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Data Exclusivity under Trips - A Review and Analysis of Article-39(3) Of Trips

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Abstract: **This paper throws light on the growing concerns of Art-39(3) of Trips. Prior to Trade-Related Aspects of Intellectual Property Rights (TRIPS) there was no such law either at the national level or at the international level which contained any provision for the protection of test data or even any other related issue. Even Article 10bis of the Paris Convention cannot be interpreted to cover such a specific obligation. With the adoption of TRIPS such an obligation was looked forward to be made in favour of innovators whose innovation cost them a lot not only in terms of money but also in terms of time and labour of mind and body. It is in the view of this hard work that such a provision has been made in the TRIPS to protect their intellect and skill so that other competitors are not able to take undue advantage of their work.**

***Keywords*-Data Exclusivity, Intellectual Property Rights, Pharmaceutical, Agricultural, drug Regulatory Authority.**

I. INTRODUCTION OF DATA EXCLUSIVITY

Article 39.3 of TRIPS protects test data which an innovator or a firm creating an innovation has to **submit for obtaining market approval of pharmaceutical and agricultural chemical products** that **utilize new chemical entities against unfair commercial use with some limited exceptions**.[1] Initially, it was only US, who demanded this provision to be incorporated. Later on, by 1990, the US was joined by the EC and Switzerland. Gradually more and more countries agreed on this issue.

The pharmaceutical industry can be said to comprise of both pioneer as well as generic companies. The former are the ones which innovate and develop new drugs and market them whereas the latter are the ones which copy some or all aspects of those drugs and sell them thereby practicing unfair competition. Therefore, this becomes one of the contentious issues of Intellectual Property Rights which called for the need of *data exclusivity*.

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.[2] This in simple words means that data exclusivity tends to protect the data which is generated by an innovator from being disclosed to other competitors so that unfair commercial use of such data may be prevented. It refers to the time period which follows after a drug has been approved by the regulatory authority. During this time period no other pharmaceutical applicant can make use of the data associated with that drug for the purpose of getting approval for his own generic product. Such data is submitted to the regulatory authority with the prior original drug and therefore the concerned regulatory authority ensures that such data cannot be relied upon by any third party for getting approval for his own generic product. The drugs which are produced by both the previous and the successive applicant, if being effectively the same, can thus be approved or rejected by taking the same data into the account. Therefore, data exclusivity is provided for the originally produced pharmaceuticals. Thus, it is a protection instrument for the pharmaceutical companies irrespective of any other IP rights.

Now, when it comes to develop a new medicine a lot of research and development process is involved which is characterized by a high degree of scientific, regulatory and economic risk. Time, effort and money in enormous quantities are invested in the development of a single new medicine. To discover and develop a new medicine takes an average of 10-15 years in which about 50000-100000 compounds are searched and investigated and only one is approved and marketed. So one could imagine the level of hard work involved in the making of a single medicine. Presently, the cost of developing a new medicine is on average more than USD 1.2 billion. Moreover, these investments in R&D have no guarantee of a return with far more failures statistically than success in the laboratory. Thus the role of data exclusivity can be understood to be so important in the light of above few lines. Therefore the main purpose of data exclusivity is to prevent the successive pharmaceutical applicants to take free-ride on the initial registrant's approval for the purpose of selling the same or similar drug at a lower price.

II. DATA EXCLUSIVITY: AS A SEPERATE INTELLECTUAL PROPERTY RIGHT

To consider 'data exclusivity' as an extension of rights under patents would be somewhat appropriate to a certain extent. However, the two differ in the very fact that data exclusivity

[1] Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries*, 1st edition, OUP, New Delhi, 2001.

[2] *Data Exclusivity in International Trade Agreements: What Consequences For Access To Medicines?*, MSF technical brief, May 2004) <https://www.citizen.org/documents/DataExclusivityMay04.pdf> (Last accessed on 22-09-2014).

qualifies to be a separate Intellectual Property Right. As a result of which both are awarded separately. Both are different concepts protecting different subject matter. Moreover, both the concepts arise from different efforts and have different legal effects over different time periods.

Patents although being an important form of intellectual property are not necessarily sufficient in creating a favourable environment which is needed to support the development of medical advances. In this sense it can be said that data exclusivity cannot be considered as an extension of patents for it does not prevent the introduction of generic versions of the innovative drug during the data exclusivity period as long as the marketing approval of the generic version does not use or rely upon the innovator's test data.[3]

In a patent, as we know, the patent holder has the right to exclude others from making, using, selling, offering for sale, or importing the patented product whereas when it comes to data exclusivity although the government accords protection to the test data, it nowhere can prevent any other manufacturer or a second applicant to prepare its own test data and submit it to the concerned authority independently in relation to the same drug which the for which the original applicant had applied. Thus, it means that data exclusivity applies in pharmaceuticals allows a generic drug in an exceptional condition which is if the generic manufacturer is able to conduct his own preclinical and clinical trials and without relying on the original applicant's test data seeks the authorisation of the concerned regulatory authorities to enter their generic drug in the market.

Moreover, in patents, the patent may get expire even before the grant of market approval or market exclusivity. Suppose, there is a drug which has been granted patent under a valid patent act, then there might be chances when there can be a condition in which the time period of patent gets exhausted before the patentee can seek the approval of the market for his drug which would have been providing it market exclusivity. A drug protected by a valid patent protects that pioneer drug effectively in a manner as not to allow any generic version of it to enter the market irrespective of the existence of market exclusivity. The second entrant cannot be directly challenged by the pioneer applicant in data exclusivity as the former can bring his own test data to be submitted. Data exclusivity merely protects the data which is submitted to the concerned agency in order to approve the product, unlike a patent, which protects the product itself. Thus, data exclusivity and patents are two distinct forms of protection where the protection of one right is independent and not linked to the other in any intrinsic way.

Apart from patents, data exclusivity can also not be considered as an expression of trade secret for the reason that since data exclusivity is submitted to the regulatory authorities for approval of a product to be entered in to the market whereas on the other hand, a trade secret is an information in regard to an invention or discovery which is not to be disclosed to any other person than the innovator. Thus, there is a remarkable distinction between trade secret and data exclusivity.

III. DATA EXCLUSIVITY UNDER TRIPS: AN ANALYSIS OF ARTICLE 39(3)

Prior to Trade-Related Aspects of Intellectual Property Rights (TRIPS) there was no such law either at the national level or at the international level which contained any provision for the protection of test data or even any other related issue. Even Article 10*bis* of the Paris Convention cannot be interpreted to cover such a specific obligation. With the adoption of TRIPS such an obligation was looked forward to be made in favour of innovators whose innovation cost them a lot not only in terms of money but also in terms of time and labour of mind and body. The developed countries were persistently trying hard for the incorporation of the provision of data exclusivity during the TRIPS negotiations to be included in the TRIPS Agreement. Although, they did not succeed completely, but a partial success was endowed upon them with the mentioning of such a provision in section 7 of the TRIPS. It is to be noted that only a reference of this concept was mentioned in section 7 as TRIPS does not exclusively talk about "exclusivity'' as such.

There is only one article in the TRIPS Agreement which is article 39(3) which talks about exclusivity stating:

"*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*."[4]

From an analysis of the above mentioned provision it seems that the TRIPS have mandated the provision of data exclusivity to be followed by the member countries. Article 39(3) aims to protect and safeguard the test data required for the registration of a pharmaceutical drug, which is to be submitted to the concerned regulatory authorities for the grant of market approval of that pharmaceutical product. However, a question is often raised in regard to the interpretation of this Article 39(3) as to what does the article actually provide i.e. whether it provides for data protection or data exclusivity. In order to settle this confusion there has been laid down a general set of requirements or conditions which is to be fulfilled in order to grant protection to the test data. The conditions are:-

IV.DATA NECESSARY FOR MARKET APPROVAL

As the Article 39(3) itself states '*Members, when requiring, as a condition of approving the marketing of...'* means that

[3] *Data Exclusivity: Encouraging Development Of New Medicines:* International Federation Of Pharmaceutical Manufacturers And Associations (IFPMA), June 2011. <*http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity__En_Web.pdf*> (Last accessed on 23-09-2014).

[4] Article 39(3) of the TRIPS Agreement.

there exists an obligation to protect test data when such a data is submitted only when required by the concerned regulatory authorities. Where a test data is submitted voluntarily or in excess by the innovator, there exists no obligation on the part of the regulatory authorities to grant protection for that data. It is important to note that where the national regulation requires such a submission of data there only can laws of data exclusivity can apply. In the absence of such a requirement by the member states, no such obligation arises.

- **UNDISCLOSED DATA**

The data protected by Article 39(3) is in the form of a written data, detailing the results of the testing of safety and efficacy of drugs and new chemical entities for agricultural purposes which pertain to human, animals and plant health whereas the other data referred in the Article includes manufacturing, conservation and packaging methods and conditions, required for the submission of such kind of information which is necessary for obtaining market approval. Thus, in order to qualify under this section, the pertinent information must be disclosed. However, this also indicates that an information which is in the public domain i.e. accessible to the public does not fall within the ambit of the word 'undisclosed'. Since, such information is already there for the public to use, it cannot generate any private right limiting the use of such information by the government or any third party.[5]

- **NEW CHEMICAL ENTITIES**

In order to obtain data protection under this article the data, which is to be submitted to the drug regulatory authorities, must be pertaining to a new chemical entity. It is very important that the chemical entity must be new. Usually anything which is new is granted exclusivity and not something which already exists and people know about it. However, the TRIPS Agreement does not provide for the definition of 'new'. It does not make it clear that whether the term 'new' should be taken in the absolute sense i.e. applied for the first time in the world on a universal basis or whether it is to be taken in the relative sense i.e. applies in the member state where it is to be filed on a local basis.

Thus, the word 'new' 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.[6] Article 39(3) can be interpreted to mean the word 'new' as data related to products with chemical entities that were not publicly known before the submission of data.

However, the TRIPS does not exclusively define 'new chemical entity'. Therefore, in no way one interpretation can be held superior to others and thus member countries are allowed to adopt flexibility in implementation concerning this field.

V. UNFAIR COMMERCIAL USE

By far till now, this phrase has come out to be the most controversial part of the clause 3 of Article 39. There have been conducted a number of debates on this part on the subject of data exclusivity. The article requires that the test data should not be disclosed unless steps are taken to ensure that the data is protected against "*unfair commercial use"*. Here, the term to be understood is the meaning of 'unfair commercial use'. This term can be understood with respect to different other aspects and their relation with each other such as what if the government of a member state relies upon the test data, submitted by the original innovator without his prior permission, to grant approval to a generic manufacturer for his generic version. This act of the government is argued by few developed countries as to constitute an *unfair commercial use*. If the government of a member state place its reliance on the test data submitted by the original dossier to permit the generic versions it would give unfair benefit to the generic manufacturer at the cost of the efforts put by the original dossier thereby causing the innovator huge loss. The generic manufacturer would be in an advantageous position of taking free ride on the hard work and efforts put in by the original dossier. It would be easy for him to obtain approval for his generic drug as he will not be required to provide his own independent test data which involves a high investment and a lot of time and labour. However, apart from all this, there is a contrary opinion which says that as such there is no absolute or a universal rule to determine when certain practices can be deemed unfair. There is no fixed parameter to ascertain as to what kind of acts constitute as unfair commercial acts. Moreover, different countries would be holding different opinions and criterions to judge when an act is an unfair act which would depend on the values and competitive advantages. TRIPS remains silent as to define the phrase which concludes that nowhere in TRIPS, it has been mentioned that there is any obligation which is to be fulfilled by the creation of such a private right. Although U.S. tried to make such a proposal to clarify this doubt in the TRIPS Agreement but no such kind of provision was incorporated in the Agreement.

VI.DATA EXCLUSIVITY LAWS IN NORTH AMERICA AND THE EU

Laws on data exclusivity have not been into much discussion for the very reason that there are not many cases which have been dealt in foreign jurisdictions. However, the concept of data exclusivity has been discussed in few prominent cases of which one is the case of the U.S. Supreme Court, *Ruckelshaus* v. *Monsanto Co*.,[7] describing the practice which was extensively used by the government authorities where they used to rely on the data submitted by the first applicant in the U.S., for assessing the applications of the second-entrants. At the time when this case happened, under such a condition, although the applicant to compensation, he was not entitled to the exclusive use of the data.

Then there was another case which was held in Canada, *Bayer, Inc.* v. *Canada (Attorney General)*,[8] where the

[5] Data exclusivity with regard to clinical data, *The Indian Journal of Law and Technology Volume 3 2007*, <http://www1.nls.ac.in/ojs-2.2.3/index.php/IJLT/article/viewFile/20/18 > (Last accessed on 24-09-2014).

[6] *Ibid*.

[7] 467 U.S. 986 (1984).

[8] Bayer, Inc. v. Canada (Attorney Gen.), [1999] 243 N.R. 170 (Fed. Ct.) (Can.).

General Court of Appeal also gave a decision similar to that of the previous case, in favour of non-grant of exclusivity. The court decided that the act of the government authorities in relying upon the data of the original applicant for assessing and granting approval to the second applicants or the generic manufacturers is legitimate[9] and does not amount to any unfair practice. The Court held that if the authority does not actually examine and rely on that confidential or trade secret information on behalf of the generic manufacturer, there is no use of data, and hence the exclusivity provision is not applicable.[10]

Where TRIPS does not mandate the provision of data exclusivity to be granted by the member states, developed countries like US and the EU community argue in favour of the grant of protection under data exclusivity. They forward the reason based on justice and fairness behind such an argument. Where patent law fails to provide protection unless data exclusivity is granted, proponents of data exclusivity argue that competitors would face no barrier to producing and registering an exact copy of the product.[11] In the EU, Council Directive 65/65[12] provides a period of data protection of either six or ten years, depending on the member state concerned: the larger member states provide ten years, while the smaller provide only six years. However, for products that are approved through the centralised procedure, Regulation 2309/93[13] provides a ten-year period of data protection. During this period of time, the regulatory authorities cannot approve any applications that seek to rely on the originator's data.[14] The U.S. law has changed since *Ruckelshaus*, with the passing of the Drug Price Competition and Patent Term Restoration Act of 1984,[15] otherwise known as the Hatch-Waxman Act, and in such a scenario the authorities now would be unable to rely on the plaintiff's data. U.S. law now specifically provides that a subsequent applicant cannot use the initial applicant's safety and efficacy data that the Food and Drug Administration (FDA) relies upon for approval for five years after the initial date of approval.[16] Furthermore, there is no requirement that the pharmaceutical product be patented, have current patent protection, or even be patentable.[17] Thus, the law protects non-patentable products or products whose patent protection will terminate before the five-year exclusivity period expires.[18] However, an initial applicant may set up financial arrangements with subsequent applicants to use the dossier in attempts to secure marketing approval. Applicants can obtain a 'right of reference' from the initial applicant, as per which permission is given by the initial applicant to rely on its data, after which the beneficiary of this right can submit its application regardless of marketing exclusivity. Further, as a balance of incentives to first entrants in the markets, the Hatch-Waxman Act provides an extension of patent term for first products.[19] Where a drug is approved by the FDA and a patent exists covering the drug, its use, or manufacture, an extension of the patent term can be granted, proportional to the period needed for regulatory approval of the product.[20]

VII. DATA EXCLUSIVITY: AN INDIAN PERSPECTIVE

The argument put forward by the multinational companies based in developed countries emphasizes on the need of protecting data generated during the discovery of a drug followed by its development. Such an argument is in their favour as they are the lead countries in the ambit of Research and Development process. It is their efforts which made the provision for data exclusivity in the TRIPS Agreement.

On the other side, developing countries have an altogether different scene. Their argument points out the fact that TRIPS does not mandate the provision of data exclusivity. So far as India is concerned, till now this provision has yet not been adopted or incorporated in any statute. Indian position regarding this concept has been till now limited only to the recommendations and suggestions of the committee set up by the government of India. In India, the sector of import, manufacture, distribution and sale of drugs is regulated by the Drugs and Cosmetics Act, 1940 (DCA). The DCA grants licence under the Drugs and Cosmetics rules, 1945 to a manufacturer to market a drug. Several amendments have been made in the Act to include new provisions which provides for a relatively easy entry of generic drugs. This has been done seeing the Indian economy which unlike the economy of developed countries will not be able to deal with strict rules of data exclusivity. Major changes were introduced in the Act in the year 1988 to include the provision of granting of approval of new drugs for manufacture or import. The generic producers are more or less benefitted due to these amendments. The changes in the Act made things easy for them as they are only required to prove that the generic version is bio-equivalent to the original drug. They

[9] Carlos M. Correa, *Unfair Competition under TRIPS: Protection of Data Submitted for Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69, 72 (2002).
[10] *Ibid.*
[11] Carlos María Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 83 (2004).
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[13] Council Regulation 2309/93 of 22 July 1993, 1993 O.J. (L 214) 1.
[14] INT'L FED'N OF PHARM. MFRS. ASS'NS.
[15] 35 U.S.C. § 156 (1988).
[16] 21 U.S.C. § 355(c)(3)(D)(ii).
[17] *Ibid.*
[18] John A. Tessensohn, *Reversal of Fortune—Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT'L LEGAL STUD. 1, 60 (1998).
[19] Data exclusivity with regard to clinical data, *The Indian Journal of Law and Technology Volume 3 2007,* <*http://www1.nls.ac.in/ojs-2.2.3/index.php/IJLT/article/viewFile/20/18* > (Last accessed on 26-09-2014).
[20] Erica J. Pascal, *The Billion-Dollar Naming Game: How Ambiguities in Patent Term Extension Provisions Allow Companies to Add Billions of Dollars to the Bottom Line*, 24 BIOTECHNOLOGY L. REP. 547, 548 (2005).

are not bound to provide any other data related to the generic drug. This allows them to enter the market quickly with their cheap prices of generic drugs. This position is however contradictory to the objectives of data exclusivity.

In the past gradual years, there has been an urge and a pressure too created by few interested innovator groups to consider the proposals to amend the DCA in favour of the concept of data exclusivity. It is proposed to add a new section 18A which would be providing for the prohibition and liability for disclosure of information. In addition to this, the organization of Pharmaceutical Producers of India requested the Government to amend schedule Y of the DCA to include a provision for data exclusivity for a period of six years from the date of marketing approval.[21]

CONCLUSION / ANALYSIS

The concept of *data exclusivity* can be put in simple words as a design which is laid down to delay the entry of generic drugs and thereby delaying the generic competition in the market as well by creating a hindrance to the excess of medicines in particular where there are no barriers for patents.

The concept though seems to be simple is complex enough regarding the several issue attached to it. Often several debates have been conducted since several years to settle issue upon this subject. The issues mainly revolve around the subject of making the generic medicines available in the developing countries particularly those having high population of HIV/AIDS. There have always been controversies regarding the interpretation of the Article 39(3) of the TRIPS Agreement. There still remains confusion as to whether the article mandates the provision of data exclusivity to its member states or not.

However, it has been argued by many developed countries that there should be such a provision regarding data exclusivity to be incorporated in the TRIPS Agreement. The fact is that TRIPS does not exclusively mandate any such kind of protection to be granted by its member states. The member states have a choice to not to adopt such a provision and if they want to adopt it, the nature and extent of such a protection depends upon the legislatures of the respective states.

In this regard, the Doha Declaration on TRIPS and Public Health has ascertained the rights of the member countries to enact legislation which help them to protect public health. This founds its application in the developing countries which are required to maximise the benefits of the flexibility which is accorded to them for the welfare of the patients, this means that they should give higher priority to the rights of the patients to access medicines rather than economic rights of patents.

As far as India is concerned it is well known for its generic drug manufacturing. It is one of the global suppliers of generic medicine. This accounts for a good amount of export from India which accrues a good income as well. Moreover, the poverty level existing in India makes it difficult to adopt the laws on data exclusivity. Therefore, India must take liberal view on the provision of the data exclusivity. Moreover, it should ensure the full utilization of the flexibilities in the TRIPS Agreement. At present, India does not recognize data exclusivity provision. It is suggested that if such provision are adopted in the Indian legislation i.e., in the Indian Drug & Cosmetics Act, it would prevent India's Drug Regulatory Authority to refer or to rely on the registered data which has been filed by an innovator.

Several times the issue regarding the adoption of laws of data exclusivity in the Indian legislation has been discussed. Although such a provision does not exist in the Indian legislation, various interested groups propose amendments in the Indian Law, to introduce data exclusivity.

However as already discussed, there are several reasons why the data exclusivity laws should not be brought into India at this stage, the primary reason being, poverty and illiteracy that marks the Indian Economy, Secondly, generic manufacturing industries, form an important part of the Indian Industrial Sector.

Therefore, the adoption of laws on data exclusivity would rather damage the commercial framework of the Indian economy. Moreover in India, most of the companies recognize the use of the test data, for the pioneer drugs, by the government as an exception. They also support the regulatory authority to use such data in making a discretion regarding the setting and allowing of a generic drug. Such an act of relying upon the data of the original applicant by the government or the concerned regulatory authorities is not considered to be an unfair commercial use but constitutes as harmonious balance between the public and private interest. It also constitutes the exercise of these sovereign functions of the licensing authority.

Thus, it can be conclude that a data exclusivity law does not seem advisable to be enacted in India by amending the DCA or The Insecticides Act to accommodate data exclusivity.

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