AGROCHEMICALS AND DATA EXCLUSIVITY

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Abstract

This paper seeks to study data exclusivity with particular reference to Indian agro-chemical products. The authors try to define data exclusivity and offeran interpretation of Article 39 of TRIPS agreement in light of data exclusivity to agro-chemical products. The paper examines the Indian position and perspective of data exclusivity by discussing the Satwant Reddy Committee Report. The author also highlights the debate pertaining to IP protection and agrochemicals in Indian scenario. The article also discusses the recent developments in India and around the globe in data exclusivity and agricultural chemicals.

I. INTRODUCTION

There are only three things that can kill a farmer: lightning, rolling over in a tractor, and old age.[1]

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[1]Bill Bryson, BRAINY QUOTE, http://www.brainyquote.com/quotes/quotes/b/billbryson390788.html? src=t_farmer; although this statement is no longer valid as the underlying theme may also be one of the causes of farmers' death.

Agriculture is a lifeline for the majority of households in India. Over 58 percent of rural households are dependent on agriculture as a sole source of income. Agriculture, along with fisheries and forestry, contributes to the Gross Domestic Product (GDP).[2] The agricultural sector remains the most significant livelihood provider in India, especially in rural areas. It engages a lot of manual power and the efforts from the various sectors. Government policies have played very central role when it comes to agriculture and these have been framed around the agricultural setup.[3] Apart from the factors like weather, seeds, equipment, fertilizers; pesticides are an essential part of agriculture. The agriculture sector is driven by many other interdisciplinary factors, one of them being intellectual property protection. Agriculture and IP has been a naïve relation but wide enough to cajole Plant Verities, farmers 'Right's, biodiversity etc. The government policies play an important role in upliftment of Indian agriculture sector but its fails to acknowledge and address the issues like IP protection relating to agrochemicals which have taken vital position in modern agricultural setup. This paper talks about this very relation and the action taken in its furtherance.

II. DATA EXCLUSIVITY AND AGRICULTURE

The development of a new agrochemical, such as a pesticide or fertilizers usually requires elaborate testing, in the laboratory or the field, on plants, or the environment, depending on the nature of the chemical and its functionality. Data exclusivity also termed as

[2]Indian Agriculture Industry: an overview as per a report jointly presented by Tata Strategic Management Group (TSMG) and FICCI, http://www.ibef.org/industry/agriculture-india.aspx.

[3]*See* https://data.worldbank.org/indicator/SL.AGR.EMPL.ZS; *see also* Total workforce vs. Agricultural Workforce (2011-12) at http://ficci.in/spdocument/20550/FICCI-agri-Report%2009-03-2015.pdf.

regulatory data protection, has a major role when we talk about the development of new agro-chemicals. According to the European Commission:

> *"Data exclusivity" refers to the period during which the data of the original marketing authorisation holder relating to (pre-) clinical testing is protected. Accordingly, in relation to marketing authorisation applications submitted after 30 October 2005 for the applications filed in the framework of national procedures or 20 November 2005 for applications filed in the framework of the centralised procedure, 'data exclusivity' refers to the eight-year protection period during which generic applicant may not refer to the information of the original marketing authorisation holder and 'marketing exclusivity' refers to the ten-year period after which generic products can be placed on the market. However, in relation to marketing authorisation applications submitted before the above mentioned dates, the wording 'data exclusivity' refers to the six or ten-year protection period granted to the original marketing authorisation (MA) holder before generic applicants can file their applications for marketing authorisation".*[4]

These tests serve as the basis on which the effectiveness of the chemicals is ascertained. These trials are conducted in the later stage as per the rules and regulations set by regulating authorities. Meeting all these procedural and developmental requirements is necessary to acquire permission to release the products in the market, which involves enormous cost. It is estimated that the average development cost of agro-chemicals is more than US$180 million.[5]

[4]European Commission, *Pharmaceutical Sector Inquiry, Preliminary Report (DG Competition Staff Working Paper)*, 17 (28 November 2008).
[5]CropLife International, 2004. *Position Paper: On the Protection of Safety and Efficacy Data for Existing and New CropProtection Chemicals*. CROP LIFE

Due to massive investment in clinical test data, agrochemical industries discourage the use of clinical experimental data by third parties. They argue that if this data is made available to other competitors or players and permission is granted to them based on the said test data then recovering the R&D costs involved in the process of evolving a new agrochemical drops exponentially. Relying on this data, if other companies enter the market with an equivalent product, then the profit or incentives of the original company would be jeopardized. The rule to prevent the use of this data by a third party has the effect of providing exclusivity to the original producer which is mostly because the cost of replicating the investment in trials to meet the regulatory requirements would be deterrent and discourage a potential competitor from entering the market.

Data exclusivity usually emphasizes on, preventing regulators from using the clinical trial data which had been the basis of approval for the original product, and supporting the chemically (or otherwise) equivalent generic product. So if a generic company needs approval during this exclusivity period (generally 5-10 years), it will have to carry out all the clinical trial again which will which will cost the same amount of time and money. If the period of data exclusivity overlaps with the patent duration, there is no effect where the patent would prevent generics from releasing the product. Hence, the relation of data exclusivity with agricultutre is very crutial as it governs the very essential tool used in modern agriculture.

III. DEBATED INTELLECTUAL PROPERTY PROTECTION FOR AGROCHEMICALS

India Patent Act, 1970 is TRIPS compliant, and data exclusivity seems to be a TRIPS-plus measure. Article 39.3 is the relevant TRIPS provision to be looking at here. It states:

> *"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. Also, 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."*

The text mentioned above includes the protection of test data against 'unfair commercial use,' but TRIPS agreement does not define the practices that would constitute unfair commercial use and so does the TRIPS member states. Moreover, the disclosure of data is permitted only in two circumstances:

1) Where it is necessary to protect the public,

2) Where data is protected from unfair commercial use.

Various developing countries, including India, interprets Article 39.3 to provide certain minimum standards concerning 'non-disclosure' obligations, usually termed 'data protection' as opposed to 'data exclusivity.' This 'non-disclosure' commitment allows for a permitted reliable standard, leaving it open to national regulators to rely upon the test data submitted to them by originators for marketing approval

for the new applicants.[6] Whereas developing countries aggressively argue that this provision mentioned above is a data exclusivity provision, but when we look into the negotiating history of TRIPS, two clauses were proposed which dealt with data exclusivity but subsequently removed before the final draft was made.[7] Charles Clift[8] views Article 39.3 as being about *data protection*. He writes,

> *"Article 39(3) does not create new property rights, nor a right to prevent reliance on the test data submitted by an originator for the marketing approval of an equivalent product by a third party, except where unfair commercial practices are involved. The article is an articulation of widely accepted legal precepts regarding trade secrets and unfair competition, not an invitation to create a new intellectual property right for test data."*[9]

While some commentators have argued the third position - that Article 39.3 points to a middle-path requiring a compensatory liability

[6]UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (Cambridge University Press, 2004) [hereinafter Unctad-Ictsd Resource Book]; CARLOS MARIA CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT, SOUTH CENTRE (2002) [hereinafter Correa- South Centre].

[7]Jerome H. Reichman, *Undisclosed Clinical Trial Data Under The Trips Agreement And Its Progeny: A Broader Perspective*, Duke University Sschool of Law.

[8]Charles Clift is chair of the Medicines Patent Pool, a Swiss charitable foundation seeking to increase access to medicine for people living with HIV in developing countries. For a large part of his career he worked as an economist in the UK Department for International Development with experience of working in Kenya, India and the Caribbean. From 2004 to 2006 he was a staff member of the World Health Organisation (WHO). In addition to his work for Chatham House, he has been a consultant to the WHO, UNITAID, the World Intellectual Property Organisation and the Access to Medicine Foundation.

[9] Charles Clift, *Data Protection and Data Exclusivity In Pharmaceuticals and Agrochemical*, Chapter No. 4.9

regime. Prof Correa[10] and other experts have interpreted Article 39(3) to be one of where the regulator simply has to ensure 'non-disclosure' of test data to other private players but can rely on originator's data to give regulatory approval. The fundamental concern posed by data exclusivity is access and affordability. And agrochemicals being at its centre makes it more sensitive.

IV. INDIAN POSITION ON DATA EXCLUSIVITY OF AGROCHEMICALS

Due to mounting pressure of Free Trade Agreements, the Department of Chemicals and Petrochemicals constituted an inter-ministerial committee (including external experts) known as Satwant Committee in February 2004 to assist them.[11]

The Satwant Committee interpreted that Article 39.3 provides two types of protection[12], namely- trade secret protection and data exclusivity. Trade secret protection means protection of data which is submitted to the regulatory authority for registration of unauthorized use or disclosure but can rely upon this information to grant marketing approval to a subsequent application for similar products without disclosing the confidential information. Whereas data exclusivity protection implies non-disclosure and non-reliance on the data from original applicant's test for granting of approval to

[10]Carlos María Correa, *supra* note 6, (From 1984-89, he was Under-secretary of State for Informatics and Development in the Argentine national government. During this period he was the coordinator of the Inter-ministerial Group on Intellectual Property. He was also from 1988 to 1991 government delegate in international negotiations on intellectual property (including the Washington Treaty on integrated circuits and the TRIPS Agreement).

[11]Office Memorandum No.11025/7/2003-PI-II, Government of India, Ministry of Chemicals and Fertilizers,
Department of Chemicals and Petrochemicals, New Delhi, (19th Feb. 2004).

[12]*Id*., ¶ 1.6, pp. 3-4.

subsequent applicants. Further, the committee says that many developed countries accept data exclusivity measures to comply with Article 39.3, but the actual reason behind this acceptance is that these countries majorly incorporate it as policy measure which is an essential requirement of Foreign Trade Agreements.

The Committee suggests that there are some agrochemicals, mainly biotech agrochemicals, where it is hard to make generics, so if protection is given to these drugs, then it will difficult for generics to enter the market. But the committee erred in considering that generic manufacturing difficulties would not affect the innovator company. The committee suggests that inclusion of data exclusivity would be a helpful measure to check the menace of spurious chemicals and pesticides, as only companies with excellent quality of products and resources will be allowed to enter the market during the period of protection.

V. COMMITTEE REPORT ANALYSIS AND POLITICAL BACKDROP

It is argued that the committee did differential treatment to agrochemicals, i.e., a period of three years data exclusivity is not based on any statistics or common understanding. The only reason the committee permitted this is, due to the presence of "me-too" products in the market. The original companies are not able to accumulate the requisite profit which is an equivalent argument favoring data exclusivity for pharmaceuticals products (which finds its mention in the said report). Hence the reason by the committee for agrochemical data exclusivity measure does not justify this differential treatment, and this evaluation is not meaningful.

Committee emphasizes on the environmental impact toxic agrochemical substances might have/ will have. As the committee talks about the pharma and agrochemical industry, it warrants data exclusivity but fails to take into consideration the delicate relationship of reliance in which consumers of agrochemicals are placed, and it goes on justifying data exclusivity policy measure by mitigating risk in agrochemical industry. Also, the committee related the marketing strategy, i.e., door to door marketing with data exclusivity, which is poles apart and such costs have very little to do with data submitted.

The Reddy committee report in 2007 recommended an amendment to Insecticides Act, 1968 for incorporation of a three-year data exclusivity period for agrochemicals, which was mainly done under pressure from big players and not in order comply with TRIPS mandates which was supposed to be as per those mandates. The Pesticides Management Bill, 2008[13]was introduced which had a data exclusivity provision:

> **Section 12:***(6) The data submitted for registration in respect of a pesticide under this section which has not been previously registered shall not be relied upon for grant of registration of the same pesticide in respect of any other person for three years.*
> *(7) Subject to sub-section (6), where a pesticide has been granted a patent, the termof non-reliance on data shall be limited to the duration of the patent.*
> *Explanation: The words "not been previously registered" in respect of a pesticide shall include its name or label expansion through "new uses": Provided that the provisions of non-reliance on data submitted for registration of a pesticide by the first*

[13]Bill No. XLVIII of 2008, http://www.prsindia.org/uploads/media/1224668021/1224668021_The_Pesticides_Management_Bill__2008.pdf.

> *registrant shall be available for the period with effect from the date of the first marketing approval granted anywhere in the world and this shall not apply to the data relating to bio-efficacy and shelf-life part of pesticides where data is to be generated for use under Indian conditions.*
> *(8) Subject to the provisions of sub-section (6), the Central Government may relax or exempt the provision of non-reliance of data submitted for registration of a pesticide by the first registrant in the following circumstances, namely:*
> *(i) (a)national emergency; or*
> *(b)In cases of urgency; or*
> *(c)public interest; or*
> *(ii) for use by the Government for academic and research purposes*

The Bill mentioned above was referred to a Standing Committee of the Parliament which was headed by Samajwadi Party MP, Mr. Mohan Singh. He submitted his report to parliament on 17th February 2009. Paragraph 14 of Reddy Committee's report was acknowledged with an amendment to increase the data exclusivity period for five years instead of 3 years. The reason given for this term extension was, as to encourage the evolution or introduction of newer pesticide molecules in the country. However, **the BJP opposed the Bill then,**[14] stating:

> "certain clauses had been inserted in it under pressure from the West and were inimical to the country's interests*." and*
> "Under the data exclusivity provision, the researcher's data

[14]THE ECONOMIC TIMES (May 06, 2010), http://articles.economictimes.indiatimes.com/2010-05-06/news/28475814_1_data-exclusivity-saffron-party-bharatiya-janata-party.

> will be his monopoly, and no one else in the world would be allowed to have control over it. "Monopoly can also lead to exploitation and a hike in the prices of pesticides. Such a clause will have dangerous consequences for the developing countries such as India," a senior leader argued."

Also, the Parliamentary Standing Committee[15] stated in its 88th report that the impacts of data exclusivity are quite severe and grave and the Standing committee strongly recommended that:

> "the Government should not fall prey to such demands of MNCs. The Government must thwart such attempts, being made at the behest of certain vested interests. It should guard against moves to enter into FTA with the USA, as the developed countries, particularly the USA, are trying to bring in certain TRIPS-Plus measures through Bilateral and Regional Agreements."

Meanwhile, the Bill was pending; the Government passed two notifications which talks about implementing data exclusivity under the Insecticides Act are as follows:
(i)No.17-2/2006-PP.I dated 30th October 2007
(ii)F.No.17-2/2006-PP.I dated 18th February 2008

Further, in Syngenta India Ltd vs. Union of India[16], Justice Bhat[17] questioned the legality of these notifications and opined that:

> *"*There is no statutory guidance, either in the substantive portion of the enactment or under the Rules, enabling even the rulemaking authority to prescribe a period of limitation for "data exclusivity."

[15]Standing Committee On Agriculture, http://164.100.47.134/lsscommittee/Agriculture/88th%20 report.pdf (2008-09).
[16]Syngenta India Ltd v. Union of India, W.P. (C) 8123/2008.
[17]http://lobis.nic.in/dhc/SRB/judgement/02-07-2009/SRB01072009CW%2081232008.pdf.

The Bill was back for consideration by the same party which once opposed it. This act of taking up the bill to the table for discussion by BJP might be assessed as to be done with an intention to give assurance to US/EU of its "good-intention" without acknowledging as what cost the country have to pay for doing the same. If this attitude by the Government persists then, patent linkage[18] In India might become a reality soon without proper consideration of its harmful effect on the country.

The whole story of Agrochemicals and data exclusivity debate related to it seems like a political story rather than an honest effort by the government to consider the issue and take up the matter seriously. The political backdrop tells about the good will establishment by the parties and not the data exclusivity issues which were claimed to be addressed.

VI. CONCLUSION

As stated initially in this article, the introduction of a data exclusivity provision with regard to agrochemicals was never established on any data-based study so there is a need for robust empirical, evidence-based policy and rethinking the whole argument of data exclusivity and its term. The author suggests that data exclusivity provisions will bring more agrochemicals in the market or cause an increase in the FDI, must be shown. As Prof. Shamnad Basheer[19] has discussed,[20] it

[18]Patent linkage refers to the system or process by which a country links drug marketing approval to the status of the patent(s) corresponding to the originator's product.

[19]Prof. Basheer is the founder of Increasing Diversity by Increasing Access to Legal Education - a trust which works on making legal education accessible to underprivileged students. Basheer was a Ministry of Human Resource Development Chaired Professor of Intellectual Property Law at the West Bengal

is very likely that such a provision would help foreign countries receive more money and not give the claimed benefit to the host country, so India needs to reconsider the agrochemical market and also the data exclusivity debate related to it.

The author is of the opinion that the regulatory issues need to be fixed and needs revision. Also, a pseudo proxy mechanism based on lobbying can be considered if relying on empirical evidence is not possible. It extends the monopoly periods of products and makes these products inaccessible.It will serve as a progressive ladder for some multinational to start demanding data exclusivity for agrochemicals– which will, in turn, make pesticides harder to access. These actions of India will be giving an impression that it is stepping down from its strong stance of a balanced IP regime and giving into the demands of big multinational companies, which in turn effects its economy, which is agriculture dependent. Therefore, the agrochemical players and the government need to look again into the regulatory provisions and requirements.

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[20]SpicyIP, *Data Exclusivity Debate: Whither Context*?, http://spicyip.com/2011/02/data-exclusivity-debate-whither-context.html.