

Data Protection: Emerging Trends

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Data exclusivity is one of the critical issues related to the pharmaceutical and agro-chemical intellectual property rights. It arises from the regulatory frame work for the marketing of medicines and agro-chemicals in the national jurisdiction. Every country has its own regulatory mechanism for the marketing approval of above products. The procedure is that the manufacturers of the above products should submit pre-clinical and clinical data relates to the safety and efficacy tests conducted by the approval authority for getting marketing authorization. The pertinent issue here is the direct and indirect use of the submitted data for subsequent registration of products similar to those originally registered.

In the United States, European Union and other developed countries, data exclusivity form of protection is given to the submitted test data. It means regulatory authorities will keep this data secret and they will not rely it for the marketing approval of subsequent manufacturer. The period of protection extends from 5-15 years. In the case of pharmaceutical data the period of protection is normally 5-10 years, where as in the case of agro-chemical data the period of protection is normally 10-15 years. Most of the developing countries do not have any form of protection to submitted test data. Regulatory authorities in those countries rely on the originator company's data when examining subsequent application for the same products. The generic manufacturers normally conducts bio-equivalency test and only wants to prove that their product is equivalent to the already approved originator's product. This process of regulatory approval system helps the generic manufacturers to market the products immediately after the expiry of patent period in the case of patented products which will eventually reduce the price of the products.

To change the existing form of regulatory approval mechanism in developing countries, in 1987, the United States under pressure formed the multinational drug and chemical companies introduced data exclusivity as a component in the intellectual property negotiations of GATT. Developing countries like India, Argentina

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opposed the inclusion of data exclusivity as a negotiating proposal in the Uruguay round negotiations. For these countries, data exclusivity is not a form of intellectual property right since the requirement of disclosure, could not be enforced in this case. The protection of data is better served by contract and civil law rather than intellectual property rules. Finally, the protection of test data is adopted subject to unfair competition rules provided under Article 10{bis} of Paris Convention for the protection of industrial property. It was added in Article 39.3 as the last substantive provision in the TRIPS Agreement and reads as:

Members, when requiring, as a condition of approving the marketing of pharmaceuticals 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.

The subject matter of the protection under this provision is undisclosed information contained in written material which details the results of scientific health and safety testing of drugs and agro-chemicals, in relation to human, animal and plant health and its impact on environment. The data to be protected must relate to a new chemical entity and obtaining it involves considerable effort. The protection is against unfair commercial use. Considerable controversy exists about the interpretation of what constitutes new chemical entity and what is unfair commercial use.

Generic pharmaceutical companies have been advocating 'new chemical entity' to be defined on the lines of novelty under the patent regime, while the pharma MNC have been advocating a definition to mean a new pharma product which has been introduced for the first time in a country irrespective of the fact whether it is patented or not. In the case of agrochemical products also MNC's are defining NCE in the latter way. But according to the standard interpretation, there is no obligation to provide protection when the test data is developed for new indication, dosage forms, combinations, new forms of administration, crystalline forms, isomers etc., because there would be no novel chemical entity involved. If the protection is granted to all kinds of chemical entities that do not have substantial innovation it will create unjustified monopoly resulting in far reaching consequences on public health.

Another controversial matter is that what constitutes 'unfair commercial use' under Article 39.3. According to US and EU any use of data submitted by the originator, for granting approval to a subsequent applicant without the authorization of the originator of the data must be considered as unfair commercial use. So there is an obligation for granting the originator of data a period of exclusivity. Hence, national authorities would not be permitted during the exclusivity period to rely on data they have received in order to assess subsequent applications for the registration of similar products.

The majority of the scholars and developing countries hold another view, that Article 39.3 does not require the recognition of exclusive rights, but protection in the frame work of unfair competition rules. Hence, the obligation of WTO member countries is to prevent the third parties from using the results of the test undertaken by another company as background for an independent submission for marketing approval, if the data acquired through dishonest practice. The use of data by regulatory authorities which is essentially a statutory function does not constitute unfair commercial use under the purview of Article 39.3.

After their failure to include fixed period of data exclusivity in the TRIPS Agreement, US is trying to impose this TRIPS-PLUS agenda through bilateral free trade agreements and bilateral trade retaliatory measures like Special 301 provision of US Omnibus Trade and Competitiveness Act. As part of this game US is pressurizing government of India to adopt data exclusivity. In India the existing practice is to give marketing approval to subsequent manufacturer through bio-equivalency test. In February 2004, Government of India constituted a high level Committee with the mandate to find out whether protection is needed, if at all it was, and how it would be enacted and enforced. After the adoption of US-India joint statement regarding the adoption of vibrant intellectual property regime and inclusion of India in the priority watch list of Special 301, there is intense pressure over government of India to enact data exclusivity which is clearly TRIPS PLUS.

Government is planning to Amend Insecticide Act, 1968 to provide 3 year data exclusivity by defining NCE as a new chemical mixture which contains an active ingredient that have not been previously approved in India. Even if the product has been previously approved in another country it still remains an NCE in India. If this decision is include in the Insecticide Act it will be death knell to domestic pesticide

manufacturers which is playing a vital role in keeping price of pesticides to normal level which is essential for a predominantly agriculture country like India.

In the case of pharmaceuticals, Ministry of Health is objecting the adoption of data exclusivity, by arguing that it is clearly TRIPS PLUS or Article 39.3 Plus. The argument raised by Ministry of Health is in consonance with the arguments of international intellectual property law experts like Carlos Correa and Prof N.S Gopalakrishnan. They argued that Article 39.3 oblige member countries to provide minimum protection to submitted test data i.e., "protection against misappropriation". Any other definition is against the negotiating history and object and principle of TRIPS Agreement and Paragraph 4 of Doha Declaration of Public health.

So as a concluding word, India has an obligation to provide trade secret form of protection to submitted test data than data exclusivity model which was rejected during the negotiating period of TRIPS Agreement. Trade secret form of protection will not affect the access to affordable medicines. Hence, Government should amend Drugs and Cosmetics Act and Insecticides Act to add trade secret form of protection to submitted test data rather than exclusivity. It should also take care about the effect of data protection in the working of compulsory license and Bolar exception under the Patent regime.