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THE INTERFACE BETWEEN PATENTS AND PLANT VARIETY RIGHTS IN EUROPE

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I. Introduction

Issues of interface between different systems of protection are one of the most interesting and complex aspects of modern IP law. Although not a completely new phenomenon, such interfaces seem to have proliferated recently. The main reasons for this development are, on the one hand, the creation of new IP systems and, on the other, the fact that the traditional IP systems (patents, copyright and trademarks) have gradually expanded their scope of application, either as a result of explicit decisions by the legislator or, more frequently, by the development of case law.

Consequently, IP practitioners are increasingly confronted with situations where the same subject-matter may, at least theoretically, fall under more than one system of protection. The most prominent example is software related innovations for which, in several national legal systems, both copyright and patent protection are available. Further examples include the specific shape of a razor head or a car grille which might be protected as a technical innovation in patent or utility model systems, as an aesthetic creation in industrial design or copyright systems, or even as a three-dimensional mark under trademark law.

In such a situation, typically the following key question arises: Should the legal framework let the relevant systems of protection work independently of each other or should it contain specific provisions for the area of possible overlap? This question comprises two main aspects:

- The first relates to the availability of protection: Should subject-matter capable of being protected under system A be precluded from protection under system B (exclusive availability) or should the innovator be able to choose one of the systems (alternative availability) or even both systems (cumulative availability)?
- The second aspect relates to the scope and exercise of the rights concerned: Should the exercise of rights under system B be autonomous from that of rights under system A, or should there be a convergence of the two systems insofar as the interface area is concerned? In particular, do the limits and exemptions foreseen in system A have a limiting impact on the rights under system B?

This key question and its different aspects are also at the centre of the discussions on the interface between patents and plant variety rights (PVRs). They play an important role in legislation and case law, both at the international level and at the national or regional level. In this context, attention is drawn to the abolition of the double protection prohibition during the UPOV revision of 1991¹, to the options provided for in Art. 27(3)(b) of the TRIPS Agreement², but also to the Novartis decision of the Enlarged Board of Appeal of the

¹ Prior to the revision of 1991, Art. 2(1) of the UPOV Convention read as follows: “Each member State of the Union may recognise the right of the breeder provided for in this Convention by the grant either of a special title of protection or of a patent. Nevertheless, a member State of the Union whose national law admits of protection under both these forms may provide only one of them for one and the same botanical genus or species.”

² TRIPS Members may exclude from patentability plants and essentially biological processes for the production of plants. However, Members must provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

European Patent Office (EPO)³ and to the Pioneer Hi-Bred decision of the US Supreme Court⁴.

These issues will be dealt with below from the perspective of European law. In this context, one has to be aware that, due to the coexistence of national and regional law, the legal framework within Europe is complex. In addition, the regional law consists of different layers (Community law and non-Community law) and is, to some extent, still work in progress⁵. Notwithstanding these peculiarities which make a comparative assessment rather difficult, European law is of particular interest for the interface problems at issue, for it contains a modern piece of legislation, i.e. the EU Directive on the protection of biotechnological inventions⁶, which was enacted, *inter alia*, with the explicit goal of promoting the fruitful coexistence of the patent and PVR systems and which directly addresses relevant interface issues in several of its provisions. It may thus give valuable guidance on possible solutions and serve as a legislative model.

II. Availability of protection

International law as set out in the TRIPS Agreement and the UPOV Convention clearly requires IP protection for plant-related innovations. Nevertheless, there is some discretion for national and regional legislators as to the form in which this protection is made available and in particular as to whether the availability of patents or PVRs should be made exclusive, alternative or cumulative⁷. European law appears to give priority to the PVR system: on the one hand, plant varieties may be protected by national PVRs or by a uniform Community-wide PVR⁸. On the other hand, European patents are excluded for plant varieties and for essentially biological processes for the production of plants⁹.

Notwithstanding these provisions, the European legal framework does not really reduce the area of possible overlap between the two systems, since the patent system remains capable of covering plant-related innovations. The reason for this is a very characteristic feature of IP rights in general and of patent law in particular, namely the distinction between subject-matter eligible for protection as such and subject-matter falling under the scope of protection. For example, a product per se may not be claimed in a patent if it does not fulfil the requirement of novelty. However, a new and inventive process for making the product is patentable, and

³ G 1/98, *Transgenic plant/NOVARTIS II*, OJ EPO 2000, 111.

⁴ *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred International Inc.*, 10 December 2001, 60 USPQ2d 1865.

⁵ The most prominent examples are the Proposal for a Council Regulation on the Community patent and the draft optional Protocol on the settlement of litigation concerning European patents.

⁶ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (EU Biotech Directive), OJ EPO 1999, 101.

⁷ *Supra*, notes 1 and 2.

⁸ On the basis of the EC Council Regulation No. 2100/94 on Community plant variety rights (CPVR Regulation). If a Community plant variety right is granted, Art. 92(1) CPVR Regulation prohibits the grant of national PVRs or patents for the same plant variety by EU member States.

⁹ Art. 53(b) European Patent Convention (EPC); Art. 4(1)(a) and (b) EU Biotech Directive. Since it also follows from Art. 53(b) EPC that microbiological processes and their products are patentable, it has been argued that plant varieties may be patented if they are the products of a microbiological process. However, this argument was rejected by the Enlarged Board of Appeal in the Novartis decision (*supra*, note 3).

the protection conferred by this process patent will extend to the product when directly obtained by the patented process.

The analysis as to where possible overlaps between the two systems exist therefore needs to be broadened in order to take into account the above-mentioned characteristic of IP law. In particular, attention has to be paid to the following constellations:

- If a patent claims a non-essentially biological process for the production of plants, the protection conferred by this patent will extend to all plants which are directly obtained by the claimed process¹⁰. According to Art. 8(2) EU Biotech Directive, this extension not only comprises the first generation plants, but also the following generations (as long as they possess the same characteristics as the first generation plants). The production or use of a plant variety may therefore fall under such a process patent¹¹.
- If a patent claims a DNA sequence, for example a gene or a vector, the protection conferred extends to any material into which the patented DNA sequence has been introduced and in which it functions¹². Such material may well be a plant variety.
- Furthermore, European patent law also permits patent claims on plants in general, i.e. claims which are not restricted to one or more specific plant varieties. If, e.g., a claim is directed to transgenic plants characterised by the insertion of a specific DNA sequence, it is considered not to be directed to plant varieties per se (and thus not hit by the patent exclusion of plant varieties) since plant varieties are defined by their whole genome and, hence, are characterised by a multiplicity of genetic traits. Nevertheless, the scope of protection of such claims may also encompass plant varieties, namely when those varieties contain the specific DNA sequence¹³.

This analysis demonstrates that, notwithstanding the exclusivity of protection of plant varieties under the PVR system, the European legal framework is far from drawing a clear demarcation line between the two systems of protection. Instead, the overlap area remains rather broad so that, on the issue of availability of protection, European law is, in its practical

¹⁰ See Art. 64(2) EPC.

¹¹ In the Novartis decision (above, note 3), the Enlarged Board of Appeal declined to infer from the patentability exclusion of plant varieties that a process claim the protection of which might extend to a plant variety has to be refused. See headnote II: “When a claim to a process for the production of a plant variety is examined, Art. 64(2) EPC is not to be taken into consideration.”

¹² See Art. 9 EU Biotech Directive: “The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.”

¹³ In view of this consequence, claims on transgenic plants were, for a considerable amount of time, very controversial in Europe. It was strongly advocated that the exclusion of plant varieties should be given a broader reading, i.e. by making unlawful those claims which merely encompass plant varieties. In the EPO appeal case law, this view was expressed in the well-known decision *Plant cells/PLANT GENETIC SYSTEMS* (T 356/93, OJ EPO 1995, 545). The issue has now been resolved by the Novartis decision of the Enlarged Board of Appeal (above, note 3) and by the European legislator. According to this legislative-judicial consensus, plants can be patented as long as plant varieties are not individually claimed. Thus inventions which concern plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety (see Art. 4(2) EU Biotech Directive; Rule 23c(b) EPC).

consequences, not so different from national systems such as the US or Australian systems which accept the patentability of plant varieties.

III. Independence versus convergence of the prerogatives of right holders

a) Overview

Since each IP system tailors the prerogatives of the right holder in a specific manner, it does not come as a surprise that the prerogatives of a patentee differ from those of a PVR holder to some extent. According to the traditional philosophy of IP law, exemptions and limits foreseen under a specific protection scheme cannot be invoked against the owner of a different IP right. The beneficiaries of an exemption are generally not considered to possess a positive right which would exist independently from the statutory scheme of the IP right in the context of which the exemption is foreseen. Courts have been very reluctant to recognise such exemptions as rights per se which would also prevail against other IP rights. A pertinent example with respect to the interface at issue is the recent Monsanto decision of the US Court of Appeal for the Federal Circuit¹⁴. It therefore appears to be a matter for the legislator rather than for the courts to take over a right limitation from a specific protection scheme to another or to create specific exemptions in the overlap area. The EU Biotech Directive uses both mechanisms, as will be demonstrated below.

b) Breeder's privilege and compulsory dependency licences

It is an important principle of the international PVR system that the right holders cannot prevent other breeders from using the protected plant varieties in research and development ("breeder's privilege"). Furthermore, any newly developed variety may be freely marketed if it is clearly distinguishable and not essentially derived from the protected variety and if its production does not require the repeated use of that variety¹⁵. Since general patent law does not contain a similar broad exemption, the EU legislator perceived the risk that patents on plant-related inventions might be detrimental to innovation activities in the plant breeding industry. The EU Directive therefore foresees the possibility of compulsory licences in cases where a plant variety right cannot be exploited without infringing a prior patent, and vice versa. A requirement for such a dependency licence is that the plant variety or the invention constitutes significant technical progress of considerable economic interest¹⁶.

However, compulsory licenses against dominant patents do not solve the issue completely since they presuppose the very existence of a new plant variety. The question as to whether the plant breeder is allowed to use patented material in his breeding activities thus remains a matter of the research exemption under general patent law. While the scope of this exemption,

¹⁴ *Monsanto Co. v. McFarling*, 23 August 2002, 64 USPQ2d 1161, 1166 ("It is thus established that the right to save seed of plants registered under the PVPA does not impart the right to save seed of plants patented under the Patents Act"); for a summary see the case comment by *J.C. Orlet*, Patent World, December 2002/January 2003, p. 8.

¹⁵ Art. 15(1)(iii) UPOV 1991; Art. 15(c) and (d) CPVR Regulation.

¹⁶ For further details see Art. 12 EU Biotech Directive and, as an example of national implementation of this provision, the UK Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002 (Statutory Instruments 2002 No. 247).

which is governed in Europe by national law, is not clear-cut, it is mostly believed to allow research which aims at improving the invention. This does not mean that automatically all plant breeding activities will be exempted from patent infringement. Nevertheless, when balancing the interests of patentees, on the one hand, and competing innovators, on the other, European patent law seems to give some comfort to the competitor, at least when compared with the situation, e.g., under US patent law.

c) Scope of right vis-à-vis farmers (exhaustion doctrine, farmer's privilege)

Following the exhaustion principles contained in Art. 16(1) UPOV 1991¹⁷ and Art. 16(1) CPVR Regulation, a farmer is allowed to use protected plant material in order to produce his harvest. In order to achieve a similar result when the plant material is covered by patents, the EU Biotech Directive contains an explicit provision which adapts the exhaustion doctrine of general patent law to the specific situation of patents on biological material¹⁸.

However, the exhaustion principle cannot be invoked with respect to acts that involve a subsequent cycle of reproduction¹⁹. Nevertheless, there is a strong tradition in PVR systems to acknowledge to some extent a so-called farmer's privilege, i.e. an exemption for farmers who use saved seed for a further round of producing the harvest. The UPOV system gives room for such exemptions under certain conditions²⁰, and its Members have made use of this exception in a rather heterogeneous manner. A high degree of variation has traditionally existed even between the national PVR systems within Europe. However, in 1994 the CPVR Regulation established a common standard for Community plant variety rights which also appears to have had a harmonising influence on the national PVR systems. According to this standard, the farmer's privilege only exists for certain agricultural plant species (fodder plants, cereals, potatoes, oil and fibre plants) and is subject to an equitable remuneration from which only small farmers are exempted²¹.

Most interestingly, the EU Biotech Directive has created an identical exception under patent law and, in this respect, directly refers to the scheme of the CPVR regulation. Due to the legislative link, patents and PVRs completely converge in this particular respect. Patent

¹⁷ “The breeder's right shall not extend to acts concerning any material of the protected variety ... which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned ...”

¹⁸ Art. 10 EU Directive reads: “The protection ... shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.”

¹⁹ This is made clear by the proviso contained in Art. 10 EU Biotech Directive (above, note 18). The dicta of the US Court of Appeal for the Federal Circuit in *Monsanto Company v. McFarling*, 64 USPQ2d 1161, 1167 (2002) (“The ‘first sale’ doctrine of exhaustion of the patent right is not implicated, as the new seed grown from the original batch had never been sold.”) appear therefore equally valid under European patent law.

²⁰ See Art. 15(2) UPOV 1991 (optional exception).

²¹ For details cf. Art. 14 CPVR Regulation and the Implementing Regulation (EC) No. 1768/95 of 24 July 1995, amended by Regulation (EC) No. 2605/98 of 3 December 1998.

lawyers will therefore have to follow the future legislative development of the European PVR system and its judicial interpretation very closely.

An important issue of the breeder's privilege under European law concerns the enforcement of the obligation of the farmer to pay an equitable remuneration to the right holder. The CPVR Regulation emphasises that monitoring compliance with the provisions is a matter of exclusive responsibility for the holders and that in organising that monitoring they may not provide for assistance from official bodies²². In order to permit such monitoring, however, the Regulation foresees that relevant information must be provided to the right holders at their request, by farmers and by suppliers of processing services²³. While the implementing rules list the items of information to be provided in some detail²⁴, there is some ambiguity as to the conditions under which the information right exists.

In particular the question arose whether the right holder may request the relevant information from any farmer or only from those farmers who have made use of the agricultural exemption with respect to the protected variety. Upon referral by a German court, this issue was recently decided by the European Court of Justice in its first judgment on the interpretation of the CPVR Regulation²⁵.

The Court took the view that an interpretation of Art. 14(3) of the CPVR Regulation as meaning that all farmers, merely by belonging to that profession, must provide the right holders with the requested information would go beyond what is necessary in order to safeguard the legitimate interests of both the breeder and the farmer. However, it also recognised the difficulty the holder has in asserting his right to information since examination of a plant does not reveal whether it was obtained by the use of the product of the harvest or of purchased seed. The holder must therefore have the right to request information from a farmer where he has some indication that the latter has relied or will rely on the agricultural exemption. In particular, the acquisition of propagating material of a protected variety should be considered to be such an indication. The Court considered that it should be possible for the right holder to make arrangements to know the name and address of the farmers who buy propagating material of one of his protected varieties, however long the distribution chain between the holder and the farmer.

This decision of the European Court of Justice, which also has a direct impact on the enforcement of plant-related patent rights, appears to be in line with a previous decision of the German Federal Supreme Court on national plant variety rights²⁶. Nevertheless, it will certainly not simplify the enforcement of intellectual property rights in plant biotechnology against European farmers.

²² Art. 14(3), fifth indent, CPVR Regulation.

²³ Art. 14(3), sixth indent, CPVR Regulation.

²⁴ See Art. 8 of the Implementing Regulation No. 1768/95

²⁵ Judgment of the Court (Fifth Chamber) of 10 April 2003, C-305/00, Christian Schulin/Saatgut-Treuhandverwaltungsgesellschaft mbH, EuZW 2003, 404. The same issue is also the subject-matter of another referral (C-182/01, Saatgut-Treuhandverwaltungs GmbH/W. Jäger) which is still pending before the ECJ.

²⁶ Decision of the Bundesgerichtshof of 13 November 2001, X ZR 134/00, GRUR 2002, 238.

IV. Conclusions

Despite its complexity caused by the coexistence of national and regional systems, European law may serve as an interesting legislative model with respect to the patent/PVR interface. At the level of availability of protection, it maintains some exclusivity for the PVR system by excluding plant varieties from patent protection. However, due to the abstract nature of IP rights, this does not avoid the fact that the protection conferred by patents may extend to plants which belong to a plant variety. The exclusivity is therefore more formal than substantial. At the level of prerogatives, European law shows a clear tendency towards convergence of the systems, on the one hand, by introducing specific cross-linking provisions in favour of the competing innovator (dependency licensing), and, on the other, by taking over an economically important right limitation (farmer's privilege) from the PVR system to the patent system. The future will show whether a further fine-tuning of the interface issues is needed.

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