Data protection a must for sustainable agriculture

UTTAM GUPTA

THE Third Patent (Amendment) Bill provides for product patent in a number of critical, knowledge-intensive sectors, including agrochemicals. Simply put, this will give the patentee exclusive rights to manufacture and sell the product during the life of the patent.

All along, the Patent Act provided for patenting of the "process" only. This led generic players to come up with the "copycat" system by taking recourse to 'reverse engineering'. And since they are able to produce at a fraction of the cost incurred by the innovator (due to savings on R&D, tests and trials), this seriously affects the innovator's ability to recover the investment. The introduction of product patent from January 1, 2005 will help level the playing field on this score. But this alone will not suffice.

Loaded in favour of me-too players

Concurrently, we need a major overhaul of the existing laws and regulations governing production/import, sale and use of the crop protection products, besides pharmaceuticals.

At present, our laws are heavily loaded in favour of the copycat producers/suppliers.

The Section 9(4) of Insecticides Act (1968) allows a subsequent applicant to manufacture/import and sell a new product registered by the original applicant on extremely generous terms, when compared to very stringent conditions imposed on the latter.

The registration of a New Active under Section 9 (3) involves submission of voluminous data including data generated in India and other countries. The data pertains to approximately 75 parameters covering technical and formulation details of the product. The dossier runs to some 40,000 pages.

The entire exercise, beginning with clearance of the product by the Central Insecticides Board for its inclusion in the Schedule and generation of the test and other data, to the submission of the dossier to the Registration Committee and its examination by the Registration Committee leading to the grant of registration takes about 3-4 years and costs the original registrant huge sums of money.

In sharp contrast, a subsequent registrant (known as the "me-too" registrant) for technical import/formulation gets the registration in just 45-60 days and for a mere Rs 100. In technical indigenous manufacture, the "me-too" registrant is only required to generate certain basic data and gets registration in about eight months to one year.

In view of the above, the "me-too" registrant is clearly placed in an advantageous position *vis-à-vis* the original registrant in terms of both time and money. While the innovator spends heavily in research, discovery and development of a new molecule, and thereafter in getting regulatory approvals (about Rs 1000 crore), the me-too registrant enjoys the fruits of his efforts.

The regime after January 1, 2005 will provide little comfort for products that are off-patent or cannot be patented (because these were filed before January 1, 1995 or do not conform to the definition of what is patentable); the "me-too" registrations will thus continue to be given.

Violates TRIPs

Globally, there exists a vast pool of technologies and new generation products that can benefit Indian agriculture. The farmers need these badly to meet the increasing threat from pests under the accelerated high-yielding varieties action plan, make agriculture environment-friendly and meet international quality standards for our agricultural exports. The provision for the "me-too" registrant acts as a major disincentive to introduction of these products.

Significantly, the Insecticides Act (1968) violates the Article 39.3 of the TRIPS (Trade Related Intellectual Property Rights) Agreement of the WTO. The article states:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural products which utilise 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".

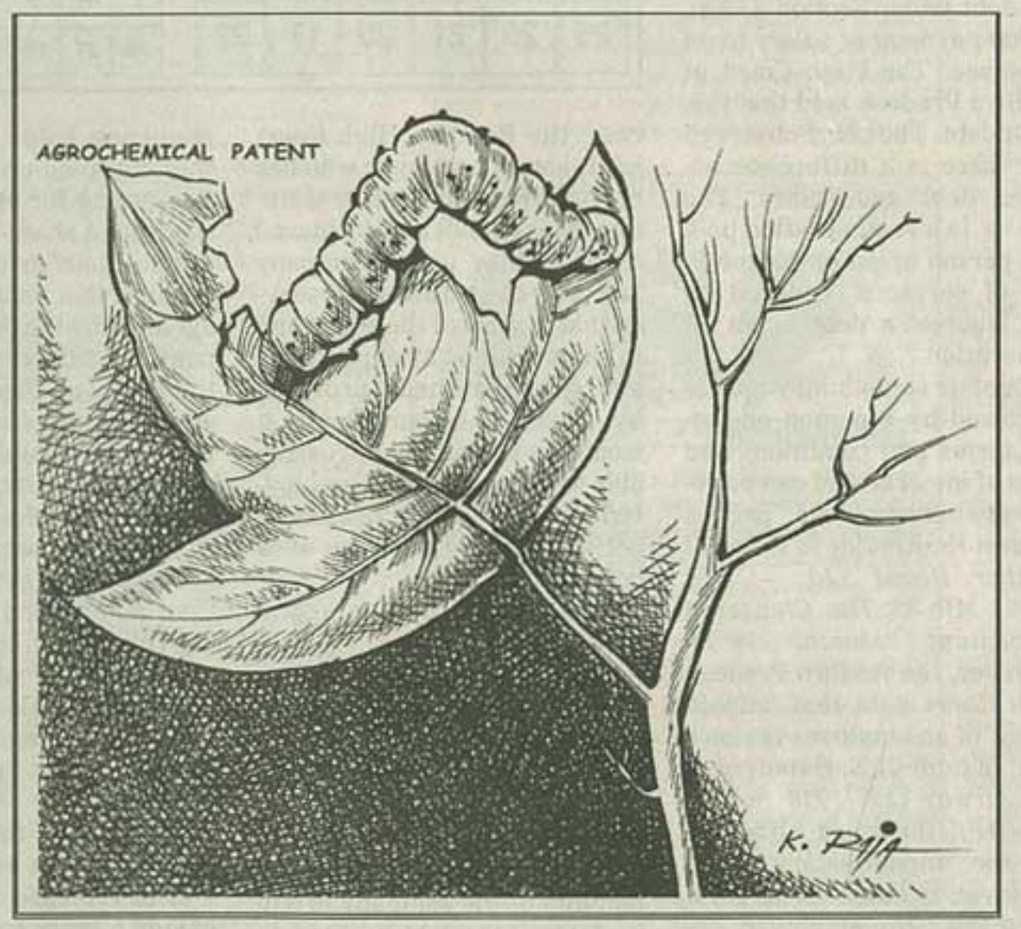
When the Registration Committee grants marketing approval to the "me-too" registrant, it actually relies on the test and other data submitted by the originator. Technically, though, at the time of giving registration to the former, it may not be actually using latter's data, the reliance is inherent.

For giving registration to the original applicant, already, the Registration Committee has thoroughly examined the data and thus satisfied it self about the efficacy and safety of the product. Therefore, it need not repeat this exercise at the time of granting approval to the "me-too" who comes to it seeking registration for the same/similar product.

We can look at this from another angle too. Contemplate a scenario where the registration of the original registrant has to be cancelled due some reason. This would automatically lead to cancellation of the registration of the "me-too".

Contrary to the impression in certain quarters, the provision for data protection is totally independent of the product patent (that is why these are included in separate sections of the TRIPS Agreement). While the latter is a contract between the innovator and the society and is meant to reward him for his innovative efforts, the former obliges the national regulatory authority to protect the undisclosed data.

The load of Article 39.3 is primarily on protecting the undisclosed test and other data, the creating of which requires considerable effort, against unfair commercial use. Such protection



cannot be denied simply because a product is off-patent or is not patentable.

Market protection necessary

It needs to be clearly understood that data protection and market protection are two sides of the same coin. The moment someone other than the original registrant gets the approval to market the same/similar product, data protection is automatically lost. Without market protection, data protection has no meaning!

The preferred mechanism adopted worldwide to protect data against unfair commercial use is an exclusivity period during which no third party may enter the market without filing its own safety and efficacy data, unless it has the approval of the titleholder of the data.

Additionally, and subsequent to the exclusivity period, the legislation provides for a compensation period, during which the competent authority may grant a marketing licence to the copy product, with an obligation on the part of the copy applicant to compensate the titleholder for the relevant studies.

Once these periods have expired, the competent national authority may grant registrations through a summary approval procedure (such procedures exempt an applicant for registration of the copycat from filing the corresponding safety and efficacy studies), but it remains under obligation to protect the studies against disclosure. In the US, the protection for a new agrochemical products consists of a 10-year exclusivity period from the date of registration, and 15 years of compensability from the date of submission. Likewise, in the European Union, the protection given to studies for agrochemical products is from 10 years of exclusivity for initial data and of five years for the additional data.

Significantly, the above norms for agrochemical products are much more stringent than the corresponding norms prescribed for the pharmaceutical industry.

In the US, for instance, the exclusive protection period for the safety and efficacy studies for the latter is limited to five years, against 10 for the former. The longer protection period for crop protection products is in recognition of the high investment risks associated with their development and maintaining existing approvals.

While in the pharmaceutical sector, one in every 5,000 molecules investigated is approved by the FDA (Food and Drug Administration), in agrochemicals, only one in 140,000 molecules studied makes it from the laboratory to the field.

Because of their chemical nature and wide range of organisms potentially affected by their use, agrochemical products have to pass through more than 120 different safety tests. Additionally, efficacy tests must be repeated in each country, even in several regions of one country, due to differences in crops, pests, agronomic practices, climatic conditions and terrains.

Apart from the developed countries, a number of developing countries also provide for data protection for Agrochemicals. For instance, China provides seven years of data protection for New Actives, five years for New Formulations and five years for New Uses. Malaysia, the Philippines and Taiwan provide for data protection of 6-8 years.

Here in India, at present, no protection is available for agrochemical products. To protect the test and other undisclosed data from unfair commercial use and meet obligations under WTO, the Insecticides Act needs to be amended to allow to the original registrant a minimum exclusivity period of five years from the date of registration. During this period, the "me-too" registrant should not be allowed to enter the market without filing his own safety and efficacy data.

The above will strike a judicious balance between the need to suitably compensate the original registrant for the efforts involved in generating the test and other data, on the one hand, and preserving the market entry of generic products without having to generate their own studies, on the other.

This fundamental change in the Act will motivate the R&D companies to accelerate the pace of transfer of new generation pesticides, increase their manufacturing bases in India and use it as a sourcing hub for export of agrochemicals worldwide. Besides, this will contribute phenomenally to research aimed at finding new solutions to the problems of dynamic agriculture.

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