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Impact of Granting Data Exclusivity in Agro-Chemical Sector

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The issue of data exclusivity in India has reignited in context of an alert in early 2015 by the Secretary General of Indian Pharmaceutical Alliance about proposed amendment in Pesticides (Amendment) Bill (IPA, 2015).[1] The proposed amendment is to introduce data exclusivity for a period of five years. It is a general perception that such amendment is TRIPS- Plus and would eliminate competition and create monopolies for agro-chemical and pesticides, thereby escalating their prices. Therefore, it becomes pertinent to analyze data exclusivity in view of the TRIPS Article 39.3 and its impact on the accessibility, availability and affordability of agro-chemicals. In context of the proposed amendments, it becomes relevant to understand the issue of data exclusivity and its impact on the agro-chemical industry in India. Also, the issues which could be faced by various stakeholders and public in general in case the data exclusivity is granted are highlighted.

Keywords: Data exclusivity, TRIPS Article 39.3, New Chemical Entity, agro-chemicals, unfair commercial use, originator, regulator, subsequent applicant

The proposed amendment in The Pesticides (Amendment) Bill to grant 5 years data exclusivity has again raised a war between originators (first applicant) and generic manufacturers (Subsequent Applicant) of relevant agro-chemicals.[1] In view of TRIPS Article 39.3, while generic manufacturers regard it to be a TRIPS- Plus situation, the originators welcome this move as being a TRIPS compliant one. TRIPS Article 39.3 states:

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

Analysis of TRIPS Article 39.3 *vis-à-vis* Insecticides Act 1986

New chemical entities (NCE): The TRIPS Agreement does not define what is meant by a new chemical entity (NCE). It is therefore, left to the Member countries to determine the NCE implied under the TRIPS Agreement in their national legislations.

(i) The Insecticides Act 1986 (hereinafter "The Act") does not provide a definition of NCE. The Act defines pesticide as "any substance or mixture of substances of chemical or biological origin intended for preventing, destroying, attracting, repelling, mitigating or controlling any pest including unwanted species of plants or animals during the production, storage, transport and distribution of agricultural commodities or animal feeds including substances intended for use as plant growth regulator, defoliant, desiccant, fruit thinning agents, or sprouting inhibitor and substances applied to crops either before or after harvest to protect them from deterioration during storage and transport".

Here it becomes imperative to mention Section 3(d) of The Patents Act, 1970 which bars from patentability new forms of known substances unless they differ significantly in efficacy. Therefore, in view of The Insecticides Act and The Patents Act, only those pesticides which are novel or display significant enhancement in the known efficacy in the new forms of existing pesticides are patentable. It is, therefore, pertinent to carry out an analysis taking both of the Acts together since the effect of granting data exclusivity is different in the case of patented and non-patented pesticides or agro-chemicals.

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(ii) As a condition of approving: The Article 39.3 obligation operates only if the statute requires submission of data as a pre-condition of approval. Thus, Article 39.3 condition would not operate if the national law provides for grant of approval based upon marketing approval of another country.

Section 9(3) of the Act provides the process of first time registration of an insecticide by the first applicant (hereinafter "the Originator"). The registration process mandates the submission of efficacy and safety data by the Originator. However, under Section 9(4) where an insecticide has already been registered by the Originator and another person (hereinafter "the Subsequent Applicant") wishes to import or manufacture that insecticide in India, the Subsequent Applicant is required to provide only bio-equivalence data to the relevant Authority. The Central Insecticides Board & Registration Committee (CIB&RC) (hereinafter "the Regulator") can take a cognizance of the Originator's data for the efficacy and safety of NCE.

(iii) Undisclosed test or other data: This would include the safety and efficacy data submitted to the Regulator by the Originator.

(iv) Involves a considerable effort: The Originator must input significant R&D in terms of time and fund to generate the efficacy and safety data required for submission to the Regulator to ensure that the insecticides meet the required criteria for marketing approval.

(v) Unfair commercial use: Under Section 9(3) of the Act, the Regulator requires the Originator to provide efficacy and safety data for granting approval. In cases of subsequent applicants who file under Section 9(4), also referred to as the generic manufacturer or the "me too" applicants, often times the Originator's data is used by the Regulator to establish bioequivalence and consequently to grant approval for such bioequivalent insecticides.[2] It is important to note that the generic manufacturer neither uses the Originator's data nor has access to them and therefore there is no unfair commercial use of the Originator's data by the Subsequent Applicant. At no time is the regulator empowered to share Originator's data with the subsequent applicant.

Data Exclusivity as a Form of Protection

Under this type of protection, the Regulator may not rely upon the Originator's data for approving the second and any subsequent applications for the same or bio-equivalent product during the period of data exclusivity. This concept implies non-disclosure and also no use of the Originator's data by the Regulator at the time of granting marketing approval to the Subsequent Applicants. Such protection is for a specific time period.[2] The specific period of data exclusivity is mentioned in the Table 1 below.

Data Exclusivity: Brief Global Overview

Generally, the protection allowed for agro-chemicals is higher than that for pharmaceuticals. While many developed countries provide data exclusivity in agro-chemicals, most of the developing countries including India do not provide data exclusivity for agro-chemicals.

Analysis of Implications of Granting Data Exclusivity

The impact of granting data exclusivity for five years is presented herein below taking the different scenarios into account:

Scenario 1: **When Product is Protected by Patent or Patent Protection has been Applied For**

Patent protection is granted for 20 years. In the situation where data exclusivity is granted for 5 years, this would not have much impact on patented products, since the data exclusivity period is shorter than patent protection. However, if any interested party challenges the validity of the patent by way of filing a revocation petition, and wishes to launch their generic product immediately after the revocation of the patent, they are not able to do so, since the Regulator may not rely upon the Originator's data to grant market approval. If data exclusivity is granted for 5 years, the Regulator would

Table 1—Data exclusivity period granted in several countries for agro-chemicals[2]

Country	Period of data exclusivity
USA	10 years with 15 years additional protection on the basis of compensability
Europe	10 years with 5 years for additional data
United Kingdom	08 years
Japan	Permanent
Canada	10 years
France	10 years
Brazil	10 years with 5 years for additional data required by the regulatory authority to sustain/maintain registration of a given agro-chemical product.

not even look at the bioequivalence data for 5 years. This indicates that even if the patents are invalid and can be challenged, the data protection ensures a monopoly for 5 years.

Scenario 2: When the Product is Neither Patent Protected nor has Patent Protection Been Applied For

The biggest impact of data exclusivity would be in the case of off-patent / non-patented products or non-patentable products. Even if the product is not protected by patent, Subsequent Applicants have to wait till the end of the 5 year data exclusivity period to enter the market or alternatively, they must generate their own data. The independent generation of such data appears to be a futile investment as the data have been already generated by the Originator and submitted to the Regulator.

Scenario 3: **When the Product is Protected by Patent and a Compulsory License is Granted**

If a compulsory license is successfully granted on a patented product, the licensee has to postpone the launch of their product until the end of data exclusivity period or has to generate the test data to obtain registration from the Regulator, which may delay the introduction of the product into the market or requires duplication of the tests which have already been conducted. The Controller of Patents, while granting the compulsory license, may have to take the data exclusivity period into consideration. However, if the compulsory license is granted for statutory reasons such as in public interest, the data exclusivity may be curtailed.

Scenario 4: **When the Product is Patented and Imported under Parallel Importation**

There is no effect of granting data exclusivity on the parallel imports in cases where the Originator and the legal importer supply the product under same brand name. However, if the Originator and the legal importer supply the product under different brand names, the importer has to meet the requirements of registration and submit the data to the Regulator. In this case, if data exclusivity is granted, the importer has to either generate its own test data or delay the marketing of the product.

Impact of Granting Data Exclusivity on the Act

Granting of data exclusivity would impact upon the Act. In that, the Act has to define the NCE. It would also impact upon the applicability of the following sections of the Act:

(1) Section 9(4) pertaining to registration of insecticides on the application of second or Subsequent Applicants;
(2) Section 17 pertaining to prohibition of the importation and manufacture of certain insecticides;
(3) Section 29 pertaining to offences and punishments;
(4) Section 30 pertaining to defences which may or may not be allowed in prosecutions under the Act;
(5) Section 33 pertaining to power of the Central Government to give directions;
(6) Section 37 pertaining to power of the State Government to make rules; and
(7) Section 38 pertaining to exemptions.

Analysis of the Issue

The issue of data exclusivity is among the most contested issues. In view of the recently proposed amendment, it becomes necessary to understand the real issues behind data exclusivity and to remove the ambiguity.

As the Originator makes a huge investment for the development of test data to submit to the Regulator, it appears unfair for the Regulator to use these data for subsequent approvals. About forty different tests in chemistry, bioefficacy and residues and toxicity are required to be performed for the registration of insecticides. Some of these tests pertaining to bioefficacy, toxicity and chemistry are required to be performed in different agro-climatic conditions in India. For the remaining tests, data from tests undertaken according to OECD guidelines abroad are accepted in India.[2]

On the other hand, it seems equally unfair and unjust to make another investment to generate the required data in case of the same product by any Subsequent Applicants. Unlike pharmaceuticals, efficacy tests for agro-chemicals must be repeated in every country, even in several regions in a country due to differences in crops, pests, agronomical practices, climate conditions and terrains. These tests are repeated periodically even after product registration for periodic reviews. The substances used for crop protection are usually toxic in nature and have adverse environmental implications, which have to be taken into account.[2]

In India, the Originator is required to generate substantial data on efficacy and safety to submit to the Regulator. It takes extensive experimentation over

3-4 years to meet the requirements mandated by the Regulator.[2] Once the Originator submits its data under Section 9(3) of the Act, large number of subsequent applications are filed by Subsequent Applicants for 'me too' registrations under Section 9(4) of the Act, virtually without any test data.

The Subsequent Applicants are at an unfair advantage since they were not involved in, nor contributed to, the huge costs of research & development which were conducted by the Originator in different agro-climatic zones for over a period of 3-4 years. The Official website of the Regulator shows that only about 256 products have been registered upto 31st December 2014.[3] Multinational companies prefer to import the insecticides rather than manufacturing them in India. As per the registration procedure under the Act, imported products can be registered under Section 9(3) of the Act and for imported products, subsequent applications under Section 9(4) are not permitted.[2] This type of strategy may deprive the country of the ability and opportunity of developing a manufacturing capacity for insecticides.

Conclusion

In case the data exclusivity of 5 years is granted for agro-chemical and pesticides, the multinational pharmaceutical companies may start demanding the data exclusivity for pharmaceutical products which will adversely impact the accessibility of the medicines. However, considering the different approaches by various stakeholders, the quick registration may be imposed on the Originator along with limiting the data exclusivity period to not extend beyond the patent term. The exclusivity may be limited to NCE only. The data exclusivity may be curtailed in cases of national emergency, and in the public interest. Such waiver may extend to cases of compulsory licenses granted under The Patents Act.

References

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