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White Paper on Data Exclusivity

A. What is data exclusivity?

Data exclusivity refers to a TRIPS Plus privilege which offers protection of data submitted by the originator (usually MNCs from developed countries) for market approval of a drug or agrochemical to the regulatory authority in each country. This data is then protected by the authority for a fixed period of time (up to 5- 10 years or more) and cannot be relied on for granting market approval to other companies for the generic version of the first registered product.

Data exclusivity is different from patent protection, which extends to 20 years under TRIPS Agreement. India allows the latter.

Data exclusivity can be either in addition to or *in lieu* of patent protection. It could operate outside the realm of product patents or patentability. It is one of the prime means for product monopoly beyond patent protection of 20 years! Data exclusivity delays the entry of generic versions of pharmaceuticals and agrochemicals. It creates a monopoly condition in favour of MNCs.

B. Data Exclusivity and TRIPS Agreement

Article 39.3 of the TRIPS Agreement – interpreted according to the ordinary meaning of the words used, in their context (notably Article 39.1) and taking into account the object and purpose of the Agreement as expressed in Articles 7 and 8 – does not require the granting of exclusive rights.



“Use by the government to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3. Granting marketing approval to a second entrant, based on the second product’s similarity to a previously approved first product, is not a proscribed “use” under Article 39.3.”

~Prof. Prof Carlos Correa, South Centre

TRIPS Article 39.3, unlike the case of patents, does not require the provision of specific forms of rights..... It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party..”

“... developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS”.

Ref: Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRIIPH), WHO- 2006 See page 124 & 181.

India signed the WTO TRIPS Agreement in 1995. Indian laws do not provide data exclusivity for pharmaceuticals and agrochemicals. This is perfectly legitimate as the TRIPS Agreement does not require countries to grant data exclusivity.

C. Data exclusivity. A subject conclusively dealt with by various Parliamentary Committees

The Parliamentary Standing Committee on Patents & Trademark (24th Oct 2008) strongly advised the Government not to grant data exclusivity. The Committee observed

5.47 “..... *The Committee feel that conceding to demand for data exclusivity would amount to agreeing to TRIPS plus provisions. Once such a demand is agreed at bilateral forum, there will be additional demands, which may relate to higher level of intellectual property right, such as extension of patent period, restriction on compulsory licences, restriction*



on parallel imports and may be on R&D activity on patented subject matter. Data exclusivity may result in delay in ensuring role of domestic enterprises through compulsory licensing system, and in preventing other parties from developing similar data.

5.48 Since the consequences of data exclusivity are quite serious, the Committee strongly recommend 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....”

The recent 36th Standing Parliamentary Committee on Agriculture, Animal Husbandry, and Food Processing in December 2021 stated the following –

1.18 “... India has a very large and growing market of Agrochemicals and with huge arable land, it will be able to attract introduction of new molecules from foreign as well as domestic companies even without provision for any data protection [Exclusivity]. The Committee feel totally convinced by the arguments advanced by the Government that the Patent period of 20 years is sufficient for inventors to gain benefits for the investments made in discovery/introduction of new molecules provided that new molecules are introduced within the patent period in the Country”

Recommendations from the Parliamentary Committees are of advisory in nature. They cannot be ignored.

D. Data exclusivity and judgments from Indian courts

*The object of patent law is to encourage scientific research, new technology and industrial progress. The price of the grant of the monopoly is the disclosure of the invention at the Patent office, which, **after expiry of the date of the fixed period of the monopoly, passes into public domain.***

~ Supreme Court in Bishwanath Prasad vs Hindustan Metal Industries

The Delhi High Court in its order dated 1st July 2009 (*Syngenta vs Union of India, WP 8123/2008*) observed that there is no statutory support to granting data exclusivity in India.



The High Court of Gujarat also took the same stand in *Crop Life India and Ors v. Union of India and Ors*.

E. Abuse of patent rights by foreign MNCs

The primary objective of the Patents Act, 1970 has been the promotion of science and technology for the benefit of our own social and economic development, and to a balance of rights and obligations under the Act.

Owning patents in India for new pesticide molecules but not commercializing them for the benefit of Indian agriculture and the agrochemical industry should be considered as a planned abuse of the monopoly rights granted under the Indian Patents Act, 1970.

Our analysis shows that for every ten patents granted since 2010 to the western MNCs for new pesticide chemistries/molecules, six have not been commercially introduced in India though they were promptly commercialized in other countries. The summary of our analysis is given below:

Particulars	No. of pesticides
No. of pesticides (new molecules) patented in India between 2010-2022	62
No. of patented pesticides (new molecules) commercially launched in India between 2010-2022	27 (44%)
No. of patented pesticides (new molecules) commercially not launched in India between 2010-2022 though launched outside India	35 (56%)

Data Source for analysis: Agribusiness by S&P Global and CIB&RC (Ministry of Agriculture)

This planned abuse brazenly contravenes the mandatory requirements in **Section 83** of Patents Act, 1970. Under this Act, a failure to commercialize the patent is unacceptable and actionable. **Section 83** of this Act carries several obligations to achieve this.



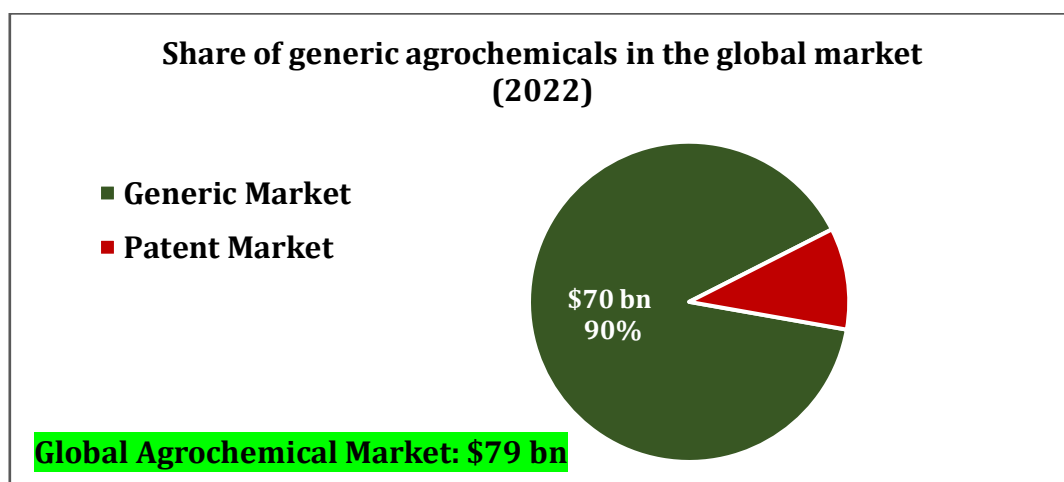
CCFI has already objected and complained to DPIIT, Ministry of Commerce & Industry and to the Controller of Patents about this abuse.

The western MNCs who do not commercially introduce all their patented molecules are now actively lobbying for “data exclusivity” to bring their old and off patent pesticide molecules to the Indian market.

This is a double whammy for India. It would only end up creating yet another market monopoly to the western MNCs beyond the patent protection.

F. In the global crop protection market, generics rule the roost

Unlike the global pharmaceutical industry, the agrochemical market is dominated by generics. Generic agrochemicals have a lion’s share of **90%** in the global market. In fact, all the 20 top selling agrochemicals in the world are generics. This offers excellent scope for Indian industry to accelerate the growth in the global markets.



Data Source: Agribusiness by S&P Global (Accessed on 1st October 2024) analysed by industry

Large number of patent expirations in the period 2024-2030 should help Indian agrochemical companies in the years to come. Granting data exclusivity to post patent and old pesticides is detrimental to India’s



interests. It will delay launch of new generics by Indian companies and gradually erode their global competitiveness.

G. India’s global leadership in export of generic pesticides

India is a leading producer and exporter of generic pesticides.

The generic pesticides produced in India are known for quality, consistency, competitiveness and sold in over 150 countries including USA, Brazil, EU, Australia, Japan, China, etc.

This sector fetches valuable trade surplus.

India is now the 3rd largest exporter of agrochemicals in the world. Ten years ago, it was 5th largest exporter.

Rank	2013		2023	
	Country	Agrochemical Export Value (\$ bn)	Country	Agrochemical Export Value (\$ bn)
1	Germany	4.1	China	8.1
2	USA	3.9	USA	4.7
3	France	3.8	India	4.3
4	China	3.7	France	4.1
5	India	2.1	Germany	3.7
	Global Export	33	Global Export	44

Data Source: WTO-ITC (Accessed on 1st October 2024)

Indian Government must in fact introduce policies that facilitate manufacture and export of generic pesticides.

H. Data Exclusivity and Trade Agreements

In various FTAs too India rejected the demand for data exclusivity. For example, In the recent EFTA negotiations, **India rejected** European FTA 'data exclusivity' demand to protect interests of generic industry.



In various international forums too, India has rejected the demands of data exclusivity.

I. Conclusion

Data exclusivity is a TRIPS Plus privilege that would work against India's economic interests and retard the efforts towards achieving **Atmanirbhar Bharat** - both in agrochemicals and pharmaceutical sector.

Aware of the inherent dangers, India has not allowed or agreed to any TRIPS Plus privilege since 1995. There is no need to yield to the fresh lobbying by the MNCs and importers. As cautioned by the Parliamentary Committee on Patents and Trademarks, the government must thwart the attempts for data exclusivity being made at the behest of certain vested interests.

Empirical evidence shows that developing countries that had granted "data exclusivity" ended up losing the domestic industry to imports and MNCs. Data exclusivity slowly erodes the economic sovereignty.

CCFI is committed to Atmanirbhar Bharat and building export-oriented industry in India for agrochemicals.

Crop Care Federation of India (CCFI) is an apex trade body for Indian agrochemicals industry with around 50 companies as members. Our members account for over 75% of agrochemicals export from India.