# Data protection demystified

UTTAM GUPTA

IN THE context of the various amendments under consideration by the Government to make the laws compliant with the TRIPS (Trade Related Intellectual Property Rights) Agreement of the WTO, two major issues at the centre-stage are (i) product patents and (ii) data protection.

From available indications, it is clear that the product patent regime for the agrochemical, pharmaceuticals, bio-technology and food industries will come into force effective from January 1, 2005. However, there is no indication whether the data protection issue will also be taken up concurrently.

Data protection, as provided for under Article 39.3 of the TRIPS Agreement, is being examined by an Inter-Ministerial Committee under the Chairmanship of the Secretary, Department of Chemicals and Petrochemicals in the Ministry of Chemicals and Fertilisers.

A Group of Ministers (GoM) under the Chairmanship of the Defence Minister, Mr Pranab Mukherjee, has recently forwarded its recommendations on the Third Patent (Amendment) Bill to the Government. However, the GoM has not revealed its mind on the issue of data protection.

Meanwhile, the issue has got embroiled in controversy, primarily due to a perception that once the product patent regime comes in to force, there will be no case for data protection. In certain quarters, it is felt that grant of data protection will be tantamount to double protection and enable the patentee to extend the patent term.

Much of the confusion on the subject arises from the lack of proper understanding that these two forms of intellectual property rights (IPRs) are fundamentally different and serve different set of objectives.

Product patent is intended to reward the innovator in exchange for his sharing his innovation with the society. This comes in the form of an exclusive right for production, marketing and use of a product containing the innovation for a reasonable length of time called the patent term.

An innovation has no meaning unless it is commercialised. The innovating company has to traverse a long journey before the product reaches the market.Considering their chemical nature and wide range of organisms likely to be affected by their use, crop protection products have to pass some 120 safety tests. The steps in reaching a new pesticide molecule to stage of commercialisation entail a huge investment of about $140 million. This is equal to the cost of discovering the molecule. And, the time-frame could be up to 10 years.

Additionally, the innovator company spends several lakhs of rupees in generating data in India as per the registration requirements. In agrochemicals, this is a must, unlike in case of drugs, where this is not insisted on if the product is approved by the FDA (Food and Drug Administration) of the US.

Now, when we talk of data protection, the reference is essentially to the need for protecting data (generated in India and abroad) that an applicant must submit for the purpose of getting market approval of his product from the regulatory authority.

A patent is intended to recognise the efforts leading to the discovery of the new molecule. Data protection, on the other hand, is connected with the efforts that commence after the discovery and continue right up to the stage of commercialisation.

For market access, the innovator has to maintain a continuous interface with the regulator all through the life-cycle of the product (latter can call for information any time). As regards patent, it is a matter of choice whether he would like to seek/maintain it in any country.

*The recommendations on the Third Patent (Amendment) Bill to the Government have got bogged down in controversy primarily due to a perception that once the product patent regime comes in to force, there will be no case for data protection. There is a need to amend Indian laws to provide data protection for a reasonable period.*

When an innovation gets patented, the entire knowledge associated with this comes into the public domain. In contrast, the data submitted to the regulator for getting market authorisation (for evaluating the safety and efficacy of the product) is proprietary. It is given in good faith and the government is duty bound to keep it confidential.

Unlike a patent, which offers market exclusivity (ME) to the patentee during the term of the patent, data protection does not offer ME as a subsequent applicant can enter the market by conducting studies and generating his own data.

From the above, it is clear that data protection is a fundamentally different form of intellectual property than patent protection. This is recognised by the WTO by incorporating a separate provision for data protection in the TRIPS Agreement i.e. Article 39.3.

The Article provides for protection of registration data submitted to the Regulator for the purpose of getting market approval. The protection is against both "disclosure" as well as "unfair commercial use". The latter connotes that the Government must not give market approval to subsequent applicant relying on the data submitted by the original registrant. Several countries already provide for data protection. For instance, the US and EU and many countries in Latin America grant 10 years of data protection whereas China grants six years. In fact, China made the necessary amendments to provide for data protection even before its accession to WTO.

It is often argued that use of data by the government to give market approval to a subsequent applicant (without his own data package) does not constitute "unfair commercial use". This argument is flawed. This applicant has not made any efforts and yet he gets access to market.

The cost of bringing the product to the market by the "me-too" registrant being a fraction of the cost incurred by the original registrant, he can price it much lower than the latter and yet get away with hefty profit margin. Clearly, he gets an unfair commercial advantage.

On the other hand, the original registrant suffers an irreparable loss, especially in a situation where the Government gives market approval to a large number of "me-too" applicants. This results in a substantial erosion of his market share and he cannot even recover the investment.

This is typically the scenario for crop protection products under the existing provisions of the Insecticides Act (1970). The lack of data protection is a major stumbling block in the way of R&D companies bringing newer, safer and potent solutions to deal with problems facing farmers.

The critics of data protection often harp on the point that it helps in ever greening of the patent. Apart from ignoring the fundamental difference between the two forms of IP (as brought out above), this view is based on a misconception that the term of data protection continues even after the expiry of patent term.

The fact of the matter is that the terms of the patent and data protection run concurrently and invariably, the term of data protection comes to an end before expiry of the patent term. To illustrate, let us take the following example.

The innovator company gets a patent in 2005 for 20 years. And it gets approval to market the product in 2015. If data protection is given for six years (as in China), its term will end in 2021, whereas the patent term will expire in 2025. Even when data protection is for 10 years (the US), the term will end in 2025.

There may be cases where the company gets market approval after an inordinate delay — say, in 2020. In this case, the data protection term of 10 years will come to an end in 2030.

This goes beyond the date of patent expiry. Still, it is wrong to conclude that the benefit of patent gets extended.

Unlike the patent, which offers market exclusivity (ME), under data protection, there is no such thing as ME. Since a subsequent applicant can get market approval (subject to submitting his own data package), for the period 2025-2030, the innovator company does not enjoy ME.

Forget about benefit, the original registrant will lose heavily as the effective period of ME offered by patent would then have reduced to only five years (2020 to 2025) — because of the delay in getting market approval. This is too short for him to be able to fully recover the huge investment!

In view of the above, considering the huge effort involved — in time and money — in conducting studies/generating the registration data and provide incentive to R&D based companies to do so, there is an urgent need to amend our laws to provide data protection for a reasonable period.

Any apprehension that data protection will lead to increase in prices is unfounded. A new product will have to demonstrate value for the price tag put on it.

In other words, price will be determined primarily by the market dynamics.With access to newer and safer products and technologies, farmers will be able to improve the quality of agriculture produce and address environment concerns.

This will also help them make their products more acceptable in importing countries (in the new world trade regime, they have become more demanding in terms of quality) and increase exports.

A host of other benefits will accrue to the Indian economy by way of MNCs setting up R&D facilities here; outsourcing of data generation activities; employment opportunities for Indian scientists and making India a hub for the manufacture of crop protection products for supply to the rest of the world.

The generic companies too will have ample opportunities to grow. They can enter into fruitful partnership with MNCs. This may include contract manufacturing, marketing pacts, etc. Moreover, with an effective system of IP protection in place, they can also take up R&D on their own.

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