

A win-win for all stakeholders

UTTAM GUPTA

THE Prime Minister has called for raising agriculture growth to 4 per cent annually to achieve an annual GDP growth of 8 per cent. Even as the farmers gear up to meet this challenge, the threat from pests and disease will increase.

We can combat this only by making way for newer and safer solutions, increasing investment in R&D and enhancing commitment to stewardship. The importance of a law on data protection has to be seen in this wider context.

In crop protection products (CPP), innovations involve huge spending. The discovery of a new pesticide molecule costs about Rs 500-600 crore. Almost an equal amount has to be spent in conducting long-term studies to commercialise it for use by farmers.

An innovator company must get an incentive to be able to recover these huge sums. The TRIPS Agreement under the WTO does this by requiring member-governments to provide for grant of patent and data protection respectively.

While the Government has already introduced product patent from January 1, a legislation on data protection is hamstrung due to the fear that this will perpetuate the monopoly power available to a patent holder. This is a myth.

Data protection is totally independent of IPR (recognised under TRIPS) and has nothing to do with patent. While the latter protects the innovation, the former protects the data generated for getting market approval of a new CPP.

To be more specific, data protection is meant to protect the investment of Rs 500-600 crore on long-term studies and the additional crores of rupees spent on generating local data to assess the safety and efficacy in Indian conditions.

Generally, both the functions — innovation and commercialisation — are performed by the same entity (an innovator has an inherent interest in seeing its baby blossom under his jurisdiction and control). But that should not lead us to believe that these functions overlap.

A patent-holder enjoys market exclusivity over the protected product. On the other hand, data protection does not offer market exclusivity. It merely protects the data of the originator. However, any other person is free to generate data and get market approval.

In view of this, one can have any number of registrations for a new CPP (supported by original studies). Any apprehension of data protection leading to monopoly in the market place is, thus, a myth.

Some feel that once the patent is granted, the requirements of data protection are automatically taken

care of. So, why should the latter be given separately? This again is a misconception. It arises in the context of the following typical situation.

For a 2005 invention, the innovator will have patent protection till 2025. With market approval in 2015 (allowing 10 years to reach that stage), data protection period of, say, for five years will continue up to 2020. Since this falls within the period of patent protection, it may appear irrelevant!

In the above situation, the innovator may be able to prevent "unfair commercial use" of his data. But in the absence of a law on data protection, he will remain vulnerable to poaching of his data (Article 39.3 of TRIPS provides for protection against both 'disclosure' and "unfair commercial use").

Critics often argue that consumers will have to pay more for data protected product. This is baseless. As

With data protection in place, we will not only avoid all the pitfalls of the present regulatory environment, but also reap a host of potential benefits for the economy and society. It will be a win-win for all.

already clarified, any number of suppliers can come in, based on their own data package. So, where is the scope for the consumers being fleeced?

Failure to protect the data has led to lopsided growth of the pesticide industry. A mind-boggling 80,000 registrations have been granted to around 400 units. Products such as monocrotophos, butachlor and several other large volume products have more than 200 registrations.

This has led to build up of huge over-capacity, leading, in turn, to unethical trade practices — supply of stock on consignment basis, long credit periods, product dumping and cutting corners on quality.

Products are sold even on unapproved crops, due to huge pressure to 'liquidate' stocks due to excess capacity.

The 'me too' remain unaware of the 'knowledge' about the compound which they produce (though with different tox profile) through reverse engineering.

Consequently, there is no transfer of knowledge/technology (vital to get the best results) to the users of new but 'me too' products.

The large-scale proliferation — based entirely on the 'me too' principle — also greatly encourages spurious products. With over 200 registrations per molecule, misuse of manufacturing licence is too obvious. No wonder, we have a huge spurious industry estimated at Rs 1,200-1,500 crore.

The message is loud and clear. The Government should grant data protection to the original registrants of newer and safer CPP under Section 9(3) of the Insecticides Act.

Protection against unfair commercial use needs to be ensured by blocking registration under Section 9(4) for a period once a CPP is registered for the first time under Section 9(3).

This will give to the original registrants the desired benefit to cover the huge investment in data generation for registration and ensuring proper development of product use through stewardship in initial years for the farmers to enjoy the full benefit of the new solution. A host of other economic benefits will also flow.

Indian agriculture now loses about Rs 30,000 crore worth of standing crops due to pests, weeds, fungus, and so on. An equivalent amount is lost during handling, storage and transportation. All this can be prevented if we make way for newer and safer products by providing for data protection.

We have a huge pool of scientists working in CSIR, ICAR and various universities. Data protection will help in exploiting their full potential and enable them develop patentable discoveries at much lower cost compared to the developed countries. This will lead to investment in R&D and manufacturing, our knowledge and skill base being comparable to the best in the world.

This will also induce global companies to outsource data from Indian facilities; China is availing itself of such opportunity by providing data protection for six years/administrative protection (AP) for 7.5 years besides product patent. They will also set up R&D facilities in India.

The spin-off will be huge investment in research and ultimately in manufacturing — creating quality employment opportunity.

With data protection in place, we will not only avoid all the pitfalls of the present regulatory environment, but also reap a host of potential benefits for the economy and society. It will be a win-win for all. Even the 'me too' registrants have not much to lose.

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