

Data Exclusivity

A TRIPS Plus Provision Impacting Farmers and Patients

1. All drug regulatory authorities require the first applicant to submit data on safety and efficacy of a new drug. Likewise, regulator for agro-chemicals and pesticides require the first applicant to submit data on safety and efficacy of a new substance.
2. The generation of this data requires substantial expenditure and effort including clinical/field trials. However, the subsequent applicants are not required to duplicate the effort as the safety and efficacy of the drug/substance is already established. They are required only to establish equivalence to the previously approved product.
3. The TRIPS Agreement therefore requires the Government to protect the data submitted for regulatory approval from "unfair commercial use" by the competitors. However, reliance on this data by the regulator for approval of subsequent applicants is not unfair commercial use. This is acknowledged by several international organizations and eminent authorities.
4. The TRIPS Agreement requires protection of data, not data exclusivity, which in the present context is synonym with market exclusivity. This market exclusivity results in extended legal monopoly. It can be granted whether the product has patent or not and is in addition to the period of exclusivity granted under the patent. Unlike in the case of patents which can be challenged and invalidated, data exclusivity cannot be challenged.
5. The WHO Commission on Intellectual Property Rights, Innovation and Public Health has recommended that:

"A public health justification should be required for data protection rules going beyond what is required by the TRIPS Agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, 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."

The basis of the above conclusion and the factors relevant to weighing pros and cons are best stated by the Commission itself in its Report on p 126.

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6. A principal argument of the proponents of data exclusivity is that it would result in increased foreign direct investment. However, the available data suggests that the introduction of data exclusivity in other countries has not resulted in any greater proportion of R&D expenditure being incurred in these countries.
7. The introduction of data exclusivity would delay the entry of affordable generic product. This is corroborated by an analysis of the new drug approvals by the EMEA for three years (2007-09). The analysis shows that of 113 drug products approved, 92 were granted data exclusivity. Of these 92, 32 drugs did not have subsisting patents for the actives. The patents had either expired or were not patentable, but they were eligible for data exclusivity. Of the remaining 60 drug products, the data exclusivity for 38 had monopoly beyond expiry of patent. Thus, 70 of 92 products approved in the EU in 2007-09, the data exclusivity period extended beyond patent expiry.
8. If India were to go TRIPS Plus and introduce data exclusivity for agro-chemicals, pesticides and medicines, not only the small farmers and poor patients will be denied access to affordable, competitively priced products, but the domestic industry will suffer irreparable loss as its ability export these products will be severely compromised.
9. The Parliamentary Standing Committee on Commerce had therefore observed in its Eighty Eighth Report on Patents and Trademark Systems in India that since the consequences of data exclusivity are quite serious, "the Committee strongly recommends 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 USA, as the developed countries, particularly the USA, are trying to bring in certain TRIPS Plus measures through Bilateral and Regional Agreements."

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