

# Crop protection products Data-holder deserves a better deal

*The original registrant of a crop protection product demonstrates its safety and efficacy to the regulator, and is committed to quality and stewardship through the product's life cycle. Farmers bank on him for new solutions to meet their crop protection needs. He should thus be assured of a certain period of data exclusivity during which he can recover the huge costs incurred in developing the product, says Uttam Gupta.*

**A**N innovation has no meaning unless it is used for economic development and the benefit of society. This involves huge efforts, particularly for crop protection products (CPP), where concerns of safety and efficacy prompt the regulator to impose stringent conditions.

These conditions require the applicant to *inter alia* conduct studies, spread over several years, to generate data.

The data generated has considerable value. It is in no way different from a tangible asset (such as land, plant and machinery) that a person acquires by spending money and effort. But when it comes to protection of rights, the person owning the data is discriminated against. Under the Indian laws, he gets no protection at all.

The owner of the data faces three types of risks. First, someone may steal his data. Second, the data submitted to the regulator may be disclosed to a third party. Third, the regulator may rely on his data for giving market approval to subsequent applicants.

Under the Insecticides Act (1968), the Registration Committee (regulator in the Ministry of Agriculture) gives market approval to a 'me-too' registrant u/s 9(4) for products registered by the original applicant u/s 9(3) on the same terms as applicable to the latter. A 'me-too' registrant does not have to submit any data!

Applicants also get registration under TIM (Technical Indigenous Manufacture) for products registered by

original applicants. A subsequent applicant has to submit minimal data to establish equivalence with the product of the original.

A 'me-too' registrant thus gets market access at virtually no cost. In contrast, an original registrant spends millions of rupees in conducting studies in the country. Added to this, several crores are spent for the cost of studies done outside the country to meet regulatory requirements.

Armed with an unfair advantage (conferred by law), the 'me-too' registrant is thus able to price his product much lower than the originator's product and yet make fantastic profits, while, the latter struggles to recover the millions spent on meeting regulatory requirements.

The law also creates a fertile ground for a flood of applicants. When one can get market entry by spending a mere Rs 100 (application fee), the temptation is too strong to resist. No wonder that the regulator receives 250-300 applications a month!

Some of us may be led into believing this is good. By adding to the number of suppliers, it promotes competition, which helps consumers by lowering prices. But what about quality and extension services (such as how to use, how much to use and when to use) that are a must for ensuring safe and judicious use of hazardous substances such as CPP?

The farmer can be assured of all these, if the product is supplied by the original registrant.

The original registrant is the one

who has toiled to demonstrate the safety and efficacy of the product to the regulator. He is committed to quality and stewardship all through the product's life cycle.

He is ever ready to conduct fresh studies and generate data to meet any new requirements that may be thrown up by persistent use or any new developments in pesticide science. More important, the farmers can bank on him for getting access to new solutions and technologies for meeting their dynamic needs.

In sharp contrast, one single act of the regulator in allowing easy entry of the 'me-too' registrant (riding piggyback on the original registrant) is enough to make him complacent and unconcerned with any of the above aspects.

Moreover, there is nothing in the Insecticides Act (1968) that will make him maintain discipline and quality. For instance, the Act does not contain any provision for minimum manufacturing and safety standards.

It has no provision for cancellation of the certificate of registration. So, even if someone is found selling substandard products, the regulator cannot cancel his registration. While the entry of the 'me-too' registrant is very easy, his exit is nearly impossible.

To sum up, a registrant, who is committed to the long-term prosperity of the farmer, is meted out discriminatory treatment *vis-à-vis* a registrant who has no such inherent commitment.

While the latter gets a chance to make a quick buck, the former struggles to recover his sunk costs. Worse, even as reputed companies are often harassed by quality control inspectors, fly-by-night operators go scot-free.

To increase agricultural production to the targeted 4 per cent per annum in the next decade, we have to bring about a substantial increase in crop yield per hectare. This will require an increase in irrigation, cropping intensity and the use of fertilisers, that will decrease the risk of pests and disease.

We can respond to the emerging challenge only by giving incentives to R&D-based companies, to bring in new

solutions to meet the dynamic needs of farmers and set up more research facilities in the country. The need for granting data protection has to be viewed in this perspective.

Article 39.3 of the TRIPS Agreement provides for protection of data against both "disclosure" and "unfair commercial use". The issue is being looked into by an inter-ministerial committee under the chairmanship of the Secretary, Department of Chemicals and Petrochemicals in the Ministry of Chemicals and Fertilisers.

While formulating its proposals, the Committee may consider the following.

First, an applicant seeking registration for a product has to give a declaration that either he is the owner of the data or he has been fully authorised by the person who generated it. The law must provide for stringent punishment for any violation.

Second, the regulator has to take foolproof measures to ensure that the data is not leaked or disclosed to any third party. This obligation should also be applicable to an organisation (for instance, Indian Council of Agricultural Research) to which the data may be given for assessment and evaluation.

Third, the regulator should not grant market approval to a subsequent applicant who cites the data of originator without his authorisation. The regulator must not, on its own, use the originator's data for giving approval to a subsequent applicant.

To determine the period of exclusivity (the period during which 'me-too' registrants are denied market access based on the originator's data), the Government should keep in mind the costs incurred in generating data, getting regulatory approvals and the recurring expenses incurred thereafter from product stewardship.

After the exclusivity period is over, the regulator may grant registration to a competitor after being satisfied that his product is the bio-equivalent (equal in quality) to the originator's product (active ingredient, impurities etc must be the same).

However, it must continue to ensure

protection of the originator's data against disclosure. The above prescription needs to be viewed in the light of removing discrimination against the originator. This will help create a level playing field and give companies the much-needed incentive to invest in creating new solutions for the benefit of farmers and agriculture.

Often, data exclusivity is confused with market exclusivity. The former is not the same as the latter. The former merely ensures that the originator's data is not used for giving market access to a competitor. It does not prevent the latter from getting registration based on his own data package. With product patent in place, there is no need for data protection or data exclusivity.

Patent and data protection are fundamentally different forms of protecting intellectual property (for details, refer article in *Business Line* dated January 4). That is why these are addressed in separate sections of the TRIPS Agreement under the World Trade Organisation.

The Government should take prompt measures (both legal and administrative) to protect the data submitted to the Registration Committee for getting market approval of CPPs against "disclosure" and "unfair commercial use". Data exclusivity has to be allowed till the originator gets a level playing field *vis-à-vis* the competitors. And protection against disclosure has to be indefinite.

This will (i) enable farmers gain access to new solutions and technologies for combating pests and diseases;

(ii) enable farmers improve crop quality and yield and enhance the country's reputation as an exporter of quality agriculture produce in the world market;

(iii) reward scientists in research institutes and agriculture universities for their efforts, and

(iv) make the country a hub for R&D in all areas, including basic research

*(The author is Resident Director, CropLife India, New Delhi. The views expressed are personal.)*