

Chapter 2

Setting the Background

One effect of the TRIPS Agreement has been the establishment of patent rights in all WTO countries.¹ The reason is to be sought in art. 27.1 of the said Agreement which explicitly demands patent protection in all areas of technology. As a result, countries that did not provide for patent rights in some or all technological areas prior to the TRIPS Agreement, are now obliged to emanate patent laws for every technological sector. Art. 27.1 does, however, establish some exceptions. One of these exceptions, contained in paragraph 3 of the same provision, is specifically designed for plant breeding. Based on this exception, TRIPS signatories may protect plant varieties through patent rights, a *sui generis* system or a combination thereof. Under a *sui generis* protection, countries are free to exclude plant varieties from patentability; however, patent rights extend on plant varieties when they incorporate patented biological material.² This is because art. 27.3 (b) provides for the mandatory patentability of microorganisms. A consequence of such provision is, thus, the patentability of plant varieties despite their exclusion from patentable subject matter in some countries. It goes without saying that this situation creates legal uncertainty and impedes access to plant varieties for breeding purposes. Hence the need to adopt an exception for breeding purposes to patent rights in those countries where patent rights coexist with *sui generis* plant variety protection systems. A *sui generis* system implemented in most WTO countries is that of the breeder's rights provided for in the International Convention on the Protection of New Varieties of Plants (UPOV).³ Two main differences distinguish this system of plant variety protection from patent rights. One concerns the subject matter; the other is related to the exception of rights. Under the breeder's rights regime, intellectual property protection is granted only to a unique combination of

¹ Please, note that least developed and developing countries have been granted a transitional period for implementing the TRIPS Agreement.

² Correa (2012).

³ For a list of UPOV Members see UPOV (2014).

genes expressed as a distinct, uniform and stable phenotype. The free access and use of material of the protected variety by other breeders is expressly allowed for the purpose of breeding their own varieties. This means that breeders are free to use their competitors' varieties to introduce beneficial traits into their own breeding lines without infringing the original breeder's rights. This practice is allowed under what is known as the 'breeder's exception'. This system of variety protection was weakened after the establishment of patents on biological material. Contrary to breeder's rights, patents provide for a stronger protection by covering not only plants, but parts of plants, single genes, and breeding methods. Even more significantly, protection is often extended to every plant containing the inventive element or resulting from a patented process. As a consequence, the use of plant material under patent law expressly requires the authorization of the patent holder. The transaction costs and difficulties related to patent licensing restrict breeder's freedom to use all available genetic material in their breeding programs.⁴ Fearing a blockage of genetic flows among plant breeding activities, breeders associations in the aforementioned European countries lobbied for the introduction of a breeding exception to patent rights.⁵ In the last years, the same issue was presented to the Dutch parliament, which adopted the same exception in 2013. The debate in the Netherlands distinguished between a 'limited' breeding exception (as already introduced in the patent laws of France, Germany, and Switzerland) and a 'comprehensive' breeding exception, that is an exception that allows the commercialization of plant varieties containing patented traits.⁶ This last type of exception was proposed by Plantum, the Dutch association of plant breeders and is recently under discussion in the House of Representatives in the Netherlands.⁷

The introduction of exceptions to patent rights for breeding purposes poses challenges to policymaking by bringing to light the difficulties of reconciling opposing interests. These new exceptions incentivize plant breeding activities, while, at the same time, they pose new limits on biotechnological companies that rely on patent protection to create innovative products. This is mainly because the pharmaceutical, biofuel, chemical, and cosmetic industry protect their innovations with patent rights, whereas the plant breeding industry often uses breeder's rights but requires access to patented biological material. These different IP instruments lead to diverse interests and market power between patentees and plant breeders.

⁴ Louwaars et al. (2009) Nr. 14.

⁵ Please, note that lobbying activities were mainly undertaken by breeders of seed-propagated crops. Breeders of asexually reproduced plants, usually acting under CIOPORA, are against the introduction of a breeding exception to patent rights. Also note that the number of patents relevant for asexually propagated plants is very low.

⁶ Trojan (2012).

⁷ See the two letters of Ms Sharon A.M. Dijksma, Dutch Minister of Agriculture, dated 27 June 2013, Vergaderjaar 2012–2013, 33 365 (R1987) Nr. 6 and 28 June 2013, Vergaderjaar 2012–2013, 33 365 (R1987) Nr. 8.

Policy implications go hand in hand with the academic relevance of exceptions to patent rights. Economic theory suggests that exceptions to patent rights inevitably weaken patentee's rights and may undermine the structure of the patent system. Since the patent system is designed to promote innovations, the desirability of an exception to patent rights may appear controversial. A breeder's exception to patent rights further raises this debate given its aim to exclude research *with* patented subject matter. Indeed, breeders have an interest in using patented traits as tools in their breeding processes. For example, breeders may introduce a patented trait on pest resistance into a new variety. This type of activity does not involve work on the patented invention. It simply uses the patented trait as a tool for introducing a gene construct into the plant genome. Thereby it is ineligible for the commonly accepted experimental use exception *on* the patented material.⁸ Many economists believe that an exception with patented subject matter significantly diminishes the incentive to invest in new technology.⁹ These divergent interests and views on the breeding exception draw attention to the difficulties legislators face in giving a definite answer to the controversy accompanying the incorporation of a breeding exception into patent law.

The following chapters shed light on the above issues by clarifying all interests involved and by offering guidance on how to reconcile these interests with countries obligations under the TRIPS Agreement. In this respect, art. 30 of said agreement is most relevant since it explicitly authorizes countries to adopt exceptions to patent rights. The vague formulation of this article, however, does not provide clear rules for WTO Member countries that decide to adopt an exception to patent rights for plant breeding activities. Although a WTO panel offered some insights on the meaning of article 30 in the EC-Canada case, the panel's decision lacked a satisfactory clarification of the conditions set in article 30.¹⁰ Thus, the question of TRIPS-compliance of national legislations that have adopted or intend to introduce a breeding exception to patent rights is still open.

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⁸ For an extensive review of exceptions to patent rights see Bently et al. (2010).

⁹ Hantman (1985), p. 617; Eisenberg (1987), pp. 177 and 225; Eisenberg (1989), pp. 1017 and 1078; Gilat (1995), p. 44; Israelsen (1988–1989), pp. 457 and 469.

¹⁰ WT/DS/114/R.

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