'DETAIL ANALYSIS OF LAW ON DATA EXCLUSIVITY – WITH SPECIAL FOCUS ON INDIA'

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-This paper tries to explain the concept of Data Exclusivity in accordance with Article 39.3 of Agreement on Trade-Related Aspects of Intellectual Property Rights (herein after referred as TRIPS Agreement). The author has also provided various statistics in relation to duration of data exclusivity protection granted in various countries. There has also been detail analysis of pro and cons of Data Exclusivity law in light of its viability in India. Further, there is comprehensive analysis on scope of data exclusivity in India through analysis of '2007 Satwant Reddy Committee Report' and thereafter coining various suggestions.

1. UNDERSTANDING DATA EXCLUSIVITY

The concept of Data Exclusivity tries to advocate protection for highly commercial test data present largely in field of agro-chemical and pharmaceutical industry. International recognition to Data Exclusivity was attained after the execution of Agreement on Trade-Related Aspects of Intellectual Property Rights (herein after referred as TRIPS) in 1994, which was result of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) ,1994. However, United States of America and Europe were having provisions of Data Exclusivity even before the enactment of TRIPS agreement.[1]

However, Data Exclusivity is nowhere expressly mentioned or defined but Data Exclusivity in simple terms can be understood as follow-

"Time period of non-disclosure and non-reliance of the pharmaceutical and agro-chemical test data which by and large has substantial role in shaping the final usable invention or product."

[1] Gargi Chakrabarti, *Need for Data Exclusivity :Impact on Access to Medicine* available at http://nopr.niscair.res.in/bitstream/123456789/2030/1/JIPR%2013(5)%20442-446.pdf ,accessed on 17-02-2017

It tries to add an another layer of protection to the existing framework of intellectual right protection. Data Exclusivity is also termed as right to market exclusivity because during the tenure of protection the regulating authority cannot allow registration of generic version of product based on originator's test data.[2] Therefore data exclusivity provides exclusivity to originator and thereby preclude third parties for seeking market approval of their products ,based on originator's test data ,for specific period of time. However , the generic producer are free to apply for market approval of their product based of their own test data .

Thus, Data Exclusivity fundamentally tries to recognize the high level cost incurred by the originator in making any product generally in the field of pharmaceutical and agro-chemical where there is presence of high cost research and clinical data , henceforth by providing non-disclosure and non-reliance upon such data third party would not be able to easily ride upon the efforts of the originator and enjoy monetary benefits.[3] Also through Data Exclusivity, the subsequent comer will be indirectly barred from entering into market because of financial incapacity as research ,clinical trial and test data involves huge financial burden. In context of India ,Data Exclusivity is a crucial issue because of greater disadvantages which are propagated by the Data Exclusivity, which are mainly trying to affect the public health due to high price goods sold by the originator.

1.1 DATA EXCLUSIVITY AND PATENT

Data Exclusivity and Patent are independent of each other and there is no dependence on any one . Patent on one hand tries to gives the patent holder the right to exclude others from making, using, selling, offering for sale, or importing the patented product while Data Exclusivity rides upon only two general concepts i.e non-disclosure and non-reliance of test data by concerned regulating authority.[4] Both Patent and Data Exclusivity can be considered to be in form of right but the Patent as a right is time bound i.e till 20years while Data Exclusivity can be in form of permanent nature also. Also protection given differs, Patent protects wide arena of rights while

[2] Kiruthika D, *Data Exclusivity and Indian Law* available at http://journal.lawmantra.co.in/wp-content/uploads/2015/09/5.pdf , accessed on 17-02-2017

[3] 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 17-02-2017

[4] *Supra* Note 2

Data Protection is limited to protection of data only. So, one can easily carve out the difference in both the intellectual property rights.

2. INTERPRETAING DATA EXCLUSIVITY THROUGH ARTICLE 39.3 OF TRIPS AGREEMENT

Article 39.3 of TRIPS Agreement reads as follow-

"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."[5]

There are seven key prerequisites which needs to be fulfilled for getting protection under Article 39.3 of Trips Agreement-

1) Data submitted for Market Approval
   - The protection under Article 39.3 is only available if the data concerned is submitted to National Drug Authority of concerned nation and if submission of data is made on voluntary requirement or on accessory basis no protection is granted.[6]
2) Scientific Data
   - Concerned subject matter for protection would be the details of results of scientific health ,safety test drugs and agrochemicals.
3) Undisclosed Data
   - The data must not be in public domain. The data must not be published .
4) New chemical entities
   - The term is not defined but easy inference can that be no prior registration of chemical is there .Moreover, the term is vague because definition of "New chemical entity" varies from territory to territory. There has been a debate as to whether the

[5] https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm accessed on 18-02-2017

[6] Animesh Sharma, *Data exclusivity with regard to Clinical Data*, available at http://ijlt.in/wp-content/uploads/2015/08/Sharma-Data-Exclusivity-with-regard-to-Clinical-Data-3-Indian-J.-L.-Tech.-82.pdf ,accessed on 16-02-2017

term "New Chemical Entity" should be evaluated in terms of the novelty requirement under the Patent law or not. But general developing understanding is this that the principles of novelty does not apply and test of safety and efficacy should be the considering parameter.[7]

5) Considerable effort
   - This means there should be substantial amount of effort involved but the TRIPS agreement fails to provide the nature of effort and this leads to ambiguity in the understanding of the term.
6) Unfair Commercial use
   - The non-disclosure obligation under article 39 requires that the test data need not be disclosed unless steps are taken to ensure that the data is protected against "unfair commercial use. The interpretation of this phrase has by far given rise to the maximum debate concerning data exclusivity. Also the parameter to measure fairness is not mentioned in TRIPS agreement, so therefore it will differ from territory to territory. The general notion in developed country is that any act of member nation which tries to benefits the competitor from the originator's test data amounts to "Unfair Commercial use".[8]
7) Duration
   - There is no express mention about the duration of the protection, so member countries are free to decide the duration of data protection.

These are the seven essentials of Article 39.3 of TRIPS agreement which holds key importance and the first six are the approving factor of data protection.

The correct interpretation that must be given to Article 39.3 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.[9]

[7] Biswajit Dhar and K. M. Gopakumar, *Data Exclusivity in Pharmaceuticals: Little Basis, False Claims* available at http://www.jstor.org/stable/4419006 , accessed on 14-02-2017.
[8] *Supra* Note 1
[9] *Supra* Note 5

3. STATUS OF DATA EXCLUSIVITY IN VARIOUS COUNTRIES

Most of the developed countries have incorporated the concept of data exclusivity ranging from different duration and consideration. The duration of protection is different in agrochemical and pharmaceutical products. Following are the duration period of various countries-

PHARMACEUTICAL PRODUCTS

A. UNITED STATES
   - Under, Hatch-Waxman Act of 1984 5 years of data exclusivity was provided in cases of new drug device while in cases of application for the approval of new indications for previous drug 3 years of protection was provided.

B. NEWZEALAND
   - 5 years of data exclusivity is provided but no data exclusivity in case of new uses or old active ingredients.

C. JAPAN
   - There is no formal system of providing data exclusivity but based on Article 14-4 of Pharmaceutical affairs law , 8 years for new drugs, 4-6 years for new indication and 10 years for orphan drugs.

D. CHINA
   - 6 years from the date of market approval.

E. AUSTRALIA
   - 5 years of data exclusivity for new chemical entity.

F. EUROPEAN UNION
   - Data exclusivity differs from various member European countries. Smaller countries provide 6 years of data exclusivity while larger Member state provide 10 years. General understanding is of 10 years which is based on 8+2+1 formula, 8years of data exclusivity, 2years of marketing exclusivity and extra one year protection if the originator obtains authorization for one or more therapeutic indication.

G. Brazil
   - 5 years of protection.

H. Mexico

- 5 years of protection based on Article 82 and 86 of Mexican Industrial Property law.[10]

AGROCHEMICAL PRODUCTS

COUNTRY	PERIOD OF DATA EXCLUSIVITY
UNITED STATES	10 years +15 years additional protection based on compensability.
EUROPE	10 years with 5 years of additional data
UNITED KINGDOM	08years
JAPAN	Permanent
CANADA	10 years
FRANCE	10 years
BRAZIL	10 years with 5 years of additional protection based on various fulfilments.[11]

4. DISADVANTAGES OF DATA EXCLUSIVITY

Data Exclusivity is highly criticized by developing countries because of its extended benefits and fear of exploitation which such protection may rear.

Major concerns are –

First, what is the point in giving such extended rights when there is already existing patent protection of 20 years on world-wide basis. Further also there is lack of any clear cut economic justification.

Second, there are high level chances of economic exploitation because the originator who enjoys data protection will have monopoly over the market and thereby have liberty to price his product. In developing countries where majority of people strive to get basic necessities of

[10] *Supra* Note 1

[11] Bharti Jain, *Impact of Granting Data Exclusivity in Agro-Chemcial Sector* available at http://nopr.niscair.res.in/bitstream/123456789/34015/1/JIPR%2021(1)%2038-41.pdf ,accessed on 14-02-2017.

life and if further their healthcare expense rises due to high prices of medicines then it will definitely turn out to be a state of helplessness.[12]

Third, the changing definition of "New chemical entity" will also entitle a product otherwise non-patentable to data protection and thereby increasing the domain of exploitation.

Fourth, the entry of generic medicines will be delayed and thereby there will be extended benefit enjoyed by the originator.[13]

Fifth, in cases where lifetime protection is granted then the subsequent comer needs to re-conduct the entire expensive clinical trial and the consequences will be that there will not be availability of cheap generic medicine.

Sixth, if data exclusivity for 5 years is implemented now then the patent holder who have entered the 16thor above years of patent protection will enjoy extended benefit if their product has still not received market approval. In this way, there is fear amongst generic companies that data exclusivity in such circumstances will lead to "Ever-greening of Patent"[14]

Seventh, 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.

Eighth, the Data exclusivity can make the concept of Compulsory Licensing under Patent law ineffective because even if a compulsory licence were granted, the licensee would not be able to function because the pioneer applicant would have been able to pre-empt the entry of competitors. In other words, compulsory licence and government use provisions would remain only in theory and not in practice.

Finally, the major concern is about the substantial impact on public health.

4.1 Advantages of Data Exclusivity

The advocates of Data Exclusivity are majorly developed countries and they are making substantial efforts for implementing Data Exclusivity protection.

Major arguments supporting their Pro Data Exclusivity stance are as follow-

[12] *Supra* Note 2
[13] *Supra* Note 1
[14] *Supra* Note 2

First, there should be concrete recognition for the originator who has spent huge finance in developing any product. Such recognition can only be given if their research data is unrevealed and protected from further disclosure.

Second, patent protection is not sufficient because it has very limited approach but when data exclusivity is provided then the originator's whose products are otherwise not patentable will also be recognized and no third party would be allowed to ride upon their effortful research data.

Third, it is not always true that commercialization of product starts immediately after acquiring patent. After filing of the patent, the clinical trial is done in most of the cases, because of it being time consuming. There are many cases in which till 17th or 18th year of patent protection, commercialization has not yet been started and therefore the originator in no case would be position to realize his huge financial investment he has put forth.[15]

Finally, the need for newer and efficient drug is big issue as world is facing huge health crisis with introduction of newer and more dreadful diseases. So, for drug development process the need for data exclusivity along with patent protection is very essential in combating such health crisis.

5. INDIAN SCENARIO AND EXISTING LEGAL SET-UP

India is not having any data exclusivity law and also India is not bound to implement Article 39.3 of TRIPS agreement as its interpretation says so. The interpretation of Article 39.3 needs to be given with the help of maxim *"expressio unis est exclusio alterius"* which says *"what is not explicitly included is thereby excluded".*

The concept of data exclusivity has altogether different approach because under this concept research data of any product irrespective of it being patentable or not needs to be protected .In this, the concerned nation's regulatory authority has been imposed with responsibility of non-disclosure and non-reliance upon originator's test data in granting market approval to subsequent comer .In India there are laws but no law is not providing mechanism for confidentiality of research data. Various laws in India are as follow-

1) The Official Secrets Act, 1923

[15] *Supra* Note 5

2) Trade secret
3) The Insecticides Act, 1968
4) The Indian Patents Act, 1970

So, no Indian Legislation incorporates facets of data exclusivity at large.

5.1 SATWAN REDDY COMMITTEE REPORT ON VIABILITY OF DATA EXCLUSIVITY IN INDIA.

Due to mounting pressure from international fraternity in regards to implementation of data exclusivity, an Inter-Ministerial Committee headed by Satwant Reddy was constituted on 10th February, 2004 to assist the The Department of Chemicals and Petrochemicals (DCPC), for suggesting measures to be adopted in the context of data protection provisions as outlined in Article 39.3 of TRIPS agreement.

The committee undertook comprehensive research and made various recommendations which are as follow-Agrochemicals And Traditional Medicines- Committee recommended strict 5 years and three years data exclusivity protection in agro chemicals and Traditional Medicines respectively .[16]

Pharmaceuticals- No immediate implementation of data exclusivity in pharmaceutical sector but transitional period approach to be considered in which pre-transition period there will be steps taken to implement minimum standard of protection and in post –transitional period 5 years of protection to be allowed.[17]

The most important observation made by committee was in relation to urgent need of data exclusivity for agro-chemicals in comparison to pharma products. Following were comparisons proposed in lieu of differential treatment[18] –

(a) Unlike pharmaceuticals, efficacy tests for agro-chemicals must be repeated in every country, even in several regions in a country due to differences in crops, pests, agronomical practices, climate conditions and terrains.

[16] Satwant Reddy, *Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement* ,available at http://chemicals.nic.in/sites/default/files/DPBooklet.pdf last accessed on 06-02-2017
[17] *Ibid*.
[18] *Ibid*.

(b) Pharmaceutical is not exposed to environment impact test which agrochemicals have to face.

(c) Post-registration process in form of periodic review, data call in by the authorities, adaptation to the advanced standards of science and technical knowledge, product stewardship is not there in Pharmaceutical, which is there in case of agro-chemical.

(d) Cost involved by the originator in case of agro-chemical is very huge and product registration is only first part of cost which in case of pharmaceutical is not there.

(e) While in the case of pharmaceuticals one in every 10,000 molecules investigated is approved by the FDA for marketing, in the case agro-chemicals only one of 20,000 molecules make it from the laboratory to the fields.

(f) Because of its chemical nature and the wide range of organisms potentially affected by their use, agro-chemicals products have to undergo more than 40 safety tests.

The other important recommendation was in relation to restricting use of data exclusivity in cases of public interest.

The present situation is that Parliamentary Standing Committee has revised the 3 years of data exclusivity to 5 years for agro-chemicals and also Pesticides (Amendment) Bill,2015 has been tabled in parliament for giving legislative nod.[19]

6. Author's Opinion

According to author, the concept of data exclusivity is a welcome step. It will act as a lucrative initiative for the originator and also accelerate drug and agrochemicals development at large. In case of developing countries, particularly India the concept of Data Exclusivity should be introduced but at no stage it should affect the public health. Author considers Satwant Reddy committee's recommendation should be translated into legislative code but the Parliament at no cost should allow exploitation to farmers in form of over price. Author suggests that Data Exclusivity in Pharmaceuticals according to Satwant Reddy committee's should not be implemented in India at this stage because of present Indian Set-up. Moreover, if later Satwant Reddy committee's recommendation are introduced then there will be two fold benefits namely better and effective agrochemicals will be there and also the untested products followed

[19] https://spicyip.com/2015/03/data-exclusivity-back-on-the-table-for-india.html (accessed on 19-02-2017)

from "me too" registration will be barred from creating any financial loss to farmers. Moreover, the effect of providing data exclusivity will be seen in international trade relationship which in return will help in accelerating India's economy.

Hence, data exclusivity is not a wrong concept but in context of India it should be implemented keeping in mind the social set up and public welfare at large.