



Plant Science Industry
Guide to Intellectual Property

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1. PURPOSE

The objective of this guide is twofold:

- To define and briefly explain the most important intellectual property rights which the plant science industry relies upon, and thus reduce any potential confusion.
- To assist industry representatives in understanding the importance of protection of regulatory data and the complementary role it plays with other intellectual property tools.

This manual is not a position paper. It does not include an exhaustive list of intellectual property rights available. It also does not address the intellectual property laws of specific jurisdictions.

2. WHAT IS INTELLECTUAL PROPERTY?

The term Intellectual Property (IP), sometimes also called industrial property, is utilised in many contexts, but is sometimes misused and/or misunderstood. By definition the term encompasses any creation of the intellect which is given the legal status of property. It broadly describes all the recognised forms of such IP, including: patents, trade secret, protection of safety and efficacy data, plant variety rights, copyright, and trademark.

This guide will focus on the six types of IP rights which are most important to the plant science industry: patents, trade secret, protection of safety and efficacy data, plant variety rights, copyright, and trademark. CropLife network members should be as specific as possible when discussing IP issues and avoid using the term IP as a catch-all for all such protection. This guide will cover IP protection available for both Crop Protection Chemicals and Plant Biotechnology.

3. INTELLECTUAL PROPERTY – AN OVERVIEW WHAT INTELLECTUAL PROPERTY PROTECTION IS AVAILABLE?

The six types of protection covered in this guide – patents, trade secret, protection of safety and efficacy data, plant variety rights, copyright and trademark – vary greatly in how they are acquired, what length of protection is provided, and how they are used. Despite these differences, however, these rights all share the fact that they are granted and enforced independently by national governments.

PATENTS provide exclusive rights to inventors for a fixed period of time in exchange for the disclosure of an invention. A patent provides the right to exclude others from making, using, selling, offering to sale or importing the patented invention for the term of the

patent, which is usually 20 years from the date the patent is filed with the national patent office.

TRADE SECRET is a formula, practice, process, design, instrument, pattern, or compilation of information which is not generally known or reasonably ascertainable, by which a business can obtain an economic advantage over competitors or customers. In some jurisdictions, such secrets are referred to as “confidential business information” or “classified information”.

PROTECTION OF SAFETY AND EFFICACY DATA is the protection from unauthorised commercial use of health and efficacy data submitted for regulatory purposes.

PLANT VARIETY RIGHTS, also known as plant breeders’ rights, are rights granted to the breeder of a new variety of plant that give him exclusive control over the propagating material (including seed, cuttings, divisions, tissue culture) and harvested material (cut flowers, fruit, foliage) of a new variety for a number of years.

COPYRIGHT is a set of exclusive rights granted to the author or creator of an original work, including the right to copy, distribute and adapt the work. This protection is available to both published and unpublished works.

TRADEMARK is granted to reduce confusion in the marketplace by preventing the unlicensed use of the registered mark, or one of a similar nature, on goods which are the same or similar to those for which the mark is registered.

Patents, Trade Secret and Protection of Safety and Efficacy Data

Although patents, trade secret and the protection of safety and efficacy data are frequently applicable for the same product, it must be noted that they are provided for different aspects of that product. The rights are also applied at different time periods. The often-referenced Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most influential international IP rights agreement. TRIPS was signed as part of the GATT Uruguay round, which established the World Trade Organisation (WTO) in 1995. All members of the WTO (including least developed, developing and developed countries) are bound by the TRIPS provisions.

Since entering into force, TRIPS has proven instrumental in enhancing the IP laws of a considerable number of countries. TRIPS sets minimum standards for protection of various forms of IP. These standards are well defined for patents

(Part II.5, Articles 27-34) and trademarks (Part II.2, Articles 15-21), but are not as definitive when calling for the protection of undisclosed information (Part II.7, Article 39). Despite being somewhat unclear, Article 39 specifically includes the protection of trade secret or confidential business information and the protection of safety and efficacy data relating to “agricultural chemical products”. As part of the proscribed protection of undisclosed information, TRIPS also provides minimum standards for enforcement of intellectual property (Part III.1-5; 7 Articles 41-46), and transitional arrangements for providing product patents for agrochemicals and pharmaceuticals (Part VII, Article 70.8).

According to TRIPS Article 27, WTO members need to provide patent protection for plant varieties and ag-biotech inventions¹; but they might choose to exclude from patentability plants and animals other than microorganisms². In cases where Members opt to exclude plants from patentability, protection of these inventions must be provided by an effective alternative system. There is no further explanation of what this alternative system of protection should be; however, the International Union for the Protection of New Varieties of Plants (UPOV) Convention for plant variety protection is considered the preferred standard for plant variety protection.

4. THE INFLUENCE OF TRIPS

Patents originated hundreds of years ago when most inventions were mechanical in nature. It was extended to the chemical industry as it developed over the last hundred years or so, but not without difficulty. Initially patents on certain chemicals were not authorised, or there were restrictions to the patent claim (e.g. processes only). Patent protection is now being extended to deal with biotechnology, again not without difficulty. Much progress has been made in recent years, both in extending the range of countries and regions with appropriate patent laws, and in reducing or abolishing the discrimination against patents for chemicals. Leverage to achieve such changes has received an enormous boost from TRIPS. Thus, the WTO Agreement has made many signatory countries improve patent laws, either to bring them into line with the minimum TRIPS standards or to eliminate discrimination against non-nationals.

The development of biotechnology and of new biotechnology-derived products, such as genetically modified plants, highlights the need for harmonisation in yet another area of patent protection. TRIPS provides the possibility of excluding plants from patentability as long as an effective alternative system of protection is applied: this raises new questions, particularly when the UPOV Convention (developed to meet the needs of conventional breeders, not biotechnological inventions) is applied as the standard mechanism of protection for protection of plant varieties.

Crop Protection Products and Products of Plant Biotechnology are subject to marketing and use approvals by government regulatory authorities. This approval is based upon the assessment of scientific studies on the products' efficacy and safety to humans, animals and the environment. Companies submit the corresponding health, safety and environmental data to national registration authorities, which, upon reviewing the data, make a decision on the suitability of the product for registration and sale. Development of registration data involves an investment of many years and large sums of money by research based companies (in 2010, the average cost for a chemical introduction was \$256 million³). A major part of the financial investment has to be made at comparatively early development stages. Moreover, the investment of time and money is of a high-risk nature since successful registration and sale of a novel product are not certainties.

Therefore the data provided for regulatory purposes to government authorities are substantial assets which must be protected against unfair commercial use by competitors who wish to benefit without having incurred the expenses to generate such data. The proprietary nature of registration data and need for the protection of these data have been widely accepted and recognised by both the WTO and the Organisation for Economic Cooperation and Development (OECD). Article 39.3 of the TRIPS Agreement calls for the protection of data submitted to national registration authorities as a remedy against unfair competition: “Members, when requiring, as a condition of approving the marketing of pharmaceutical or agricultural chemical products which utilised new chemical entities, the submission of undisclosed test

¹ TRIPS Article 27.1 Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

² They can also exclude from patentability essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

³ Phillips McDougall. (2010). The cost of New Agrochemical Product Discovery, Development & Registration and Research & Development prediction for the Future. http://www.croplife.org/files/documentspublished/1/en-us/REP/5344_REP_2010_03_04_Phillips_McDougal_Research_and_Development_study.pdf

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.”

5. PATENTS

A patent is a set of exclusive rights granted by a state (national government) to an inventor or their assignee for a limited period of time in exchange for a public disclosure of an invention. The procedure for granting patents, the requirements placed on the patentee, and the extent of the exclusive rights vary widely between countries according to national laws and international agreements. Typically, however, a patent application must include one or more claims defining the invention which must be new, non-obvious, and useful or industrially applicable. The exclusive right granted to a patentee in most countries is the right to prevent others from making, using, selling, or distributing the patented invention without permission. It is just a right to prevent others' use for a limited period of time. Under TRIPS, patents should be available in WTO member states for any inventions, in all fields of technology, and the term of protection available should be the minimum twenty years.

6. TRADE SECRET

Broadly speaking, any confidential business information which provides an enterprise a competitive edge may be considered a trade secret. Trade secrets encompass manufacturing or industrial secrets and commercial secrets. The unauthorised use of such information by persons other than the holder is regarded as an unfair practice and a violation of the trade secret. Depending on the legal system, the protection of trade secrets forms part of the general concept of protection against unfair competition or is based on specific provisions or case law on the protection of confidential information. The subject matter of trade secrets is usually defined in broad terms and includes manufacturing processes, names and addresses of scientist, composition of formula, and analytical methods for impurities, among other elements. While a final determination of what information constitutes a trade secret will depend on the circumstances of each individual case, clearly unfair practices in respect of secret information include industrial or commercial espionage, breach of contract and breach of confidence.

7. PROTECTION OF SAFETY AND EFFICACY DATA

Fundamentally, the data generated by a company for the registration of its products are owned and thus forever proprietary to that company. This fundamental principle is based on every individual person's "ownership right". This ownership right is a fundamental right in many countries and applies to everything of value. In the past, a number of countries applied this principle to the handling of regulatory data and, consequently, provided protection of that data from commercial misuse for an infinite period of time. Although this principle appropriately continues to apply to trade secrets (e.g. information on manufacturing processes and the like), some governments now look differently at proprietary health, safety and environment registration data. They accept that protection of safety and efficacy data is required but for various reasons (such as the aim to avoid repetition of animal studies by a second registrant) they apply time limits to the protection and thus effectively limit the proprietary rights of the data owner.

In practice, governments grant the data owner a period of exclusive use for the data: most countries provide ten years for crop protection chemicals. The exclusivity period provides that these data are not available to be used or cited by any secondary applicant without the express permission of the data owner. It is similarly understood that regulatory authorities should not violate the period of exclusivity by allowing reliance on data submitted by the primary applicant to be used in the review of registration submissions of secondary applicants.

KEY POINTS ON PROTECTION OF REGULATORY DATA

1. Enforceable trade secret and protection of safety and efficacy data prevents unfair competition, and is therefore a valuable instrument to encourage industry to invest in the development and registration of new active ingredients and products. This incentive will only be effective with a meaningful and reliable protection system in place.
2. Safety and efficacy data submitted to regulatory authorities are proprietary to the submitting company and must be protected from unauthorised use for the benefit of any secondary applicant. It is, however, recognised that in principle secondary applicants are free to generate their own data unless prohibited by specific legislation, e.g. patent law.
3. Registrations/authorisations should not be granted to applicants who are not the rightful owners of the data submitted to the registration authority or have not been granted access to the data by the data owner.

4. The method and extent of protection of safety and efficacy data in each country/region – including a period of exclusive use (i.e. length of period of protection of data) by the data owner – should be determined by local authorities.
5. In countries where protection of safety and efficacy data is not currently provided for or where the opportunity for improving existing provisions arises, protection of safety and efficacy data should be put into effect by conferring a minimum period of exclusive use to the data owner.

Provision of exclusive use (for data in support of a new registration) should:

- At least ensure a minimum ten-year exclusivity period for new chemicals, to the titleholder of the studies (beginning from the date of market approval of the innovative product in the country where the product is approved);
- Allow authorisation of the market entry of a copy product only following the expiry of the ten-year exclusivity period based on safety and efficacy data provided by the first registrant – provided the copy product registrant demonstrates that the chemical profile of the copy product (including the active ingredient) is equivalent to the original product or has its own safety and efficacy data, and therefore does not represent an unacceptable risk to users, consumers, or the environment;
- Establish that any publication of data summaries for the benefit of transparency does not represent disclosure to the public domain and the loss of protection;
- Establish that the exclusive period starts with the 'effective' date of approval, i.e. the date the registrant is permitted to commercialise the product. It should also make it clear that during review by regulatory authorities the data submitted for registration are to be treated as confidential business information, and are therefore "naturally" protected from being cited or used by secondary applicants.

8. PLANT VARIETY RIGHTS

The UPOV Convention was signed in Paris in 1961 and entered into force in 1968. It was revised in 1972, 1978 and 1991. UPOV provides a framework for IP protection of plant varieties. These rights are most often referred to as plant variety protection (PVP) rights or plant breeders' rights. To be eligible for protection, the plant variety must be:

- distinct (the most important requirement), i.e. distinguishable by one or more characteristics from any other variety whose existence is a matter of common knowledge;

- stable, i.e. remain true to its description after repeated reproduction or propagation;
- uniform, i.e. homogeneous with regard to the particular feature of its sexual reproduction or vegetative propagation;
- novel, i.e. not have been offered for sale or marketed, with the agreement of the breeder or his successor in title, in the source country, or for longer than four years in any other country⁴.

An application for plant variety protection requires the completion of an application form, a description of the variety, and the deposit of propagating material. This material is not publicly available and only a government institution may use this material to conclusively demonstrate stability and homogeneity through grow-out trials. UPOV '91 Act extends the scope of the breeders' rights in three ways. First, it increases the number of actions for which prior authorisation of the breeder is required, from 'propagating for the purpose of commercial marketing, selling and marketing' under UPOV '78 Act, to any production or reproduction; conditioning for the purpose of propagation; offering for sale; selling or other marketing; exporting; importing; and stocking for the above purposes, under '91 Act.

Second, such actions are not just in respect of the reproductive or vegetative propagating material as with UPOV '78 Act, but also encompass harvested material obtained through the use of propagating material, and propagating and harvesting material of so-called "essentially derived" varieties (EDV). Third, protection is extended from at least fifteen years to a minimum of twenty years.

The right of breeders to use protected varieties for the creation of new varieties and to market these new varieties without authorisation from the breeder of the protected variety (the 'breeders' exemption') is upheld in both versions. One difference though is that UPOV '91 Act states that if a new variety is deemed to be essentially derived from a protected variety, the breeder of a new variety is required to seek permission from the owner of that protected variety before commercialising the variety considered to be EDV. It is sometimes assumed that under UPOV '78 Act a farmer is allowed to re-sow seed harvested from protected varieties for his or her own use, and the later version does not. In fact, such a 'farmers' privilege' is not referred to at all. The minimum standards of the Convention establish that the breeder's prior authorisation is required for 'propagating for the purpose of commercial marketing, selling and marketing' as mentioned under UPOV '78 Act. Although the farmers' privilege is not compulsory, most countries that are members

⁴ Under UPOV 1991: material of the variety must not have been sold more than one year before application in the source country and four years in any other country.

of the 1978 Convention do indeed uphold it. UPOV '91 Act is more specific about this matter. Whereas the scope of the breeder's right includes any production or reproduction and conditioning for the purpose of propagation, governments can use their discretion in deciding whether or not to uphold the farmers' privilege.

According to Article 15 of UPOV '91 Act, the breeder's right in relation to a variety may be restricted "in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting... the protected variety...". However, in doing so, Member States must provide mechanisms to safeguard the legitimate interests of the breeders. In Europe, this last requirement has resulted in a provision of the relevant legislations where farmers may save seed of only a limited number of species and, unless they are regarded as a small farmer, they are requested to pay a royalty which must be at least 50% of the royalty which is paid on certified seed. As yet the overwhelming majority of UPOV members are in Europe, North America, Latin America and Australasia. However, the interest amongst developing countries in joining UPOV is increasing and one can expect that many more of them will become members in the next few years.

9. COPYRIGHT

Copyright and related rights protect the rights of authors, performers, producers and broadcasters, and contribute to the cultural and economic development of nations. This protection fulfils a decisive role in articulating the contributions and rights of different stakeholders and the relation between them and the public. The purpose of copyright and related rights is twofold: to encourage a dynamic creative culture, while returning value to creators so that they can lead a dignified economic existence, and to provide widespread, affordable access to content for the public.

10. TRADEMARK

A trademark can be a word, a device, a number, a symbol, a distinctive shape, a colour, or any combination of these, which is used to identify goods or services so as to distinguish them from the same or similar goods or services coming from another source. In many countries, exclusive rights in a trademark are acquired from the moment of first use. However, registration of the mark invariably confers stronger rights than mere user rights. Unlike other forms of IP protection, a trademark can generally be kept alive forever, provided its use is safeguarded and renewal fees are paid.

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