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Patentability of life forms in Europe

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I. Introduction

The European Patent Organization (EPO) with its currently 36 member states has a longstanding practise on granting patents for inventions based on biological material[1]. Between 1980 and 2005 the EPO granted ca. 850 patents for new plants and animals[2]. In 2007 alone, the number of patent applications related to transgenic plants and animals amounted to 480. In 1998, the European Union codified this practise by passing the EC Directive 98/44/EC on patenting of biotechnological inventions (Directive).

This paper will give a short analysis of the regulations on patents for plants, animals, and breeding methods in Europe followed by a discussion of the legal situation regarding the requirement to disclose the origin of the genetic resource within a patent application. A brief introduction of the European Patent System can be found in the first footnote.

II. Legal framework for the patentability of life forms

The main body of the European Patent Convention (EPC) contains only one provision regarding the patentability of life forms. According to Art. 53 (b) EPC plants and animal varieties as well as essentially biological processes are excluded from patentability. The provision has been further specified by 25 years of jurisdiction of the opposition division as well as the different boards of appeal, which are the review bodies of the EPO. This case law has been confirmed in great parts by the Directive, which has been passed in order to harmonize European national patent laws on this matter and, thus, create legal certainty within the European Union. This should encourage investment in the field of biotechnology and promote the free trade of biotechnological inventions. As the EPO is not a member of the European Union the Directive had no binding force for the EPO. In order to achieve the desired harmonization at the level of the EPO its Administrative Council decided to incorporate the central provisions of the Directive in the implementation rules of the EPC (rule 23b-e EPC) and

1 The EPO is the executive organ of the European Patent Organisation, an intergovernmental organisation that was set up in 1977 on the basis of the European Patent Convention (EPC). The EPO provides a single patent grant procedure governed by the EPC, which results for the applicant in a bundle of national patents for those countries that have been indicated in the application. As a consequence each national part of the European patent has to be enforced in the respective country according to national law. The applicant may as well choose the national application route and file his applications at the respective national patent office under national law

2 These patents concern mostly genetically modified organisms given that results of traditional breeding methods generally do not fulfil the patentability requirement of inventiveness.

clarified that the rest of the Directive shall be used as a supplementary means of interpretation. Thereby the Directive became also relevant for those EPO member states that are not part of the European Union.

1. Patents on plants

a) Exclusion of plant varieties

An invention has to be new, inventive, capable of industrial application and reproducible in order to be patentable. As the techniques and results of traditional breeding methods are not sufficiently repeatable and often do not reach the necessary level of inventiveness to deserve access to patent protection an independent system of plant variety protection was set up to protect plant varieties. In Europe the breeder can either apply for protection of his new plant variety at the Community Plant Variety Office or at the respective national offices. The material part of the national breeder laws follows the Convention for the Protection of New Varieties of Plants 1961 ("UPOV Convention), which his been revised in 1972, 1978 and 1991. These "breeder's rights" protect plant varieties that are new, distinct, uniform and stable. The case law of the EPO has found, drawing on Article 2(2) of the UPOV Convention 1961, that plant varieties means a "multiplicity of plants which are largely the same in their characteristics and remain the same within specific tolerances after every propagation or every propagation cycle". Reason for excluding plant varieties from patentability in Art. 53 (b) EPC was to avoid double protection, a requirement that was originally stipulated in Art. 2 (1) of the UPOV Convention. Although the 1991 Act abandoned the ban on dual protection Art. 53 (b) EPC still upholds this principle.

According to the jurisdiction of the EPO, the two forms of protection, i.e. patents and plant breeders' rights, constitute a single comprehensive system of industrial property protection for plant innovations permitting neither overlapping nor gaps in the protection of eligible subject-matter[3]. Accordingly, inventions ineligible for protection under the plant breeders' right system are patentable provided they fulfil the other requirements of patentability. On the other hand, protection by patents is excluded for a variety regardless of the way they are produced, i.e. even if the invention regards a genetically modified variety it is excluded from patentability.

In 1993 the Board of Appeal (BoA) was presented with a case regarding a patent for a transgenic plant that was resistant to certain herbicides due to its genetic modification[4]. The board decided that a genetic modification would turn the group of plants into a variety. In *Novartis II* the Enlarged Board of Appeal (EBoA)[5] took a different view holding that the genetically created herbicide resistance would not create a plant variety as this resistance could also be transferred to other varieties. Thus, the

3 Novartis II, G 1/98, OJ EPO 2000, 124

4 Plant cells/PLANT GENETIC SYSTEM, T_356/93, OJ EPO 1995, 545

5 The EBoA is the highest instance of the EPO's Boards of Appeal. Its tasks are to ensure uniform application of the law and to clarify points of law of fundamental importance that emerge from procedures pending before the EPO.

technical feasibility of the invention was not only confined to one plant variety[6]. Therefore, the invention would not be excluded from patentability, regardless of the fact that the claim might also embrace a plant variety. Furthermore, the board clarified that – although a patent cannot be obtained for a plant variety – it may well be obtained for a method to produce such variety. This would apply even in the light that products produced by a protected process are also covered by patent protection according to Art. 64 (2) EPC. This means, that patent protection for plant varieties can be achieved indirectly by claiming a process to produce such a variety.

b) Exclusion of inventions contrary to morality and ordre public, Art. 53 (a) EPC

Although it was overruled in part, the decision *PLANT GENETIC SYSTEM* is still of interest for its ruling on Art. 53 (a) EPC. According to this provision, inventions the exploitation of which would be contrary to morality and *ordre public* are excluded from patentability. Until the early 90s the morality clause had played a rather insignificant role. It started to gain importance when the first patents for biotechnological inventions had been granted and has ever since then been used as an argument against patenting living matters[7]. It was argued, inter alia, that the patenting of genetically modified plants would pose irreversible environmental risks and could seriously endanger biodiversity. Although the Board agreed that the concept of *ordre public* would also encompass the protection of the environment it held that the exclusion under Art. 53 (a) EPC would require a sufficient substantiation of the threat. In the present case, the Board held that the appellant only provided evidence of *possible* harm to the environment, e.g. possible hazards due to spread of genes or the possible risk to the ecosystem, which was not enough in order to deny a patent. Instead, the Board emphasised that it was rather the duty of special regulatory bodies or authorities to assess the risk of a new technology – if patented or not – and to allow or restrict the application of such.

2. Patents on animals

The first European patent on a transgenic animal was granted in 1992 for a transgenic mouse that was susceptible to carcinogens due to an introduced oncogene[8]. The case did not only break records with regard to its extraordinary consumption of time and human resources[9], it also contains important clarifications as to the patentability of animals. Bearing in mind that for animals – unlike plant varieties – no other industrial property right was available, the BoA held that Art. 53 (b) was to be narrowly construed and only applied to certain categories of animals but not to animals as such[10].

Furthermore, the Board considered Art. 53 (a) EPC and concluded that it was necessary to carefully weighing up the suffering of the animal and the risk to the environment on the one hand and the invention's usefulness to mankind on the other. Another slightly different balancing test has been

6 ibid.
7 However, it should be noted that only recently, in cases regarding the patentability of human embryonic stem cells, this provision has actually been used by the Board of Appeal in order to limit a patent claim
8 EP 0169672
9 Although the application for the patent was filed in 1985 it was not until 2004 – after the opposition of 17 parties and after two appeals - that the EPO submitted its final decision.
10 Oncomouse/HARVARD I, T 19/90 OJ EPO 1990, 476

adopted by the Directive and later introduced in the implementation rules of the EPC in order to specify the morality clause of the EPC and the national patent laws. According to rule 23d (d) EPC processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such process, are excluded from patentability. Thus, genetic modification of test animals for other than medical purposes, e.g. for the development of new cosmetics, are excluded from patentability if the modification causes suffering to the animal. The exclusion does not only comprise the animal but also the method of modification, thereby avoiding patenting of the animal through the backdoor of method claims.

3. Patents on breeding methods

Under the process exclusion of Article 53(b) EPC, European patents shall not be granted for essentially biological processes for the production of plants and animals. In an earlier decision the EPO defined the notion of "essentially biological process" on the basis of the degree of technical intervention. If the latter played an important role in the determination of or control over the results, the process was no essentially biological and, thus, might be patentable[11]. Consequently processes, which include genetic manipulation of the plant or animal, are not essentially biological processes[12]. A new explication was introduced with rule 23 b (5) EPC (Art. 2 (2) Directive), which limits the exclusion to "processes that consist *entirely* of natural phenomena such as crossing and selection"[13].

The much narrower wording of rule 23b (5) EPC created a great deal of uncertainty regarding the necessary degree and nature of human intervention. As a consequence, the EPO granted several controversial patents on breeding techniques such as "marker assisted breeding". Such processes involve traditional breeding methods and only include as preceding step a genetic screening method in order to detect the appropriate breeding material.

A recently granted patent on marker assisted breeding regards an invention that relates to methods for producing new broccoli plants. The patent also claims the seeds, the plant and edible parts of it. The claimed method comprises several conventional steps of selecting and crossing and backcrossing. The only step that is not considered conventional is the use of molecular markers during the selection process in order to choose the broccoli lines which subsequently are to be crossed. It is important to note, however, that the use of molecular markers is a well-known step in the selection of plants with desired characteristics and has been used before in the context of breeding broccoli[14]. Thus, the technical step that is added to the process of a mere biological process is only of trivial nature. Yet, a claim like this allows the protection of a conventional plant that has been bred with the claimed

11 Guidelines for Examination of the EPO, No. X-232.2.
12 Oncomaus/Harvard II, T_315/03; Novartis II, G 1/98, OJ EPO 2000, 124
13 The BoA already criticised this provision as self-contradictory given that systematic crossing and selection as carried out in traditional plant breeding would not occur in nature without the intervention of man.
14 In the description of the patent it is says with regard to the screening method "There are many methods available in this field, such as real time PCR, Northern Blot analysis, quantitative PCR, etc., all of which are part of the practical skills and knowledge of the average skilled artisan."

method. In order to receive some guidance on this issue, the BoA referred the appeal on this patent to the EBoA[15]. The case is still pending. However, if the exclusion of essentially biological processes from patentability is taken seriously, an additional trivial technical step cannot suffice to allow patenting of otherwise traditional breeding methods.

III. Scope of patent protection

1. General Rules

The Directive contains detailed provisions regarding the scope of the patent. These regulations departure in many ways from the general limitations recognised under patent law as they consider the special characteristic of biological material to be able to replicate itself.

Under the general principle of exhaustion of patent rights the protection of a specific patented product ends when this product has been placed on the market by the patent holder or with his authorization. Thus, the consumer may freely offer, sell, use, repair or destroy the patented product. Taking that biological material is self-replicating the question was whether protection should end with the first generation produced by or with authorization of the patent holder.

Art. 8 (1) of the Directive extends the scope of protection to any future generation derived from the patented biological material given that it still possesses the characteristics that made the material inventive. Only following generations that have lost these characteristics are patent-free. Art. 8 (2) refers to patented methods that produce biological material with specific characteristics as a result of the invention. The provision goes far beyond the generally accepted principle according to which the scope of a method patent only extents to the directly obtained product. According to Art. 8 (2) Directive all further generations – regardless of the way they have been obtained - fall within the scope of the patent provided that they still possess the specific characteristic.

Protection is also extended in horizontal direction, i.e. to other biological material in which the inventive product has been incorporated (Art. 9 Directive). Thus, also new plant varieties as a product of cross-breeding fall within the scope of protection if the specific genetic information has been incorporated in the new variety. Consequently, it is common to claim only parts of a plant, such as a gene that is to be incorporated by means of genetic engineering. This is often sufficient in order to cover a number of potential varieties or crops incorporating the gene and has the same effect as patenting the plant as a whole[16].

2. Limitations of scope

15 G2/97

16 UK Commission on Intellectual Property Rights – Integrating Intellectual Property Rights and Development Policies, 2002, p. 65

Art. 10 of the Directive excludes future generations from patent protection if the biological material has been placed on the market for the purpose of propagation or multiplication; in other words: If patented seed has been sold for the purpose of planting the seeds the plant grown from this seed is not covered by patent protection. However, the resulting plant may be sold but not be used for further propagation. Thus, the buyer of the patented seed cannot safe seeds for further sowing; neither may he sell the obtained seeds.

Another rule applies, however, with regard to certain crops, such as potatoes, forage crops and grains, if the buyer of the patented seed is a farmer. Before the implementation of the Directive only the breeders' rights system allowed farmers to re-use seeds they have obtained for the purpose of further propagation. The farmer's privilege has been adopted by Art. 11 of the Directive and is now also part of the national patent laws in Europe. However, under the privilege the farmer is not allowed to sell the seeds or exchange them with other farmers. He may only save seeds for further cultivation on his own farm in exchange of a payment that has to be considerably less than a licence fee.

3. Breeders' exemption

The law governing plant variety rights contains a breeder's exemption which does not exist under patent law. According to this exemption the underlying genetic resource embodied in a protected plant variety is freely available to third parties for the purpose of breeding other varieties and subsequently selling those varieties. Without being obligated by the Directive the German patent law contains a privilege for the use of biological material for the purpose of breeding, discovering and developing a new plant variety. Unlike the breeder's exemption contained in plant variety protection this privilege is not extended to the subsequent commercial use. Thus, a new plant or plant variety that still possesses the specific characteristics of the patented plant can only be brought on the market after a licence has been obtained. If the patent holder is unwilling to grant a license the breeder may obtain a compulsory licence under the condition that the patent holder is entitled to a cross-license on the protected variety (Art. 11 Directive.). Regrettably, due to the lack of a clear requirement in the Directive there is little harmonisation on this matter within the European Union.

IV. Disclosure of origin

1. Recital 27 of the Directive

The disclosure of origin of a genetic resource and associated traditional knowledge is an important transparency measure in order to ensure compliance with access and benefit-sharing requirements (ABS) as they are stipulated in the Convention on Biological Diversity (CBD)[17]. As the European Community is member of the CBD it is bound by the mandatory access and benefit-sharing requirements of the Convention.

17 For more details see: Sarnoff/Correa, Analysis of options for implementing disclosure of origin requirements in intellectual property requirements, 2006, p. 5

In its Preamble in recital 27 the Directive states that the patent "should include information of the geographical origin if an invention is based on biological material of plant or animal origin". Recital 27 is not only non-binding by nature but also by its wording. The second part of the preamble clarifies that the inclusion of information of origin is without prejudice to the processing of the application or the validity of rights arising from the granted patent. During the debate regarding the proposal for the Directive the European Parliament suggested to make the disclosure of origin a binding requirement. However, at that time the European Commission rejected this motion stating that this would go beyond the obligations of the CBD[18].

2. Implementation of recital 27 in European national law

Due to the non-binding character of recital 27 its significance remains of symbolic nature impeding that European patent law can add weight to the mechanisms of ABS. To date only six European member states – mostly driven by the political wish to demonstrate support for developing countries - included the requirement of disclosure of origin in its patent laws. However, the scope of the required disclosure as well as the consequences of non-compliance differs to a great extent:

Denmark, Belgium, Sweden and Germany require patent applicants to disclose the geographical origin of the material, if known. They have basically opted for a one-to-one implementation of recital 27. Only Norway adopted a more extensive requirement: According to para. 8 (b) of the Norwegian Patent Act the inventor shall disclose the country which provided the biological material and also the country of origin, if this is different. Furthermore, information whether prior informed consent has been sought is also required, if this is required by the providing country or country of origin. Romania amended its patent law which now requires the disclosure of the source of traditional knowledge if the state of the art includes such knowledge. None of the countries introduced a disclosure requirement for evidence of fair and equitable ABS.

Whereas in Sweden, Germany and Romania a violation of this requirement has no consequences, Norwegian and Danish laws provide at least for criminal sanctions but leave the validity of the patent unaffected. Initially, Belgium has proposed legislation according to which non-compliance would be contrary to the concept of *ordre public* and morality on the basis that there was a breach of the CBD. However, this draft was not adopted. Instead, Belgium has introduced a formal requirement for disclosure of geographical origin. Theoretically, failure to comply with this requirement could result in the patent application not being processed. However, this is unlikely to occur as the Belgian patent office does not examine compliance. For patents that have been granted, wrongful disclosure would not affect their validity, but could result in a fine.

So far the impact of the legislation has been very small. Main reason for the limited impact of these requirements is that they only refer to national patent applications. Consequently, a very small number of patent applications are affected by this legislation.

18 COM (97) 446 final, 95/0350 (COD)

3. The proposal of the European Community

In May 2005, the Permanent Delegation of the European Commission submitted a proposal to the World Intellectual Property Organization (WIPO) concerning the disclosure of genetic resources and associated traditional knowledge in patent applications[19]. The proposal includes a mandatory requirement to declare the country of origin or, if unknown, to disclose the source of the specific genetic resource in patent applications. It furthermore contains the option to require the applicant to declare the specific source of traditional knowledge associated with the genetic resource. Should the applicant fail or refuse to comply with this requirement the application should not be further processed. However, after the patent has been granted sanctions for incorrect or incomplete information should be imposed outside the field of patent law. With this limitation the proposal remains half-hearted and will not achieve the aim to support effectively the enforcement of measures for ABS.

V. Final remarks

The European Patent System (together with the system of plant variety rights) provides the inventor with a strong protection mechanism for new plants and animals. In a hearing of a commission of the German Parliament in May 2009, the majority of experts has been in favour of amending the Directive in order to avoid patenting of plants and animals altogether. However, outright exclusion of patents for inventions based on biological material does not seem to be the best solution as, in most cases, research and development is driven by the incentive inherent in the perspective to gain a monopoly right for a certain period of time. Instead, more consideration should be given to the prevention of unjust or disproportionately broad patents.

One example is the understanding of "essentially biological processes" which should exclude conventional breeding techniques that only contain a trivial technical step. To award patent protection for conventional breeding methods and, consequently also for conventional plants that have been produced by the patented method, clearly conflicts with idea that stands behind the patent system, i.e. providing the inventor with a just reward that is commensurate with the creative performance he has disclosed to the public.

Furthermore, a mandatory disclosure of origin requirement should be integrated into the patent law system using the deterring effect of denying a monopoly right in order to enforce ABS measures[20]. However, it should not be left to the national legislators, like suggested by the Swiss proposal submitted to the WIPO in 2003[21], whether or not to include a binding disclosure requirement into their

19 WIPO/GRTKF/IC/8/11

20 There are also other necessary measures which are frequently suggested, such as establishing a notification system. For more details see for example: Sarnoff/Correa, Analysis of options for implementing disclosure of origin requirements in intellectual property requirements, 2006.

21 WIPO/PCT/R/WG/4/13

patent laws. Existing disclosure requirements in European national laws only apply to national patent applications and, thus, are of limited scope. Additionally, different national approaches cause legal uncertainty and hamper recognition and enforcement of the requirement with respect to patent applications of foreigners. In order to ensure worldwide implementation of the disclosure requirement an international treaty, such as the TRIPS Agreement, should obligate member states to do so[22].

22 Art. 29 TRIPS seems to be the most appropriate place to integrate the disclosure requirement, see for example: Bucher, Der Schutz von genetischen Ressourcen und indigenem Wissen in Lateinamerika, 2007