Data exclusivity - a practical model for India

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Post WTO-TRIPs compliance, Indian pharma industry's wish-list would naturally have been dominated by a data exclusivity free regime. A plain and sensible reading of Article 39(3) of TRIPs would lead a public interest protagonist to believe and hope that this scenario prevails. However, if not by express interpretation, but by implied compliance, majority or almost all countries have, one way or the other, opted for providing data exclusivity. While a few developing countries are opting for strengthening data exclusivity, the majority of developing countries having domestic pharmaceutical manufacturing and research (developmental) facilities, are looking at or re-looking at ways and means of protecting National Health and public interest needs and emergencies without unduly compromising the international reputation on TRIPs compliance.

At a time when the TRIPs compliance issues are being challenged by an overseas corporation (with domestic links) in an Indian Court (?) and at this juncture, when a basic preliminary draft of data protection is being discussed by Inter-ministerial Committee, it may be worthwhile to look at our options while complying with Article 39(3) of TRIPs.

On an earlier occasion the following options were suggested:
1)Data Exclusivity for a fixed period to be calculated from a common priority date of first market approval any where in the world.
2)One "NCE" based dosage form only to be considered. New use or indication, new strengths, new packings, change in excipients or delivery system not to be considered for additional exclusivity.
3)Exception from "Data Exclusivity" to be given to compulsory licence holder to obtain regulatory approval under a granted compulsory licence.
4)All "Data Exclusivities" to expire with the expiry of the corresponding NCE Patent.
It is understood that an option for grant of generic approvals based on bio- equivalence reports without "government use of clinical data" submitted by innovator, provided there is no patent infringement issues, is top on governments current consideration. While this might ideally overcome objections to "use" (unfair or commercial or not) of "data", this might still not satisfy the protagonists of a strict data protection regime. The other option of granting 3 to 5 years (why not 4 years as in existing new drug approval in Schedule 4 of Drugs & Cosmetics Act) as in 122 E - Explanation (ii), would probably meet all aspirations of data exclusivity. However, this option can be implemented in India, only with adequate provisions to protect public and national interests.

An option of restricting data exclusivity only to
1) New Chemical Entities (NCEs)
2) Those drugs which are introduced in the country within a year of its global launch (1st introduction in a WTO member country).

3) Direct commercialization and voluntary licences (and not to compulsory licences)will probably meet the balancing requirements essential to protect public health interests as well as health emergency solutions, with any of the above options.

Unlike (the non-event that it is) the TRIPs review promised in the TRIPs Agreement itself (with 4 years), it would be advisable to incorporate a provision that the terms of data protection/data exclusivity will be reviewed after 3 years.

While majority of SMEs are not even aware of the implications of data exclusivity, a few semi-literate Indian pharma companies and researchers are clamoring for introducing data exclusivity. Introduction of data exclusivity in pharma field, would adversely affect at least partially, the hitherto proven capabilities of Indian generic industry. Consequently, there will undoubtedly be a short term monopoly and adverse pricing scenario impacting public health interests. Being a recognized international pharma front runner and forward player, India would do well to keep up its image as an IP/patent/data honoring participant. While doing so India could articulate its designs to tackle the public health interests and related balancing provisions as a model to the rest of the world, especially developing countries who are grasping for ideas and solutions.

The contribution of Indian national pharmaceutical industry, its entrepreneurship, research and development capabilities and above all its services to the healthcare sector through affordably low-priced essential life saving as well as latest research molecule-based advanced dosage forms have never been adequately acknowledged at home. Indian Pharma's potential and capabilities have, however, found widespread acknowledgement and appreciation overseas, especially among developing and least developed countries. At the same time, the "big pharma" companies in developed countries, such as Europe and USA, have not only got alerted to the threat of impending technological dominance from India, but also have realized the need to restrict and stifle the strong entrepreneurial initiatives. Fortunately for them and unfortunately for the domestic industry, a few governmental agencies, departments and ministries have been helping the cause of dousing the fire of National Pharma's self-motivation and enthusiasm to move up the pharma research ladder. One of the highly debated and controversial "TRIPs compliance" agenda which could impact Indian domestic pharma's future growth profile is "data exclusivity". Even though, the industry has serious concerns to adopt this provision, the global direction in which Indian pharma is growing, makes it imperative for India to provide confidence and assurance to our overseas partners and clients that we prefer "compliance" within flexibilities, without prejudicing domestic national public health interests.

A practical model for drug exclusivity which takes care of the national needs for healthcare support can be envisaged to assuage the pressures and anxieties of the developed member countries on the following lines:
1. Data exclusivity only for NCEs - Once a dosage form based on an NCE is granted a data exclusivity, other dosage forms, strengths etc. will be automatically share the same period and the exclusivity will expire simultaneously.

2. Data exclusivity restricted to only those NCEs whose dosage forms will be introduced in India within one year of its marketing approval elsewhere in the world or the starting of data exclusivity anywhere else (whichever is earlier).
3. The term for data exclusivity to be fixed for 4 years from date of application or 3 years from date of marketing approval, whichever is shorter.
4. Applications for marketing approval for generics which can be approved on the basis of bio-equivalence studies (without having to refer to the 'data') to be approved provided these generics are not infringing valid patents in India or are supported by valid patents in India (by generic applicant).
5. Grant of compulsory licenses to be also deemed as eligible for access to "data" being not unfair commercial use. Once a compulsory license is granted, the submission for marketing approval or export approval to be granted exempting such examination for approval from provisions of data exclusivity.
6. The provisions as above relating to data exclusivity in pharma to be reviewed within a period of 4 years from commencement of the procedure.
7. A "data exclusivity" monitoring and review committee to be formed, having representatives of Health Ministry, DCGI, ICMR, Ministry of C&F, Commerce and Industry as well as industry associations, intellectual property practitioners and public health related NGOs.

Any suggestion on a highly controversial subject such as "data exclusivity" is bound to draw fire from all "sides". A suggestion is, however, better than no suggestion.

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