Linking Patent and Data Exclusivity

It is rightly said that developing a drug is a risky business as launching a new drug to market requires huge amount of investment in terms of money and time involved in research and development starting from drug discovery, efficacy confirmation, clinical trials, drug regulatory approval for marketing of a product including a number of compliances.

To start marketing a drug, company needs to take approval from drug regulatory authority. The regulatory approval is granted on the basis of clinical trials data. Clinical trials (which take a really long time) are must for Drug regulatory approval. Thus, by the time, clinical trials are completed for a drug; a large span of the patent term has expired.

To address the situation, many countries in the world have Data Exclusivity Provision which provides the originator company with rights to exclude third parties from relying on the data to obtain marketing approval for a specific period of time. Though, it does not prevent third parties from generating their own data. It essentially allows for a period of time during which the competing firms may not use the innovative firm's safety and efficacy data (proprietary preclinical and clinical trial results) to obtain marketing authorization for a generic version of the drug.

Indian Scenario

The Drugs & Cosmetics Act, 1940 is the primary legislation for the drug regulation in India. As of now, the Indian law has no statutory protection for the data that is submitted to regulatory authorities for seeking marketing approval of drugs.

The requirements of data submission on animal testing for permission to undertake Phase I, Phase II and Phase III clinical trials were laid down in the revised Schedule Y of the Drugs and Cosmetics rules (elaborated below).

- Section 2.4 (a) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says for those drug substances which are discovered in India all phases of clinical trials are required.

- Section 2.4 (b) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says that for those drug substances which are discovered in countries other than India; the applicant should submit the data available from other countries and the licensing authority may require him to repeat all the studies or permit him to proceed from Phase III clinical trials.

- Schedule Y of the Drugs and Cosmetics Act 1945 which makes the entry of generic drugs relatively easy and expeditious under DCA. Generic manufacturers are only required to prove that the generic version is bio-equivalent to the original drug.

The advocates for data exclusivity put forward the following arguments:

- Protection should be in the form of exclusivity for a period of atleast 5 years from the date of market authorization.

- Since, data exclusivity is not related to patent protection, therefore it should be provided irrespective of the life of a patent.

- Since a large sum of money is spent in generating the data and information, it is unfair to allow other companies to use that data, without investment and going through the arduous process of generating information, for developing generic versions of the drug.

The issue of Data Exclusivity has also been addressed by Delhi High Court in a recent decision titled ROCHE PRODUCTS (INDIA) PVT LTD & ORS versus DRUGS CONTROLLER GENERAL OF INDIA AND ORS where Biocon and Mylan produced biosimilar of Roche's breast cancer drug (Trastuzumab). The Patent for Roche drug expired in the year 2010, pursuant to which Biocon and Mylan had been selling the biosimilar version of Trastuzumab after obtaining approval from DCGI.

Amongst the various issues addressed by the court, one was about the legality of DCGI's decision to grant approval to Biocon (defendant no. 2) and Mylan (defendant no. 3) in the absence of any phase 1 and phase 2 clinical trial.

Addressing the issue, the court stated following:

"No doubt, defendant No.2 is entitled to rely upon the plaintiffs' published data relating to the plaintiffs' Trastuzumab which can be used by defendant No.2 for conducting comparative tests and thereby establishing biosimilarity but such use cannot be extended to defendant No.2's test dossiers and/or marketing material in the absence of all clinical trials required"

"After having considered the arguments of the parties, I am of the opinion that unless Government of India frames policy to declare as to whether after expiry of patent, the data in public domain can be used as pathways or not, the regulatory authority can neither disclose nor rely upon the first applicant's data at the time of granting marketing approval to the subsequent applicants. It is for the Government to decide that such protection for certain fixed period to the innovator should be granted or not."

With the above finding/s of court, it can be foreseen that the data exclusivity provision may soon be mooted in India. There are news reports of Pesticides (Amendment) Bill being introduced in parliament to grant data exclusivity for a period of five years.

The news of the Data Exclusivity Regime however brings question on the implication of these provisions on public health and scope of such provision. The question being asked is whether the data exclusivity term should be independent of Patent term or overlap with the patent term. In other words whether the patent and data exclusivity should be linked or kept as separate provisions. At the same time raising the question whether TRIPS provide for such exclusivity, the interpretation of Article 39.3 of the TRIPS and if it obliges data exclusivity or not.

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