1] Jaya Bhatnagar and Vidisha Garg, *India: Data Exclusivity*, available at http://www.mondaq.com/india/x/79418/Information+Security+Risk+Management/Data+Exclusivity, accessed on 14-08-2015.

[2] Praveen Dalal, *Data Exclusivity: An Indian Perspective*, available at http://www.ipfrontline.com/, accessed on 23-08-2015.

qualifies as an independent intellectual property right. Patents and data exclusivities are awarded independently. Unlike a patent, which gives the holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product, the protection that governments must accord proprietary test data does not prevent any manufacturer from running its own tests and submitting the results to the regulatory authorities. Data exclusivity also differs from a patent in that it is not a right that the pioneer firm can invoke directly against a generic firm. Data exclusivity merely protects the data given to the agency in order to approve the product, unlike a patent, which protects the product itself. Thus, data exclusivity and patents are distinct forms of protection – the protection of one right is neither dependent nor linked to the other in any intrinsic way[3].

THE ADVANTAGES OF DATA EXCLUSIVITY

The purpose of data exclusivity is to ensure that the initial registrant of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers contend that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant's approval and sell the same or similar drug at a lower price[4]. One argument for data exclusivity laws is that pharmaceutical manufacturers will have a greater incentive to develop drugs for diseases that are considerably more prevalent in developing countries.

DATA EXCLUSIVITY UNDER TRIPS

The controversy surrounding data exclusivity has in large measure been related to the different interpretations given to the relevant provisions of TRIPS. Section 7 of TRIPS is entitled Protection of Undisclosed Information, and article 39 therein talks about data exclusivity. TRIPS introduced the first international standard on the subject. Article 39(1) talks about protecting member states against unfair competition and article 39(2) states that natural and legal persons have the possibility of preventing information lawfully within their control from being disclosed to others without their consent in a manner contrary to honest commercial practices. Article 39(3) is the provision directly concerning data exclusivity and reads as follows: "Members, when requiring, as a condition of approving the marketing of a pharmaceutical or of agricultural or 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 when necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use"[5].

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]Animesh Sharma, *Data Exclusivity With Regard To Clinical Data*, available at http://www.ijlt.in/archive/volume3/Sharma%20-%20Data%20Exclusivity%20with%20regard%20to%20Clinical%20Data%20%5b3%20Indian%20J.%20L.%20&%20Tech.%2082%5d.pdf , accessed on 11-08-2015.

[4] Jeremy Clark Ogusky, *Data Exclusivity Regulations in India*, available at http://www.bilaterals.org/, accessed on 01-09-2015.

[5] Dr. S. R. Myneni, *Law of Intellectual Property*, 5th Ed, Asia Law House, Hyderabad, p. 611.

3. To protect such data against disclosure, unless steps are taken to ensure that the data is protected against unfair commercial use.

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.

AN ANALYSIS OF ARTICLE 39(3)

Data Necessary for Marketing Approval

Article 39(3) makes it clear that the first condition for its application is that a member state stipulates data submission as a condition for obtaining marketing approval for pharmaceuticals or agrochemical products. Thus, the obligation to protect test data only arises in the member states where national regulations require the submission of such data. If a member state opts not to require this data, article 39(3) will naturally not apply.

Undisclosed Data

To qualify for protection under article 39(3), the pertinent information must be undisclosed. This means that information that is already public does not fall within its scope. Any requirement for the submission of published or otherwise disclosed information to national regulators shall not generate any private right limiting the use of such information by the government or third parties, since the information is already available to the public.

New Chemical Entities

Another important condition for the application of article 39(3) is that the data must refer to a 'new chemical entity'. TRIPS, however, does not define the term 'new'. The word "new" thus refers to the status of a chemical entity within the marketing approval system, not with respect to the state of the art or novelty in the patent sense. Only data related to products with chemical entities that were not publicly known before the submission of the data would be eligible for protection.

Considerable Effort

Article 39(3) mandates protection when the process of obtaining the data involved a "considerable effort". However, the article is vague about the type of effort involved or the magnitude of it that would be deemed considerable. The term may be interpreted to mean the concentrated or special activities, physical or mental, that are extensive in scope or duration. The national regulatory authorities may call for the applicant to prove that the information for which protection is sought is the outcome of considerable effort.

Unfair Commercial Use

The non-disclosure obligation under article 39 requires that the test data not be disclosed unless steps are taken to ensure that the data is protected against "unfair commercial use". However, since there is no absolute or universal rule to determine when certain practices should be deemed unfair, it is likely that different countries will judge the fairness of certain situations differently, depending on their values and competitive advantages. Article 39(3) could have certainly adopted a stance prescribing reliance on clinical data and specifying a

time period for protection. The U.S. had in fact made such a proposal in the TRIPS negotiations, but the proposal was not incorporated into the final text of TRIPS. Article 39(3) can be clearly distinguished from the more explicit provision in the earlier NAFTA agreement, in which disclosure and reliance of clinical data is specifically proscribed, and a minimum exclusivity period of five years is stated. One of the most important rules of statutory interpretation is that what is not explicitly included is thereby excluded (*expressio unis est exclusio alterius)*. Keeping this rule in mind, the drafters of TRIPS certainly had the opportunity to impose more specific requirements of data exclusivity, but chose not to do so[6].

Summary

In sum, article 39(3) clearly requires some form of protection for test data, but does not require member states to grant exclusive rights. Its main purpose is not to prevent the use of such data by governments, but to prevent unfair use by competitors. The language, context, principles of statutory interpretation and purpose of the article do not support an interpretation that the required protection can be implemented only on the basis of exclusivity rights. This interpretation is confirmed by the history of the negotiation of TRIPS. The United Nations Conference on Trade and Development (UNCTAD) has also stated that "authorities are not prevented [under article 39(3)]… from using knowledge and data, for instance, to assess subsequent applications by third parties for the registration of similar products. The correct interpretation that must be given to article 39 is quite clear and unambiguous at this point. TRIPS does not make granting of data exclusivity rights mandatory, but gives the member states the freedom to choose the nature and extent of protection they want to offer[7].

GLOBAL SCENARIO

A review of the national laws relating to the protection of registration data in the major WTO member states reveals that most of these countries have recognized and appreciated the role of data exclusivity. Although there is no uniform standard that is followed by the countries while enacting and implementing the laws related to data exclusivity, the period for which the originator can enjoy the exclusivity after the marketing approval is generally between 5 to 10 years. In 1984 the US became the first country to enact data exclusivity legislation. The Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act", actually relaxed the level of protection afforded to testing data in the US. 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. Many developed countries in the EU, Australia, New Zealand and the Andean Group countries have a system for providing data protection whereby the results of the invention for which a patent has been granted would not be available to public and R&D agencies for a period of five years. In some countries a provision has been introduced to extend the term of a patent by a maximum of five years if the market approval authority takes unduly long time to give the approval. However, there is a group of countries which deny the TRIPS mandate, and India is one amongst these countries[8].

INDIAN SCENARIO

The Indian law has no statutory protection for the data that is submitted to regulatory authorities for testing for approval of any manner of products. Although India is a signatory to the TRIPS Agreement, no new provisions of law have been introduced to protect test data. The existing legal provisions are inadequate and compensation-focused. The requirements of data

[6] Prof. A. Chandrasekaran, *Intellectual Property Law*, 2nd Ed, C. Sitaraman & Co.Pvt.Ltd, p. 413.

[7] Supra note 3.

[8] *Supra note 1.*

protection and exclusivity obligations are *proactive* in nature, i.e. focused on preventive mechanisms. There is no legislation corresponding to the "Hatch Waxman Act".

Relevant Indian Laws

The Official Secrets Act, 1923, is a legislation binding public servants from disclosing or using any confidential information in an unauthorized manner, so as to affect the security, sovereignty and integrity of the country. However, the scope of this legislation is very limited as it does not ensure data protection, but is limited to protection against disclosure of the data which is only one of the elements of data protection. There is no provision to address protection against unfair competition caused by third party to unlawfully rely on the originator's proprietary data. Although, this statute acurrantly grants an aggrieved party the right to claim damages in a civil suit and receive civil remedies for stolen test data submitted to the regulatory authorities, it does not proactively ensure protection against unfair commercial use of the data. Thus, the Official Secrets Act, 1923 does not ensure data protection pursuant to TRIPS Article 39(3) standards.

Trade secret protection is a common law remedy to prevent the disclosure of information, but it is a private remedy that is untested against regulatory authorities in India. Furthermore, even if such a tool may be employed to restrain the misuse of test data, it again does not prevent the regulatory authorities from relying on it themselves for the purpose of granting approvals to second registrants.

The Insecticides Act, 1968 is the most relevant legislation in India, from the point of view of crop-protection chemicals. Under section 5 of the Act a registration committee is established which is empowered to scrutinize the formulae of insecticides and verify claims relating to its efficacy and safety for human beings and animals, and as such is the regulatory body that sets rules, procedures and controls the testing process. Under this Act, the registration committee requires data relating to chemistry, bio-efficacy, toxicity, packaging and labeling.

The Indian Patents Act, 1970 is another important legislation. However, the Patent Act is applicable only to patentable inventions and does not protect new use of a known substance or formulations by combinations. Further patent protection extends only to the invention but not to the data generated by the originator.

In a nut shell there is no specific law for the protection of undisclosed information in India and a third line of protection, beyond patent protection and confidentiality is the need of the hour[9].

ARGUMENTS IN FAVOUR OF DATA EXCLUSIVITY IN INDIA

Drug developers contend that they cannot introduce new drugs in the market without data exclusivity laws to protect their interests. Proponents of data exclusivity refer to the success of the Hatch-Waxman Act in the USA, which has so far resulted in dramatic benefits for consumers. Hence, introduction of data exclusivity would end up benefiting the consumers in a big way. Furthermore, one of the most significant problems for developing countries like India is the formulation of products directed at diseases or conditions that are not normally found in developed countries. Drugs catering to the needs in India will only be developed if

[9] Alfred Adebare, *Data Exclusivity: The Implications for India*, available at http://www.articlealley.com/, accessed on 11-08-2015..

data exclusivity laws exist in India[10]. It is only when sufficient protection is accorded to drug manufacturers that they will come to India and spend their resources and time on developing drugs for diseases endemic to India. Another argument is that granting a reasonable data exclusivity period will make India an attractive destination for research and development work.

WHY SAY NO TO DATA EXCLUSIVITY?

There are various reasons why data exclusivity rights should not be granted in India.

Firstly, there seems to be no clear economic justification as to why data exclusivity should be granted to firms that already avail a patent protection term of twenty years globally for their products.

Secondly, India is a major supplier of the world's generic medicines and exports two-thirds of its generic drugs to developing countries. If data exclusivity rights are granted, this respectable status that India enjoys in the eyes of the developing world would certainly be lost and new data exclusivity provisions may have a disastrous affect on health conditions worldwide.

Thirdly, the research-based pharmaceutical industry claims that data exclusivity provides incentives for companies to generate the necessary data, since without marketing exclusivity, brand-name companies would not want to conduct expensive preclinical tests and clinical trials.

Fourthly, there is a possibility that data exclusivity would actually provide incentives to delay the entry of new products for MNCs would prefer to keep prices high in developed markets by delaying their entry into the developing world at lower prices.

Fifthly, data exclusivity would render redundant the use of a compulsory licence, a market exclusivity waiver on patents provided by TRIPS in the event of a health emergency.

Sixthly, in order to enter even small and marginally profitable markets, generic competitors would be required to duplicate expensive and time-consuming clinical trials in order to establish safety, quality, and efficacy. Another concern is that animals and other research subjects are dangerously exploited if the second applicant has to replicate studies already performed by the pioneer company.

Finally, If the data exclusivity law is enacted as mandatory for all 'new drugs' as presently defined under the Drugs & Cosmetics Act (DCA), drug companies will be able to enjoy de facto monopoly rights over trivial changes that may not even be patentable under patent laws for lack of inventiveness, but still qualify as new drug under the DCA. This can arguably constitute protection to an unreasonable extent for pioneer pharmaceutical companies[11].

INDIA'S STAND ON DATA EXCLUSIVITY

There has been tremendous pressure on India from the countries like the United States and the European Union, in the form of trade sanctions on the issue of data exclusivity, unsurprisingly because most of the pharmaceutical giants belong to these countries. According to them, after the expiry of the first transition period in 2005, India has an obligation to incorporate data exclusivity in its domestic legislation[12]. While the originators make a strong

[10] AIDS Drugs Threatened, N.Y. TIMES, Mar. 5, 2005, available at http://www.nytimes.com/, accessed on 28-08-2015.

[11] *Supra note 3.*

[12] Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*, available at https://www.who.int/, accessed on 26-08-2015.

case for data exclusivity, the domestic sector has very mixed views ranging from supporting the MNC position to one which is against the government conceding the demand for data exclusivity, including market exclusivity. Generic manufacturers in the country are gripped with the fear that granting this right would lead to ever greening of patents. For example if data exclusivity in the country is allowed for, five years, and a patented drug is introduced in the 19th year of the 20-year life of a patent, it could effectively extend the patent protection to 19 plus 5 equaling 24 years. This has triggered many companies to advocate that data exclusivity must run concurrently with the term of the patent.

The advocates for data exclusivity put forward the following arguments:

- Protection should be in the form of exclusivity for a period of atleast 5 years from the date of market authorization.
- Since, data exclusivity is not related to patent protection, therefore it should be provided irrespective of the life of a patent.
- Since a lot of money is spent in generating the data and information, it is not fair that other companies should be allowed to use that data, without going through the painful process of generating that information, for developing generic versions of the drugs[13].

The Indian government has consistently taken the stand that Article 39(3) does not oblige member states to introduce data exclusivity legislation in the country. In fact, the TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity. Article 39(3) of TRIPS says that WTO members should protect *"undisclosed information and 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". Data protection against unfair commercial misuse as mentioned in TRIPS is totally different from data exclusivity. The use of data by the Drug Controller is a legitimate, non-commercial use and is TRIPS compliant. However, succumbing to the mounting pressure from the United States and EU, on 10th February, 2004, the Department of Chemicals and Petrochemicals (DCPC), Ministry of Chemicals and Fertilizers, Government of India constituted an Inter-ministerial Committee as a Consultative group to suggest the steps to be taken by the Government in the context of Article 39(3) of the TRIPs Agreement as well as to determine whether data exclusivity to agrochemicals, traditional medicines and pharmaceuticals can be covered under the existing legal framework or if there was a need to have a new legislation in this regard.

SATWANT REDDY REPORT ON DATA PROTECTION PROVISIONS UNDER ARTICLE 39(3) OF THE TRIPS AGREEMENT

After considerable deliberations, on 31st May 2007, the Satwant Reddy Committee presented its report on regulatory data protection under Article 39(3) of TRIPS. Its findings are that Article 39(3) does not require *"data exclusivity"* and that it may not be in India's national interest to grant *"data exclusivity"* to pharmaceutical drug data. It relied on paragraph 4 of the Doha Declaration to support this interpretation. The report noted that the flexibility in the provisions of TRIPS Agreement allowed a country to determine appropriate means of protecting test data. It was also realized that data requirements for registration of agro-chemicals differ considerably from those for pharmaceuticals.

The following recommendations were made by the Committee:

[13] Dr. S. R. Myneni, *Law of Intellectual Property*, 5th Ed, Asia Law House, Hyderabad, p. 612.

Agrochemicals And Traditional Medicines

The committee recommended data protection for a fixed period of three years and five years for agro-chemicals and traditional medicines respectively. In such fixed period, the Drug Regulatory Authority would not rely on the data submitted by the originator while granting marketing approval on second and subsequent applications.

Pharmaceuticals

The approach recommended for pharmaceuticals included a transitional period in which initial steps will be taken to implement the standards of minimum data protection. This period will can be followed by a post transition period which will afford a fixed period of data protection for a period of 5 years in which the Drug Regulatory Authority would not rely on the data submitted by the originator while granting second and subsequent marketing approval. The report also suggests certain safeguards in public interest to take care of adverse effects on public health or situations of health emergencies

Current Status

The report is under examination by the Government Authorities. So far, no formal communication has been made by any Government Authority in this regard. It is not clear whether the Government would adopt the suggestions of the Satwant Reddy report and implement provisions of data exclusivity. The Indian Pharmaceutical Industry has however had a negative approach to the report's recommendation and have been lobbying for a "*no data exclusivity*" policy[14].

CONCLUSION

As noted above, there are several reasons why data exclusivity laws should not be brought into India at this stage. The argument that data exclusivity must be provided in Indian law to be in compliance with TRIPS is fallacious. This interpretation of TRIPS finds support from most Indian pharmaceutical companies. Use of pioneer data by the authorities for granting approval to a subsequent product is not an unfair commercial use, but is a harmonious balance between public and private interests, and is also the exercise of a sovereign function of the licensing authority. The introduction of product patents in India has provided further protection to pioneer manufacturing companies, and the generic industry in India as well as the general health of ordinary citizens seems likely to suffer if data exclusivity were brought into effect in India[15]. Thus, it does not seem advisable to enact data exclusivity laws in India or to amend the DCA or the Insecticides Act to accommodate data exclusivity. This, however, does not mean that no change at all is required in data protection laws in India. While the Indian pharmaceutical sector is largely against data exclusivity, it does support a stronger system of data protection in India. There is no express provision in the DCA or the Rules obligating the Drugs Controller General of India to keep the data submitted to him under these laws in confidence. Thus, the DCA should be amended not to focus on data exclusivity but to introduce mandatory provisions for ensuring the safety and quality of drugs.

[14] *Supra note 1.*
[15] *Supra note 3.*