THE BREEDER'S EXCEPTION TO PATENT RIGHTS AS A NEW TYPE OF RESEARCH EXCEPTION

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ABSTRACT

Art. 27 (c) of the Agreement on a Unified Patent Court (AUPC) provides for a new type of exception to patent rights at European level: the breeder's exception. This provision limits the effects of patent rights for "the use of biological material for the purpose of breeding, or discovering and developing other plant varieties". The breeder's exception has already been incorporated into the national patent laws of France, Germany, the Netherlands, and Switzerland. When the AUPC enters into force, the exception will be mandatory for all of its contracting parties. This paper will explain the reasons for introducing the breeding exception into the patent system as well as its importance for academic and business purposes. It will also highlight how scientific developments influence legislation.

KEYWORDS

Breeder's exception. Patent rights. Research exception. Plant breeding. Innovation.

A NEW TYPE OF EXCEPTION TO PATENT RIGHTS: THE BREEDING EXCEPTION

Exceptions to patent rights remove liability for infringing patent rights. Contrary to "exemptions from patentability" which exempt patented material *ex ante*, exceptions to patent rights allow specific acts that would not be permissible otherwise (CHRISTIE, 2011; KUR, 2008: 5).This means that third parties can freely use patented material for particular purposes. The main purpose and most recurrent use of exceptions to patent rights is research on patented material that aims to verify, design around, experiment or improve the invention; to challenge the validity of the patent; or to invent around the patented elements (VAN EECKE, KELLY, BOLGER & TRUYENS, 2009). Another type of exception, which is quite controversial in the patent community, is the exception that exempts research with the patented invention, i.e., when the invention is used as a tool to achieve an aim. Another reason for differentiating between research exceptions is the commercial intent. When the exception allows research for obtaining commercial profit, it may significantly detract from patentee's economic return and thus hamper innovation. Hence countries allow only for exemptions without commercial intent. It is, however, not easy to distinguish between research with or without commercial intent, especially if research is conducted by academic institutions. Courts have decided cases based on the intent to commercialize the invention. US judges, for example, decided in *Embrex Inc. v Service Engineering* that a patent on a method for inoculating chicks against diseases *in ovo* was infringed by university researchers who were trying to find a way to work around the patent because the ultimate objective of scientific researchers was commercialization.

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The aforementioned types of exceptions to patent rights are common practice in most countries. Civil law countries have introduced them into patent laws, while common law countries have often decided the scope of exceptions to patent rights in court (PRIFTI, 2015: 80-95). The formulation of exceptions varies broadly among countries and it is not easy to understand which acts fall under a type of research exception. With the internationalization of the patent system, it became necessary to find a definition of an exception to patent rights that could join the diversity of national laws. Art. 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the only provision that provides for exceptions to patent rights, establishes the following:

> Members may provide *limited exceptions* to the exclusive rights conferred by a patent, provided that such exceptions do not *unreasonably conflict with a normal exploitation* of the patent and do not *unreasonably prejudice the legitimate interests* of the patent owner, *taking account of the legitimate interests* of third parties (*emphasis added*).

The vagueness of this provision does not allow concluding which type of research exception can be deemed permissible at international level. World Trade Organization (WTO) members should adopt exceptions to patent rights in line with the spirit of art. 30 of the TRIPS Agreement but their compliance with art. 30 is to be decided case by case by a WTO panel. Since TRIPS has entered into force, only one WTO panel has addressed the issue of interpretation of article 30 while examining the EC-Canada case. Following a complaint of the EC and its Member states in 1998, the panel analyzed the compliance of section 55.2 (1) and (2) of the Canadian Patent Act. Section 55.2 (1) concerns the regulatory review exception or the so-called Bolar exception, while section 55.2 (2) is referred to as the stockpiling exception. The Bolar exception, firstly established in US law, allows pharmaceutical firms to start the necessary studies, tests, and trials before the patent expires, in order to obtain regulatory approval[2]. The stockpiling exception was subject to the successful implementation of regulatory aprovals. Afterward, competitor firms could start to manufacture and stockpile patented goods in the 6 months preceding patent expiry. The rationale of this exception was that of permitting competitors to place their products into the market immediately after patent expiry. The WTO panel rejected this second exception, but upheld the compliance of the Bolar exception.

The interpretative outcome of the panel on article 30 has been deemed limited because it provided a general argumentation instead of clarifying the meaning and the content of each step of art. 30. One important aspect of the decision regards the specification that the conditions of article 30 should be cumulatively satisfied[3]. Several commentators have criticized the approach of the panel because it does not take into account the particularities of domestic innovation systems, the principles and objectives of the TRIPS Agreement, and it might refrain countries from adopting flexible solutions based on their different and evolving socio-economic needs (CORREA, 2005: 10-16; KUR, 2011: 239-240).

Against this background, it is not possible to define *a priori* which type of research exception can be deemed permissible under art. 30 of the TRIPS Agreement. The

[2] Section 271-e-1 of the Drug Price Competition and Patent Term Restoration Act, informally known as the "Hatch-Waxman Act" [Public Law 98-417] after a court case *Roche Products v Bolar Pharmaceutical*, 733 F.2d 858 (Fed. Cir. 1984).
[3] Para. 7.20 WT/DS114/R.

introduction of the breeding exception to patent rights may further increase this legal uncertainty since it aims at exempting patented material that is used as a tool in breeding processes with commercial intent. This provision limits the effects of patent rights for "the use of biological material for the purpose of breeding, or discovering and developing other plant varieties"[4]. The breeder's exception was first incorporated into the national patent laws of France[5], Germany[6], the Netherlands[7], and Switzerland[8], and recently in art. 27 (c) of the Agreement on a Unified Patent Court (AUPC)[9].

In order to understand the breeding exception to patent rights, it is important to clarify that the breeding exception to patent rights should not be confused with the breeder's exception to breeder's rights provided for by the International Convention on the New Varieties of Plants (UPOV)[10]. The latter is based on the use and betterment of existing plant varieties for the purpose of creating new varieties. The breeding exception to patent rights has the same purpose of creating new varieties, but it aims at using patented biological matter. Under the current research exception, breeders (provided they have the necessary resources and innovation capacities) or researchers might use and improve patented material but this is not specifically relevant in the process of plant breeding. The main objective of those who breed new varieties is to access patented traits since they confer particular characteristics to the plant. These traits may be crossed out during the breeding process or might be present in the final variety. Therefore, the main interest of breeders is to use patented material as a tool. This means that the breeding exception aims at exempting research done with protected subject matter.

With respect to the distinction of non/commercial purposes, the breeding exception has a commercial intent since it serves to create products that will be put into the marketplace. Indeed, using patented material only for breeding varieties that will never be commercialized has no practical utility. The very purpose of plant breeding is that of making plant varieties available for the whole society. Commercial purpose, thus, is inherent in the breeding process. The commercial purpose and the use of the patented material as a tool in the breeding process put the breeder's exception in stark contrast with other type of exceptions to patent rights. Although academics have shown the compliance of the breeder's exception to patent rights with the TRIPS Agreement, it is important to understand the rationale of such type of exception, which appears to be an exception within an exception.

DO WE NEED A BREEDING EXCEPTION TO PATENT RIGHTS?

This new type of exception was introduced as a result of plant breeders' lobbying (PRIFTI, 2015: 64). The associations of plant breeders in France, Germany, the Netherlands, and Switzerland exercised influence for the introduction of the exception both in their respective parliaments and in Brussels. The reason for lobbying was based on the necessity to access breeding material and maintain a kind of open innovation in

[4] For understanding of these terms, please refer to PRIFTI (2013).
[5] Article L. 613-5-3 of the Code de la Propriété Intellectuelle adopted in 2004.
[6] Section 11.2.b of the Patent Act adopted in 2005;
[7] Article 53.2.b of the Dutch Patent Act.
[8] Article 9 (e) of the Federal Act on Patents for Inventions, adopted in 2008.
[9] Agreement on a Unified Patent Court (AUPC), (2013/C 175/01).
[10] Art. 15.1 (iii) International Union for the Protection of New Varieties of Plants, Paris, 2 December 1961, as revised at Geneva on 10 November 1972, 23 October 1978, and 19 March 1991 (Geneva: UPOV. UPOV Doc. 221 (E), 1996).

breeding lines. Breeders feared that the intersection between plant breeder's rights provided for in the UPOV Convention and patent rights on biological material would block breeding programs. This may occur when a plant variety is contemporarily protected with breeder's rights and patent rights. For example, plant breeder's rights may cover a cauliflower, but a genetic sequence in the cauliflower that confers resistance to pesticides may be protected through patent rights. In this situation, plant breeders need to obtain a license from the patentee every time they need to use the cauliflower. Patentees, on the other hand, could freely use the variety because plant breeder's rights are not as restrictive as patent rights. They allow others to use the variety and create new distinct varieties. Only if the variety is similar, remuneration is required[11]. Another difficulty with accessing patented varieties can be associated with the costs of licensing. Not all breeders can afford to pay licensing fees, and moreover, patentees can refuse to grant licenses. For these reasons, the intersection between these rights was deemed to highly increase transaction costs for breeders and block breeding programs. This concern may be especially important in cases of widespread plant diseases, food crises, and emergency situations where breeders need immediate access to biological material. The relevance of the matter brought together business interests and the breeder's exception to patent rights was widely accepted within the biotechnological industry.

In order to allow for the free use of patented material in breeding programs, countries could have broadened the interpretation of their research exception. However, they chose to introduce a specific exception. This is because EU countries, with the exception of Belgium, exempt from infringement only research done on patented subject matter. Since this type of exception aims only at determining the scope of a patented invention, its claims, how it works, seeking an improvement, inventing around the patented invention or doing pure research, it does not allow working with patented material for breeding purposes. Therefore, there was a need to expand the scope of the research exception in order to include breeding activities. Moreover, it was necessary to provide for exceptions that cover commercial purposes since the breeding exception is an exception with commercial intent. If the scope of the research exception had been broadened in order to include research with commercial intent, the incentive to invent in other sectors might have been affected. In this context, the introduction of a specific exception to patent rights appeared as the most appropriate solution.

DIFFERENT TYPES OF BREEDING EXCEPTION

The above-explained exception is often termed a "limited breeding exception" as opposed to a full, a broad, or a comprehensive breeding exception. After the Dutch Parliament adopted a limited exception in December 2013, the debate in the Netherlands focused on the introduction of a "comprehensive breeding exception"[12]. A comprehensive exception to patent rights has been advocated by the Dutch Association of Plant Breeders (Plantum). This type of exception would permit breeders to insert patented biological material and further commercialize the plant varieties containing these patented elements. Plantum's proposal is concerned only with patented products (gene traits) and not with patented processes (breeding techniques). Such choice is based on breeder's interest to freely access biological material for plant breeding

[11] Art. 14.2 of the UPOV Convention.

[12] 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.

purposes and harmonize the UPOV and patent system. Therefore, the comprehensive breeding exception would not cover the simple commercialization of varieties containing patented traits, but only those improved varieties that are a result of breeding activities (TROJAN, 2012: 10-12). The formulation of the comprehensive breeding exception might, thus, be as follows: "The effects of a patent shall not extend to the use of biological material for breeding, discovery and development, and commercialization of a new variety type". Such a broad patent exception for the breeding sector differs from the scope of breeder's rights provided for in the 1991 UPOV. This act recognizes exceptions to plant breeder's rights in its article 15, but circumscribes them to the concept of essentially derived varieties (EDVs). The aim of this provision is to avoid plagiarism in breeding. In simple terms, this means that breeders, who make trivial improvements to the original variety, should pay royalties to the first breeder. Practice has, however, shown that the determination of an EDV is very difficult. Litigations over EDVs are costly and involve extremely complicated scientific aspects (WÜRTENBERGER, 2006). In order to avoid these challenging situations, the Dutch breeders, proposed a comprehensive breeding exception. This type of exception has not yet been adopted.

THE BREEDING EXCEPTION AND INNOVATION

One important concern is whether the breeding exception can disincentivize innovation. The concern is based on the neoclassical economic theory that views patent protection as a necessary incentive for innovation (KITCH, 1977)[13]. Here we must distinguish between the concerns of plant breeders and those of the biotechnological industry. We must further differentiate between the limited and the full breeding exception since the incentives for innovation change based on the type of exception. The following paragraphs will explain innovation concerns for both plant breeders and biotechnological industry.

Biotechnological companies and innovation

It is important to clarify that whoever holds a patent on genetic material that could potentially be exempted from the breeder's exception has an interest in the effect of the exception on innovation. Exceptions to patent rights weaken the incentive to innovate, but at the same time they allow newcomers to enter the market. It is not possible to know in advance the effects of the exception on innovation and there is no specific study on the breeder's exception to patent rights. This may be due to the multifaceted and cumulative nature of innovation. Decisions on innovation processes depend upon many factors and it is often not easy to take all these factors into account. However, some studies on patent protection have shown that patents are an important means to recoup investment for the pharmaceutical, biofuel, chemical and cosmetic industry (HARABI, 1996; LEVIN, NELSON & WINTER, 1987: 783). These industries patent inventions on genetic material that can be applied in breeding lines. When the protected material is freely used by plant breeders, their incentives to invest may weaken. There has, however, been no controversy in this regard. The issues at stake are high in the case of a comprehensive breeder's exception. In this case, the biotech industry has firmly opposed its introduction. Monsanto, for example, has sent a letter to Dutch ministries explaining the negative consequences of a full breeding exception (PRIFTI, 2015: 139)[14].

[13] Please, note that this theory has recently been challenged based on new institutional economics reasoning. See, for example, ANDERSEN & KONZELMANN (2008).

[14] The letter of Monsanto to the concerned Dutch ministries:

The fact that this type of exception has not yet been introduced shows the importance of the matter. If the biotech sector had to choose between a limited and a full exception, it would certainly opt for the first.

Plant breeders and innovation

Plant breeders have an interest to have a constant flow of germplasm in order to improve their breeding lines and create more plant varieties. They use plant breeder's rights provided for in the UPOV Convention to protect their varieties. As explained above, plant breeder's rights are a form of open innovation that allows third parties to freely access and improve protected varieties. If the new variety created by this process is similar to the protected one, a remuneration fee is to be paid to the first breeder. If the new variety is different, the breeder can freely commercialize it. This system provides incentives for breeders to innovate and at the same time, it maintains an open collaboration in the sector. The breeding exception to patent rights helps breeders maintain this system and increase innovation when breeding lines are enriched with genetic inventions. The comprehensive exception would certainly bring more benefits to plant breeders.

Society and innovation

In order to give an exhaustive response to the question of whether the breeder's exception increases innovation, it is necessary to consider the effects of patent law on society given that the aim of patent law should be that of incentivizing innovations. What matters here is not a judgment of value on the patent system, but on the scope of patent rights. The question of the optimal design of patent law for promoting innovations has been comprehensively analyzed by SCOTCHMER (1991; 2004). She sustains that the main challenge that economics faces for promoting innovations is providing the right incentives. In this context the core question is: how to reward innovators for the contribution they provide and at the same time enable other innovators to create new innovations? This question stems from the cumulative nature of innovations. Plant breeding is a good example of cumulative innovation. Old plant varieties offer an input for new varieties of plants as well as assure a "quality-ladder" innovation process because each variety builds upon a previous variety and at the same time it allows for further improvements. In this respect, access to patented genetic material becomes crucial in order to promote new varieties of plants.

Access to patented innovations depends on the strength of patent protection. Strong patent rights put high barriers to access, whereas weak patent rights set lower boundaries. Weak patent rights, thus, might facilitate cumulative innovations. But it is not clear whether strong patent rights lead to more innovation in a cumulative context. This is mainly because strong patent protection has two main effects. Firstly, it increases return to R&D in the short run. According to the economic theory, this generates high incentives to invest and consequently, more innovation. Secondly, it increases the costs for R&D activities in the long run for other innovators who would be forced to invent around or obtain a license on the protected invention. This means that cumulative innovation comprises a trade-off between the incentive to innovate and access to knowledge as a public good. Here it should be emphasized that accessing knowledge is crucial for cumulative innovation, even though this may be to the detriment of the first innovator. This point can be illustrated by the following example:

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http://vorige.nrc.nl/multimedia/archive/00242/Patentrecht_09-07-0_242612a.pdf (Accessed 24 October 2013).

in a situation where a particular crop (wheat) or plant (potato) is affected by a pest or disease, and the only way to avoid the extinction of the plant is to use a patented genetic sequence, there is no doubt that from a social perspective, it is preferable to have immediate access to the patented material. If the breeder's exception were not adopted, breeders or governments would have to negotiate a license with the patentee. The time and the financial resources dedicated to such process would certainly delay breeding processes and put the creation of new plant varieties at risk.

A cost-benefit analysis also suggests that exceptions be adopted when their benefits overcome losses for the society. MOSCHINI and YEROKHIN argue that when R&D costs are low, relative to the potential returns, a broad exception may be desirable because it provides a large pool of innovators in follow-up inventions. On the contrary, when research is costly and risky, a broad exception may not render enough incentives to invest (MOSCHINI & YEROKHIN, 2007). Since patentee's research is costly and risky, a broad exception may not render enough incentives to invest. This argument does not favor the introduction of a full breeder's exception. However, public policy issues that promote the right to food or emergency situations such as food crisis would urge the legislator to weaken patent rights. The main concern here regards the incentive to innovate: does the breeding exception provide incentives to innovate for patentees and at the same time allow breeders to create new varieties of plants? Studies have answered this question in affirmative for the limited breeder's exception, but have doubts with respect to the full exception.

CONCLUSION

This article explains the necessity to adopt a new type of research exception in order to accommodate the interests of all stakeholders involved in plant breeding. This exception has generated many worries among some patent holders who claim that its introduction will severely cut investments in biotechnological research. They accept the introduction of a breeding exception that builds upon UPOV (so-called "limited exception"), but firmly oppose a full breeding exception. As per now, the debate on a full breeding exception seems to be most relevant in the Netherlands, where the parliament has adopted only the limited breeding exception for the time being. Finding a solution for a full breeding exception that takes into account the interests of patentees, plant breeders, and society, is not an easy task. This task requires the understanding of the role of the patent system on incentivizing innovations and their diffusion.

It also requires an understanding of science and its evolution. The breeder's exception to patent rights was required only after the development of new technological inventions, such as modified genetic sequences. The technical function of these inventions was deemed worth of patent protection. It is apparent, thus, that scientific advancements in biology influenced a change in the law. The constant development of science may put continuous pressure on the legislator to update the legal framework and respond to societal needs. This is a challenge for both the national and international legal systems.

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