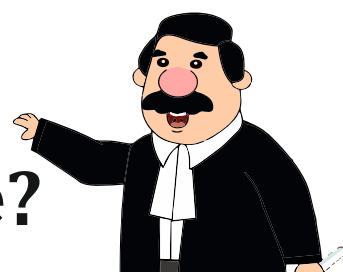
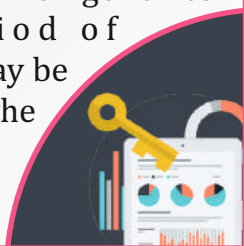


Why is “data exclusivity” called a TRIPS-Plus measure?



Data exclusivity refers to fixed term protection of test data submitted by the patentee to the regulatory authority to prove safety and efficacy of a new drug or agrochemical. The data exclusivity disallows registration of generics during the period of exclusivity which may be within or beyond the patent term.



TRIPS-Plus measure refers to any measure that is not provided in the text of the TRIPS Agreement*. It is a measure that goes beyond the scope of the TRIPS Agreement. Data exclusivity is one such measure.



*The Agreement on Trade-Related Aspects of Intellectual Property Rights.

Negotiating history (1986-94) of the TRIPS Agreement shows that a minimum 5-year data exclusivity was proposed by the USA and European Community (EC). But this was opposed and rejected by India and others during the negotiations.



The final text of Article 39.3 of the TRIPS Agreement, adopted in Marrakesh, Morocco on 15 April 1994 omitted any reference to data exclusivity period.

TRIPS Article 39.3 incorporating 5-year data exclusivity proposed by the USA and EC at the Ministerial Meeting in Brussels, 1990.

Parties, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the originator of which involves a considerable effort, shall protect such data against unfair commercial use.

*Unless the person submitting the information agrees, **the data may not be relied upon** for the approval of competing products for a reasonable time, generally **no less than five years**, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, Parties shall protect such data against disclosure, except where necessary to protect the public.*

Word count of proposed text: 111

Text of TRIPS Article 39.3 finally adopted by WTO members in Marrakesh, Morocco in 1994.

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.

Word count of final text: 78

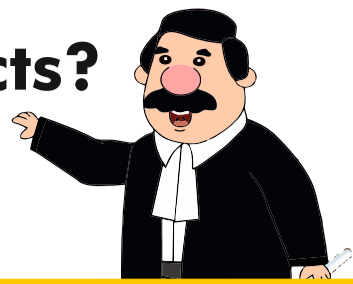
TRIPS Article 39.3 in force since 1995 merely requires the regulatory authorities to protect (keep) the test data against disclosure and unfair commercial use as defined under Article 10bis of Paris Convention.

While authorizing generics (pharma or agrochemical) after the patent period of 20 years, the Indian regulatory authorities do not disclose the data submitted by the first registrant. All that they do is to confirm that the generic product is chemically similar to the patented product first commercialized. This is a TRIPS compliant practice as observed by UNCTAD (United Nations Conference on Trade and Development) and followed by many countries.

The 88th Report of the Parliamentary Standing Committee on Patents and Trademarks Systems in India (2008) strongly advised GOI not to grant of any form of data exclusivity to drugs and agrochemicals as it would only benefit the MNCs.



Data exclusivity to off patent products? It would run counter to the object of Indian Patents Act.



Indian Patents Act is unique in the world. Our Supreme Court succinctly captured the object of our patent law when it observed:



“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, 13-12-1978).

The Act grants monopoly for a fixed period of 20 years after which the technology must enter the public domain for the competition to set in.

Pertinently, the Act requires patented products be commercially introduced without undue delay.

Section 83 of the Patents Act carries several obligations and conditions to serve the object of the Act.

Section	What it requires?	Observations
83 (a)	patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay ;	Data exclusivity, if granted to off patent products, would render all these important provisions practically inoperative.
83 (b)	[Patents] are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;	A data exclusivity period of, for example 5 years, offers economic incentive to the patentee to delay the commercialization of the patented drug or pesticide till the end of patent term of 20 years. Reason? This delay would effectively extend the monopoly period from 20 to 25 years i.e. 20+5 years.
83 (c)	The protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology , to the mutual advantage of producers and users ...,”	Therefore, the data exclusivity, if granted, would run counter to the object of the India's Patents Act which requires;
83 (f)	“... the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology;	(a) Commercial launch of the patented technology & product without undue delay. (b) Release of the patented technology & product into public domain immediately after the patent term of 20 years to encourage introduction of generic versions.
83 (g)	Patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.	

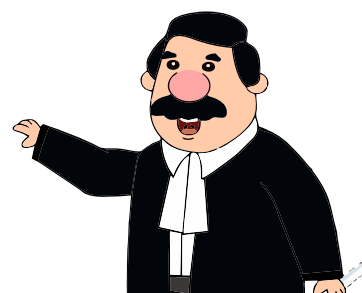
MNCs are lobbying for data exclusivity to off patent products in India as it would kill two birds in one stone.

- (i) It would render Section 83 of the Patents Act practically inoperative and dilute the object of the Act.
- (ii) It would make India a profitable dumping ground for the old, off patent pesticides and drugs.

There is no obligation under the TRIPS Agreement to grant the data exclusivity.

Data exclusivity, a TRIPS-Plus privilege, is highly detrimental to our country's economic interests as observed by the Parliamentary Committee on Patents and Trademarks (88th Report - 2008).





What does TRIPS Article 39.3 require? Data protection or Data exclusivity?



Misrepresentation by vested interests impair proper understanding of the crucial Article 39.3 of the TRIPS Agreement. This advocacy paper separates facts from fiction.

The TRIPS Article 39.3 must always be read in conjunction with Article 39.1 in order to understand it completely and correctly.

TRIPS Article	Text	Interpretation
39.1	<i>In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information..... and data submitted to governments or governmental agencies in accordance with paragraph 3.</i>	<p>Article 10bis of the Paris Convention broadly defines unfair competition as <i>any act contrary to honest practices</i>.</p> <p>Examples include such acts as dishonest, fraudulent business practices, misappropriations, theft etc.</p> <p>Permissive reliance of test data received from the patentee by the authorities after expiry of patent period is not tantamount to unfair competition. It is not a dishonest business practice either.</p>
39.3	<i>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.</i>	<p>Article 39.3 neither refers to “data exclusivity” nor market exclusivity rights for a fixed period.</p> <p>It only requires “data protection” against disclosure and unfair commercial use.</p> <p>The obligation is to protect data confidentiality and not grant of any exclusivity rights to the data.</p> <p>GoI's Position:</p> <p><i>“While data protection is something which must be respected, data exclusivity is well beyond the provision of Article 39.3 of TRIPS Agreement... grant of data exclusivity for pharmaceuticals and agrochemicals would have considerable impacts....”</i></p> <p>– Min. of Commerce, Govt of India, 29th March 2011.</p>

The Article 39.3 of the TRIPS Agreement requires to be interpreted and understood applying the Latin maxim “*expression unius est exclusio alterius*” which means “**what is not explicitly included is thereby excluded**”.

WTO members' TRIPS obligation under Article 39.3 is limited to provide “data protection” to ensure that data are not disclosed directly to third parties while approving the generics. India's existing regulatory framework for medicines and pesticides adequately meet this obligation under TRIPS Agreement.

The data protection and non-disclosure obligation does not disallow permissive reliance of the test data for authorising generics as held by UNCTAD. This would not imply unfair commercial use.

“ **Authorities are not prevented... from using knowledge of such data for instance, to assess subsequent applications by third parties for the registration of similar products.** ”

- UNCTAD, The TRIPS Agreement and developing countries, UNCTAD/ITE/1, 1996, p 48.

Data exclusivity is a TRIPS-Plus privilege. Since it is a TRIPS-Plus privilege and not provided for in the TRIPS Agreement, the USA and EU force its inclusion in the Free Trade Agreements (FTAs) with developing countries.

Data exclusivity *de facto* confers market exclusivity beyond the patent period. The effect of this could be most egregious in India that has a robust generic industry. Generic pharma and pesticide products have a huge share of **56%** in India's chemical export of **\$48 bn** (2020-21).

Data exclusivity, if granted by India, other countries which rely on India's export will also suffer as data exclusivity will increase the cost of India's off patent - generic medicines and pesticides. It will considerably erode the export competitiveness of our generic products. Data exclusivity would weaken **Atmanirbar** and **Make in India** initiatives of the government.

