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PESTICIDE PATENT AND DATA PROTECTION - HOW THEY HELP INDIAN FARMERS AND INDIAN INDUSTRY

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ABSTRACT

Respecting intellectual property rights is one of the basic prerequisites for creating an innovation and R&D based value-added manufacturing sector in any country. Agrochemicals have been chosen as one of the champion sectors. But how can India be a global supply hub without harmonizing with global regulatory policies and practices? This paper is aimed at establishing the benefits of both patent and data protection for Indian agriculture and Indian industry. Many Governments appointed Committees and also the Parliamentary Standing Committee for Agriculture (2008-09), after detailed deliberations and interaction with all stakeholders and all sections of industry, have recommended protection of regulatory data (PRD). This is to encourage introduction of new molecules for the Indian farmers, and to honour India's obligation under the TRIPs agreement. The recommendations by such eminent authorities should not be overlooked. Almost all countries of the world give PRD for 6-15 years for any molecule registered for the first time in their country.

This paper puts forward a fact-based scientific analysis of prevailing arguments, both in favour and against protection of regulatory data (PRD). This covers following aspects:

a) How are patents and data protection different?
b) What are the myths and realities in the arguments of PRD?
c) Evidence of support for the arguments in favour of PRD
d) What will be the benefits accrued to Indian farmers and industry through PRD?

How are patents and data protection different?

Patents provide protection for a newly discovered pesticide molecule for a period of time. Protection of regulatory data (PRD) prevents unauthorized commercial use of safety, health and efficacy data generated by the molecule discoverer owned by the applicant, and is required for registration purposes in India. This is also provided under Rule 39.3 of the TRIPs Agreement. Patents provide commercial protection of 20 years from the date of patent being granted. Out of this, 8-10 years are spent to secure commercial registration in the first country of introduction. This the typical time required for data generation and the approval process of the country's regulatory authorities. In India it takes another 5-7 years to generate local data and get registration from the CIB&RC. Therefore on an average only 4-5 years of patent period is left when a new patented product can be commercially launched in India. The argument that patent holders do not launch new products during the early years of securing patents is fallacious. If and when the registrations timelines can be reduced through reforms and process improvement; there will be greater incentives for faster introductions of new molecules in India.

Patent and data protection are two different issues (Fig. 1). A 'patent' on a pesticide molecule is of no use, if the regulatory data is not provided to the satisfaction of the pesticides registration authorities. There are many instances where patented products fail to be

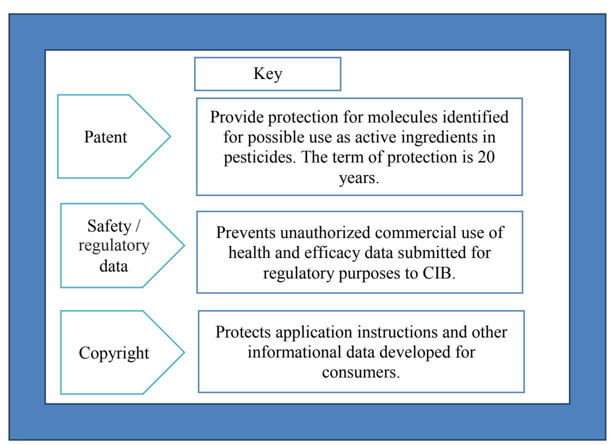

Fig. 1. Difference between patent and protection of regulatory data

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commercialized, because the regulatory data was not acceptable for safety/ bioefficacy etc. by the registering authorities in certain countries. No regulatory data protection (PRD) is required for molecules till they are covered by patent. The PRD is needed only for an off-patented molecule when it is being introduced for the first time in the country. Ms. Satwant Reddy Committee 2007 (Former Secretary, Chemicals, Government of India) recommends: "Data protection and patents are the two most critical and relevant intellectual property rights for agrochemicals industry globally. These are distinct forms of protection- protection of one right is neither dependent on the other nor linked to the other. Data protection is meant to be accorded by governments to the proprietary test data and not to the product. The generic companies can generate their own tests and seek marketing approval based on that for a similar product. Therefore, there is no obligation to limit data protection to patented products only."

Registering any molecule for the first time requires expenditure of around ₹ 15 to 20 crores and takes 5 to 7 years to obtain registration. Then another ₹ 25 to 30 crores are spent over a 3-4 years to market and sell by carrying out product demonstrations, its publicity, staff and dealership set up, and product stewardship etc. Hence, to register a molecule for the first time in India (patent or off-patent) takes ₹ 40 to Rs 50 crores over a period of 6-8 years; and the registration is possible only due to the submission of the prescribed regulatory data, which meets the satisfaction of the Registration Committee. If, however, no PRD is provided, then 'me too' applicants can get the registration within a year of launching and at a very small cost of up to ₹ 75 lakhs and thereby denying level playing field to the first registrant who has invested significant sums, as indicated above. There is therefore low incentive to introduce off-patented molecules in India, in the absence of PRD. It is for this reason that a minimum five years period for data protection should be provided to encourage registration of off-patented molecules and provide greater crop protection solutions to our farmers. The argument that data protection encourages late introduction of old global molecules by MNCs in Indian market is neither true nor relevant. Companies will essentially introduce only such molecules where they see that it has the potential of commercial success and gets acceptance of farmers' w.r.t. its value proposition and price competitiveness. From the farmers' viewpoint, it is immaterial whether it is old or new, as long as it meets their expectations, and is registered after its due safety and efficacy evaluation.

Also there are cases, where old molecules are formulated in a different way to increase their safety/ efficacy or used in combination to increase their spectrum of pest control or for reducing their costs etc. The argument that the issue of data protection is being raised only now is false; the issue is in discussion since 2003; with the Satwant Reddy Committee (2007); Pesticide management bill (2008) and the Standing Committee of Parliament on Agriculture (2008-09), all had recommended data protection. These recommendations by such eminent authorities have been made after detailed deliberations, interaction with all stakeholders, and the same should not be overlooked.

Myths and realities

There are several myths created against data protection, which needs to be addressed with scientific facts and rationale.

Postscript and Evidence of support for the arguments in favour of PRD

It is for this reason that almost all countries of the world such as USA, EU, China, Japan, Indonesia, Malaysia, Philippines, Thailand and Brazil give PRD for 6-15 years for any molecule registered for the first time in their country.

a) Satwant Reddy Committee (Chaired by Former Secretary, Chemicals, Government of India) in 2007 had recommended three years regulatory data protection to honour India's obligation under the TRIPs agreement, after consultations with all segments of industry and all national associations.

b) Pesticide management bill 2008 (section 12) mentions that registration data cannot be relied upon under subsection (6) and shall not be granted during a period of three years of the date of its registration unless a letter of consent is enclosed with the application, in original, from the registrant of that pesticide.

c) Standing Committee of Parliament on Agriculture (2008-09), revised PRD from 3 to 5 years in its 46th Report dated February 2009.

d) Dr. Dalwai Committee on Doubling Farmers Income in 2018 had recommended that PRD would bring in many newer pesticides to India. Also recognized that India needs newer pesticides and PRD will encourage their registration in India.

e) India is internationally committed to the patent regime and therefore India is legally committed to article 39.3 TRIPs Agreement.

Myth	Reality
Regulatory data is inexpensive	Registration of a molecule being introduced for the first time in the country takes – ₹ 15-20 crores for registration and 5-7 years for a new molecule being developed from scratch ₹ 25-30 crores for marketing, stewardship, etc. over 3-4 years, and a total of ₹ 40-50 crores over 6-8 years Any person has all the right to obtain the registration of the same molecule by generating the required data and going through the registration process.
Regulatory data protection will create monopoly	In order to get "me too" registration, one needs a first registrant. But in the absence of PRD, if new off-patented molecules are not registered for the first time in India due to lack of incentives for covering their introduction cost, then "me too" will also suffer in the long run.
New pesticides are invariably imported and results in country's forex outflow	In 2019, only around 11,000 mt of formulation imports took place at a CIF value of around ₹ 1800 crores. The formulation value addition to technical product is generally about ₹ 80,000/ tonne. Hence, the so-called "loss of value addition" in terms of indigenous value is only around ₹ 88 crores - an insignificant amount in a ₹ 45,000 crore industry.
Patent and data protection increases product prices	No molecule will withstand the judgement of cost vs. benefits/ value. Product pricing ought to be such that the farmer becomes conscious of its cost implications. In fact, low prices have induced gross misuse, overuse and incentivized spurious and substandard products.
PRD is a disadvantage to generics	PRD will greatly enhance the generic industry. Once the PRD period is over they will all be available for TIM registration. In fact, the enlarged range offers great opportunities for Indian companies to increase their exports/ local business. A much larger range of products will encourage healthy competition, rather than 500 plus registrants of the same formulation competing for market share.
No other country provides regulatory data protection	USA, EU, China, Japan, Indonesia, Malaysia, Philippines, Thailand and Brazil give PRD for 6-15 years for any molecule registered for the first time in their country (Table 1).

f) Indian farmers are being deprived of newer products due to the policy of not providing PRD. In their interest, the policy ought to change.

Benefits that will accrued if PRD is allowed

Accelerated introduction of newer and safer molecules and serve the interest of the farmers.

a) Changing pest disease, weeds, climate change and cropping patterns require newer solutions: 180 molecules have come off patent from 2000 to 2020: this offers huge scope to attract their introduction in India.

b) Ensure proper product use through stewardship during the PRD period.

c) Increasing agricultural exports by encouraging use of molecules permissible in countries of imports.

d) Newer molecules will be registered only after stringent safety related checks, thereby Improving nutritional security.

Table 1. Protection of regulatory data - global vs Indian scenario

Country	New Active Substance (Years)	Formulations (Years)
EU	10	10
USA	10	10
Canada	10	10
Australia	8	5
Kazakhstan	10	10
Brazil	10	5
Columbia	10	
China	6	6
Indonesia	6	6
Taiwan	8	8
Philippines	8	8
Malaysia	6	6
Thailand	10	10
India	0	0

e) Outsourcing opportunity for more and more data generation at Indian research institutions

f) Setting up of R&D facilities/ technologies for manufacture of newer molecules in India.

g) Make India as a manufacturing hub for global supplies of agrochemicals, as demonstrated by many domestic companies.

h) Employment generation for Indian scientists and engineers.

i) Increasing opportunity arising from ban/ phase out threat for mancozeb, chlorpyriphos, glufosinate in certain countries requires adding new range for global exports.

CONCLUSIONS

Keeping in mind farmers' interest and global best practices, the Government should consider implementation of protection of regulatory data (PRD) for new molecules introduced for the first time in the country for a minimum period of five years from the date of registration in India. Government policy decision of PRD ought to be driven only on the basis of what is in the interest of the farmers, and not by what benefits of any section of the industry.

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