THE HINDU • BUSINESS LINE
TUESDAY, MAY 16, 2006

DATA EXCLUSIVITY VS PATENT

The myths and the realities

Uttam Gupta

Data exclusivity must not be confused with patent. For a patent grant, an innovation has to fulfill the three criteria of "novelty", "inventive step" and "capable of industrial application". Following patent grant, the entire knowledge associated with innovation comes into public domain, unlike in the case of DE.

In February 2004, the Government constituted an Inter-Ministerial Committee to examine whether our laws meet the requirements of Article 39.3 of TRIPS on Data Protection (DP).

The Article states: "Members, when requiring, as condition of approving the marketing of pharmaceutical or agricultural chemicals 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. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."

The above brief clarifies the scope and intent of the Article. It requires members to protect such data against both "disclosure" and "unfair commercial use". While the first requirement is straightforward, the second requires explanation.

Data have "commercial value" as they give the originator marketing rights. Now, if another person also gets these rights without having to submit his own data (hence, no effort), this will give the latter an "unfair commercial advantage".

This can be prevented by allowing a period of "exclusivity" (commonly called Data Exclusivity or DE) to the originator/first applicant during which period a subsequent applicant cannot get market approval citing former's data.

This will enable the originator recoup his investment in generating the data. At the same time, users will have access to the original knowledge (not possible if dozens of "me-too" registrants also apply from day one). On expiry of the DE period, the "me-too" applicants can be given market approval by demonstrating the parity of their products with that of the originator/first applicant.

The above dispensation fully complies with Article 39.3, is fair to all stakeholders and, in the current context, is in the best interest of Indian agriculture. Yet, the picture is clouded by a host of myths.

MYTH-1

The use of the originator's data by the government for giving market approval to subsequent applicants does not constitute unfair commercial use.

REALITY

The Registration Committee (RC) – a statutory body created under the Insecticides Act (1968) – is the sole authority that grants registrations for agrochemical products. Without its authorisation, no manufacturer/supplier can make/sell the product. Now, if the RC also grants registration to subsequent applicants without requiring them to generate their own data, that will constitute unfair commercial use.

MYTH-2

Under Article 39.3, India is under no obligation to grant DE; that by giving protection against disclosure alone, we would have complied with its provisions.

REALITY

Protection against disclosure merely prevents subsequent applicants from having unauthorised access to the data. It does not prevent the Regulator from granting them market approval, by relying on the originator's data. Consequently, the requirement of protection against unfair commercial use would still be violated. This can be complied with only by the grant of DE for a certain period. To ensure full compliance with the TRIPS agreement, the law must provide for protection against disclosure and DE.

MYTH-3

With DE in place, subsequent applicants will be prevented from generating their own data for seeking market approval.

REALITY

A person is free to come up with his own data for getting market approval. DE is only aimed at preventing a subsequent applicant from piggybacking on the data of the originator/first applicant.

MYTH-4

A law on DE will enable the originator/first applicant establish monopoly in the market place.

REALITY

This is ruled out as subsequent applicants can get market approval based on their own data. DE must not be confused with patent, which confers monopoly to the patent holder during the patent term.

MYTH-5

The DE will prevent the regulator from comparing the data of subsequent applicants with that of the original registrant.

REALITY

This is hypothetical. The data of subsequent registrants have to stand scrutiny – in terms of "safety" and "efficacy" effects – on their own.

MYTH-6

A product already approved/in use abroad is not an NCE.

REALITY

Even if an agrochemical product is already approved/in use abroad, the applicant must conduct long-term studies (three-four years) in India to assess its "safety" and "efficacy" under local conditions. Clearly, the RC treats the product as an NCE. Otherwise, it would not mandate studies in India for assessment of its impact on soil, crop, pests, users and the environment.

MYTH-7

To be eligible for DE, a product should meet the criteria of NCE as per patent law.

REALITY

Registration data and innovation are two separate intellectual properties. TRIPS agreement clearly recognises this by providing for DP and patent protection respectively under different articles.

Therefore, it won't be logical to transpose NCE as defined in the context of patent to read the provisions of the Article on DP. An attempt to do so would result in a dangerous situation whereby products not patent-protected will not qualify for grant of DP.

MYTH-8

With DE in place, the Patent Office cannot refer to the data/information submitted by the patent holder for examining other patent applications.

REALITY

The DE protects registration data (read long-term studies for getting market approval for a product whether protected by patent or not). It is irrelevant to the grant of patent. For a patent grant, an innovation has to fulfil the three fold criteria of "novelty", "inventive step" and "capable of industrial application". Following patent grant, the entire knowledge associated with innovation comes in public domain. Thus, it makes no sense to presume that the Patent Office cannot refer to information that is public knowledge.

MYTH-9

Grant of DE, in addition to patent, leads to double protection.

REALITY

Patent and DE are meant to protect distinct IP rights. Hence, there is no question of double protection. DE protects efforts involved in registration data. The applicant must generate it irrespective of whether the product is protected by patent or not. What happens if DE is not granted? An original applicant not protected by patent (not meeting patentability criteria; innovation of pre-1995 vintage or patent term expired) will be left in the lurch. Without DE, even an applicant enjoying patent protection at the time of registration could be vulnerable if the residual patent term is small.

MYTH-10

DE helps in ever-greening of patents.

REALITY

Ever-greening is a euphemism for extension of patent term. In simple terms, the apprehension is that grant of DE will enable the patentee to enjoy monopoly even after expiry of the patent term.

Unlike patent, grant of DE does not give market exclusivity. Thus, competitors are free to enter the fray immediately on expiry of patent term. Even so, generally, the DE term ends much before the expiry of patent term. Thus, for an innovation in 2005 and registration in 2015, DE for five years will end in 2020 while a patent would expire in 2025.

MYTH-11

DE will render Compulsory Licences granted in respect of patent protected products redundant.

REALITY

Compulsory licences (CL) are granted in exceptional situations. This should be treated strictly as an exception rather than a rule; otherwise, the very objective of patent grant will be defeated.

Even so, the expressed fear is baseless as the compulsory licensee can get registration based on his data. If need be, the government can even waive the condition of the licensee having to submit his own data. When, it can break a patent temporarily by granting CL (to address an emergency situation), it might as well break DE.

MYTH-12

Grant of DE will affect growth of the generic industry in India.

REALITY

The term "generic" is used to connote some thing that is "unbranded" or not protected by patent or trademark. Its use in the context of DE is a misnomer. DE gives protection to anyone who puts in an effort to generate registration data. Therefore, all companies, innovators or generics which are committed to R&D, will have the opportunity to grow.

Without DE, there will only be a proliferation of "me too" manufacturers/suppliers. All the myths are the result of a mind-set that views DP/DE through the prism of patent. This must change. Data Registration is an independent intellectual property. This must be protected by grant of DP/DE to the original registrant.

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