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Unfair commercial use of regulatory pharmaceutical data

According to article 39.3 of the TRIPS Agreement, *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.*

The notion of unfair commercial use remains one of the crucial interpretative issues of the quoted provision. The main question is whether a reliance by a national authority on data submitted by one entity in order to evaluate a subsequent application, filed by another entity, constitutes an "unfair commercial use" of the data.

This paper aims at discussing possible interpretations of article 39.3 TRIPS and presenting divergent ways of its implementation in various legal systems with reference to pharmaceutical and agrochemical products.

Three main approaches are indicated and analysed here:

- exclusivity approach – existing in the UE and US pharmaceutical legislation,
- compulsory licence approach – present in the EU and US agrochemical legislation,
- free reliance approach – on the example of pharmaceutical and agrochemical legislation of India.

At the end the paper deals with the issue of expansion of the exclusivity approach through growing number of the EU- and US- free trade agreements, assessing it i.a. in the light of the concept of ceiling rules in TRIPS.