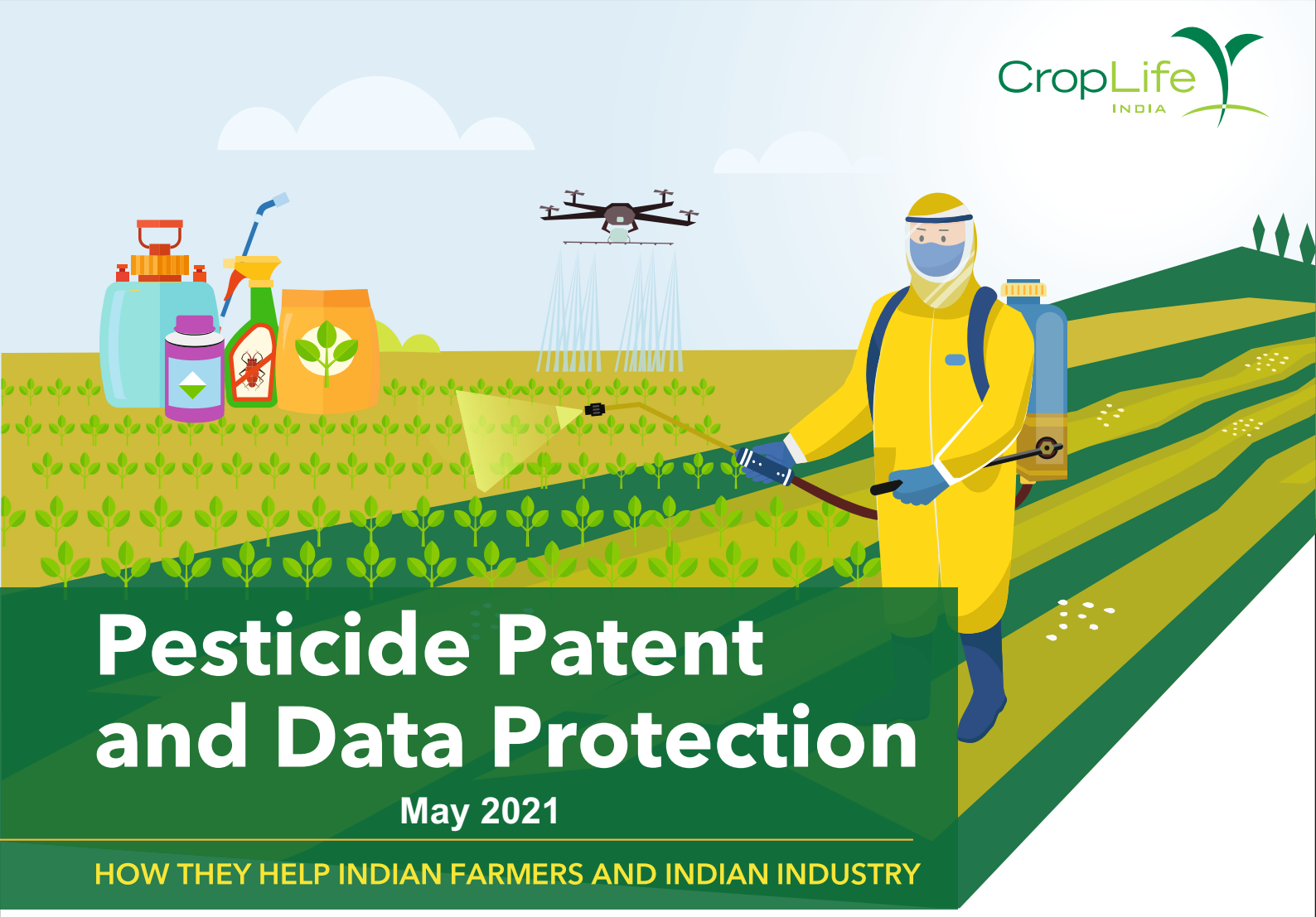

Pesticide Patent and Data Protection

May 2021

HOW THEY HELP INDIAN FARMERS AND INDIAN INDUSTRY

Few sections of the Industry are spreading misconceived notions against Intellectual Property and Patent protection, which will hurt agricultural productivity and farmers' prosperity in India.

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.

KEY TERMINOLOGY

Patent	Provide protection for molecules identified for possible use as active ingredients in pesticides. The term of protection is 20 years.
Safety / Regulatory Data	Prevents unauthorized commercial use of health and efficacy data submitted for regulatory purposes to CIB.
Copyright	Protects application instructions and other informational data developed for consumers.

HOW ARE PATENTS AND DATA PROTECTION DIFFERENT?

Patents provide commercial protection of 20 years from the date of patent being granted. Out of this, 8-10 years are spent tosecure 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. Therefore 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. 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 commercialized, because the Regulatory Data was not acceptable for safety/bio-efficacy etc. by the registering authorities in certain countries. No Regulatory Data Protection (PRD) is required for molecules till they are covered by patent. PRD is needed only for an off-patented molecule when it is being introduced for the first time in the country.

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 ₹ 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 upto ₹ 75 lacs 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 absence of PRD. It is for this reason that a minimum 5 year 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 his 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.

MYTHS AND REALITY

MYTHS	REALITY
Regulatory Data is in-expensive	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 • A Total of ₹ 40-50 crores over 6-8 years
Regulatory Data Protection will create monopoly	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.
	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 metric tonnes 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 per 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 v/s 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, over-use and incentivized spurious and sub-standard 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.
	Satwant Reddy Committee (Chaired by Former Secretary, Chemicals, Govt of India) in the year 2007 had recommended 3 years Regulatory Data Protection to honour India's obligation under the TRIPs agreement.

Does Data Protection create monopoly and goes against the interest of domestic industry?

The argument that data protection provides monopoly is false as every person has all the right to obtain the registration of the same molecule by generating the required data and going through the registration process, rather than taking a free ride on time and cost borne by the inventor.

In any case, once the PRD period of say 5 years is over, then anyone else can get registration at a fraction of the cost incurred by the first registrant.

It is important to keep in mind that 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.

Is it true that new pesticides are invariably imported at the expense of farmers and the country's forex outflow?

The claim that new products (both patented and off-patent first time introductions in India) are only imported in India at the expense of the country's forex reserve, and without any investment generated in India - is both misleading and malicious.

In 2019 as per the import data statistics, only around 11,000 metric tonnes 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 per 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.

Around 120 formulations imports products have been registered by CIB & RC, bringing in an investment of ₹ 3300 - ₹ 5500 crores with employment to thousands of science and field staff. This is because innovators spend anywhere between ₹ 40 to ₹ 50 crores over a 5 - 7 years period, in India, to first generate data, obtain registrations, and then spend on market development, farmer training, product publicity, field work and demonstrations apart from training scores of farmers on safe and judicious use of the product as a part of product stewardship.

Formulation imports almost always pertain to specialty category, which are either not available in India (at the time of first registration) or for which requisite raw materials, technology etc. are not available in the country. These new chemistries lend better sustainability, pesticides' resistance management, environmental fate and safety to the users; and more conducive for domestic and exported food chain for their safer chemistries.

Moreover Government has already allowed relaxed guideline for TIM (Technical Indigenous Manufacturing) vs FI (Formulation Import) wherein Generic players can rely upon embedded technical dossier/data submitted along with Formulation import, to obtain TIM & FIM vs FI registrations in significantly lesser timeframe with very low quantum of data/ information and negligible investments. The RC by these guidelines has given all the opportunity for the "Me too" registrant to take the advantage and seeking to register the technical.

While around 120 formulations have been registered for imports, only about 30-35 account for 80% of the total import. This shows that not all the formulations introduced have become commercially successful. Once newly introduced molecule through importation route gains a reasonable market presence, then its manufacturing activity follows in many cases, either directly or through contract manufacturing by local manufacturers. Formulations Imports are then converted to the manufacture of formulation and then to manufacturing of the technical in India. This is the well-established process of gradual progression in the global supply chain continuum, and there are many such examples demonstrated by local manufacturers. That is how the Indian manufacturing facilities have not only become the hub of Global Sourcing but are also continuously expanding its foot-print.

Does Patent and Data protection increase product prices; and go against the interest of the farmer?

This argument of higher prices of new products assumes that the farmer has no sense of judgement of cost v/s benefits/value and would pay any price for a new molecule. The farmers of today apply sagacity and judgement to buy a new molecule. Many molecules have not succeeded in India due to their price/value proposition in the commercial judgement of the farmer, as a proof of this.

Also it needs serious consideration whether low prices are always in the interest of the farmers. As an example of the case of Imidacloprid of 18.2% EC, a very effective broad spectrum insecticide, is presented herewith to explain this:

When introduced by Bayer, the cost per acre to the farmer was ₹ 320 - ₹ 330/- per acre in 2001-02. But today with more than 500/600 plus registrants, the cost per acre has come down to ₹ 80 - ₹ 85/- per acre, inducing the farmer for excessive use. He/she ends up using 4 times the dosage without affecting his wallet, which can lead to indiscriminate use due to low prices.

Hence, product pricing ought to be such that the farmer becomes conscious of its cost implications. "Cheap" does not necessarily mean "best" in the interest of the farmer. In fact, low prices have induced gross misuse, over-use and incentivized spurious and sub-standard products. Massive proliferation has resulted in excess capacity resulting in unethical business practices and a thriving market for spurious and sub-standard generic products.

RECOMMENDATIONS ON REGULATORY DATA PROTECTION

Made by Government and Parliamentary Committees

Committee	Year	Recommendations
Ms. Satwant Reddy Committee (Former Secretary, Chemicals, Govt of India)	**2007**	**Recommended 3 years Regulatory Data Protection** to honor India's obligation under the TRIPs agreement, after consultations with all national pesticide associations.
Pesticide Management Bill, 2008 **(Section 12)**	**2008**	"Notwithstanding anything contained in this section, where a pesticide has been registered on the application of any person, any other person desiring to import or manufacture the pesticide or engaged in the business of import or manufacture thereof, shall, on application and on payment of prescribed fee, be allotted a registration number and granted a certificate of registration in respect thereof on the same conditions on which the pesticide was registered under-sub-section. Provided that registration in respect of a pesticide, data of which cannot be relied upon under-sub- section (6) **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. (Sec. 12 in PMB-2008)
Standing Committee of Parliament on Agriculture, 2008-09	**2008-09**	Considering that 5 year period is needed for effective stewardship, the committee **revised PRD from 3 to 5 years** in its 46. (Report dated Feb' 2009).
Dalwai Committee on Doubling Farmers Income	**2018**	**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.

Above recommendations by such eminent authorities have been made after detailed deliberations, interaction with all stakeholders, and the same should not be overlooked.

Postscript

a) 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.

b) Satwant Reddy Committee (Chaired by Former Secretary, Chemicals, Govt of India) in the year 2007 had recommended 3 years Regulatory Data Protection to honor India's obligation under the TRIPs agreement, after consultations with all segments of industry and all national associations

c) Pesticide Management Bill 2008 (section 12) mentioned that registration data cannot be relied upon under sub-section (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.

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

e) 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

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

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

REGULATORY DATA PROTECTION

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

There are several benefits that will be accrued if PRD is allowed by the Government:

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

b) 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

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

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

e) Newer molecules will be registered only after stringent safety related checks, thereby improving nutritional security

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

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

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

i) Employment generation for Indian scientists and engineers

j) Increasing opportunity arising from Ban/Phase Out threat for mancozeb, chlorpyriphos, glufosinate in certain countries requires adding new range for global exports.

Keeping in mind farmers' interest and global best practices, we earnestly request the Government to consider implementation of Protection of Regulatory Data (PRD) for new molecules introduced for the first time in the country for a minimum period of 5 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.

About CropLife India:

CropLife India is an industry association of 15 R & D driven member crop science companies (both Indian and Multinationals), jointly representing approximately 70% of crop protection market and responsible for 95% of the molecules introduced in the country so far. Member companies have annual global R & D spend of 6 billion USD and are firmly committed to engaging with the farming community to enable Safe, Secure Food Supply.

http://www.twitter.com/croplifeindia

www.croplifeindia.org

https://www.facebook.com/CropLife-India-294987004243407

https://www.youtube.com/channel/UCxhQznHtSPpzUXrGG-gYPnQ

https://www.linkedin.com/company/croplife-india

https://instagram.com/croplifeindia?igshid=xpuv5chjh7ap