

NEW RULES OF THE EUROPEAN PATENT OFFICE FOR BIOTECHNOLOGICAL INVENTIONS

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I. Introduction

The Biotech Directive 98/44/EC¹ of the EU entered into force on July 30, 1998. The EU member states are required to implement the Directive into their national law by July 30, 2000.

The European Patent Organization - not being a EU member state - is not subject to this formal requirement of implementing the Directive. It is, however, highly desirable to have a common standard throughout Europe regarding the patenting of biotechnological inventions. The European Patent Organization recently decided to implement the rules of the Directive into the Implementing Regulations to the European Patent Convention.

The following Rules are derived from Chapter I of the Directive, which regulates the patentability of biotechnological inventions. Although the principles set forth in said rules of the Directive themselves are based on the relevant provisions of the EPC and established case law and practise, the Implementing Regulations of the EPC were amended in order to ensure that the patentability provisions of the EPC also continue to be interpreted in line with the Directive.

Under Article 164(1) EPC the Implementing Regulations are an integral part of the Convention and, hence, are equally binding to the Boards of Appeal of the EPO (Article 23(3) EPC) and to national courts. For the practical application of the convention, only the interpretation laid down in the Implementing Regulations is binding to the Boards. Other interpretations of individual provisions are possible

¹OJ ECL 213/13 and OJ EPO 1999, 101

only where it is specifically demonstrated that the provisions of the Implementing Regulations are inconsistent with the Convention itself.

Therefore, the addition of the Rules for Biotechnological Inventions to the Implementing Regulations emphasizes that the general provisions of the Convention apply unrestrictively to such biotech inventions as well and helps prevent the creation of a separate body of law. Much of the following comments and explanations are based on a report of the Standing Advisory Committee before the European Patent Office (SACEPO) summarizing the 30th Meeting of 17-18 June, 1999 in Munich.

II. Amendment of the Implementing Regulations by the introduction of new Rules 23b to 23e.

The following chapter shows the new Rules and their basis in the Directive, either in the recitals (Rec), or the articles (Art.) or in the EPC.

Rule 23b General and definitions	<u>Basis in Directive or EPC</u>
(1) For European patent applications and patents concerning biological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.	Rec. 15
(2) "Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.	Art. 1(1) Art. 3(1)
(3) "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a	Art. 2(1)(a) R. 28(6)(a)

biological system.

EPC

Basis in
Directive or EPC

- (4) "Plant variety" means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:
- (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- (c) considered as a unit with regard to its suitability for being propagated unchanged.
- (5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection
- (6) "Microbiological process" means any process involving or performed upon or resulting in microbiological material.

Art. 2(3)

Art. 2(2)

Rec. 33

Art. 2(1)(b)

Rule 23c

Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

Art. 1(1)

Rec. 15

- (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

Art. 3(2)

Rec. 34

A. 52(2)(a)

EPC

Basis in
Directive or EPC

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| (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety | Art. 4(2)
Rec. 29,31 |
| (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety. | Art. 4(3)
Rec. 32
A. 53(b)
EPC |

Rule 23d

Exceptions to patentability

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

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| (a) processes for cloning human beings; | Art. 6(2)(a)
Rec. 40 |
| (b) processes for modifying the germ line genetic identity of human beings; | Art. 6(2)(b)
Rec. 40 |
| (c) uses of human embryos for industrial or commercial purposes; | Art. 6(2)(c)
Rec. 42 |
| (d) 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 processes. | Art. 6(2)(d)
Rec. 45
A. 53(b)
EPC |

Basis in
Directive or EPC

Rule 23e

The human body and its elements

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| (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. | Art. 5(1)
Rec. 16,34
A. 52(2)(a)
EPC |
| (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. | Art. 5(2)
Rec. 17-26 |
| (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. | Art. 5(3)
Rec. 22,24 |

III. Comments on the new Rules**Rule 23(b) - General and definitions**

Rule 23b affirms the principle that inventions in biotechnology are already patentable under existing law (see also Directive Recital 15), defines the area to which the provisions of Chapter VI apply and contains the basic definitions of terms in the field of biotechnological inventions. Paragraph 1 establishes that the provisions relate to the application and interpretation of the Convention and further specifies that the Directive itself is also to be used to interpret the provisions. The aims in particular are to ensure that the recitals preceding the provisions of the Directive are also taken into account and to promote a uniform Europe-wide interpretation of the relevant provisions.

The reference to the Directive as a supplementary instrument of interpretation is primarily of a declaratory nature, as the Directive has to be observed anyway under general principles of interpretation in international law (Article

31(3) Vienna Convention on the Law of Treaties (VCLT)). One may assume that EPC contracting states not belonging to the EU (such as CH) will also implement the principles of the Directive in their national law.

Rule 23b(2) defines the concept of "biotechnological invention" on the basis of Rule 28(1) EPC and with reference to Article 3(1) of the Directive. In that sense inventions are to be considered biotechnological if they concern or use biological material.

Rule 23b(3) gives the definition of "biological material" currently contained in Rule 28(6)(a) EPC and incorporated in the Implementing Regulations in 1996, as now formulated in Article 2(1)(a) of the Directive².

Rule 23b(4) adopts the definition of the concept of "plant variety" from Article 5(2) of Regulation (EC) No. 2100/94 on plant variety rights, which is binding in accordance with Article 2(3) of the Directive. The definition follows the wording of the concept of variety as set forth in Article 1(vi) of the 1991 UPOV Convention. The EPO boards of appeal have hitherto always used the UPOV Convention's concept of variety as the basis for interpreting Article 53(b) EPC³.

Rule 23b(5) in keeping with Article 2(2) of the Directive specifies more precisely when a process for the production of plants or animals is "essentially biological". This in particular gives a more specific meaning to Article 53(b) EPC and establishes that only production processes based entirely on natural phenomena are excluded from patenting. Although the EPO boards of appeal have hitherto not given an explicit decision to that effect⁴, the interpretation developed by the boards falls within the framework of the proposed definition.

² see Administrative Council decision dated 14 June 1996 - OJ EPO 1996, 390

³ see T 49/83, Propagating material/CIBA-GEIGY, OJ EPO 1984, 112; T320/87 Hybrid Plants/LUBRIZOL OJ EPO 1990, 71 and T 356/93 Plant cells/PLANT GENETIC SYSTEMS OJ EPO 1995, 545

⁴ see T 320/87 Supra, T19/90 Onco-mouse/HARVARD OJ EPO 1990 476 and T356/93 Supra

Rule 23b(6) defines the concept of a microbiological process within the meaning of Article 53(b) EPC somewhat more broadly than is indicated by the case law of the boards of appeal⁵. Thus, in keeping with Article 2(1)(b) of the Directive, the definition would in particular also cover processes which as claimed include both microbiological and non-microbiological steps.

Rule 23c Patentable biotechnological inventions

Rule 23c establishes that biotechnological inventions are in principle patentable under the Convention. It includes a non-exclusive list of items which are explicitly considered patentable.

Rule 23c(a) relates to the demarcation between invention and discovery under patent law and to the concept of novelty. In keeping with the applicable provisions of the Convention and with previous Office practise, as well as with Article 3(2) of the Directive, it is explicitly stated that biotechnological material may be considered patentable even if it already occurs in nature. This particularly applies to genes which are isolated from their natural environment by means of technical processes and made available for industrial production. Such genes are also new, because they were previously not technically available to the public.⁶

Rule 23c(b) does not affect the exclusion of plant and animal varieties from patentability under Article 53(b) EPC. Rather, it indicates that a plant grouping characterized only by a particular gene - but not by its whole genome - is not covered by the protection of new varieties and therefore is in principle patentable. This also applies if such plant grouping comprises plant varieties. The provision complies with Article 4(2) of the Directive and clarifies the scope of Article 53(b) EPC⁷.

⁵ T 356/93 Supra

⁶ see e.g. Relaxin Decision of an Opposition Division, OJ EPO 1995, 308 and T 301/87 Alpha-Interferons/BIOGEN, OJ EPO 1990, 335

⁷ see also Recitals 29 to 31 of the Directive

The Rule is not in keeping with the interpretation of Article 53(b) EPC adopted in T 356/93 - PGS. It will need to be reviewed if the Enlarged Board of Appeal confirms the "PGS interpretation" in the above-mentioned referral case "Transgenic plant/NOVARTIS"⁸.

Rule 23c(c) affirms the principle laid down in Article 53(b) EPC, whereby a microbiological or other technical process or a product obtained by such a process is in principle patentable. It also makes explicitly clear however that product claims for plant or animal varieties cannot be granted even if the variety is produced by means of a microbiological process. That does not affect the derived protection of such a variety as the direct product of a patented process⁹

Rule 23d Exceptions to patentability

Rule 23d lists a number of exceptions to patentability under Article 53(a) EPC. The list is non-exhaustive and is to be seen as giving concrete form to the concepts of *ordre public* and morality. Letters (a)-(d) adopt the wording of Article 6(2) of the Directive. Rule 23d might create difficulties in practise. This rule requires the waiving of the suffering of an animal against the benefit to man or animal. It might become very difficult in real life to perform the proper application of this rule in a given case. Moreover, this rule might open the door for opposing European patents in the field of transgenic animals by stressing the suffering of animals as the result of a certain transgenic modification.

Rule 23e The human body and its elements

Rule 23e adopts the exact wording of Article 5 of the Directive. Paragraph 1 excludes from patentability the human body at all stages of its formation and

⁸ T 1054/96 Transgenic plant/NOVARTIS, Referral Decision to the Enlarged Board of Appeal OJ EPO 1998, 511

⁹ see Article 64(2) EPC which states that the protection conferred by a process patent shall extend to the products directly obtained by the claimed process.

development, in particular the human germ cells. As paragraph 2 specifies, however, this exclusion does not apply to elements isolated from the human body or otherwise produced by means of technical processes. These, particularly a sequence or partial sequence or a gene, are consequently patentable even if their structure is identical to that of naturally occurring elements. Thus where such sequences are the subject matter of an invention, it is necessary to indicate their industrial application. How much information will be necessary to fulfill this requirement is open so far and most likely will depend on the facts of the case. Therefore, it might be sufficient if it is made credible that a claimed sequence is useful in forensic medicine, diagnosis, as genetic marker, etc. It might be a successful strategy to disclose several conceivable modes of industrial applications in the application. If one of the presumed industrial applications is then actually associated with the claimed sequence then this industrial application requirement should be fulfilled.

IV Summary

As one may take from the above comments, the new Rules being effective from September 1, 1999 might not bring many big changes in the EPO's practise with regard to the patenting of biotechnological inventions. The one big change vis-à-vis the current practise can be seen in Rule 23c(b) which acknowledges the patentability of transgenic plants or animals. It might, however, happen that the examination of the Novartis case by the Enlarged Board of Appeal results in a deletion or amendment of said Rule. Therefore, applicants cannot yet be sure that an application directed to transgenic plants or animals is no longer barred by the exclusion of plant or animal varieties from patent protection as given in Article 53b EPC. One may expect the decision in the Novartis case by the Enlarged Board of Appeal by early summer of 2000. Until then, the patentability of inventions concerning transgenic plants and animals remains open despite the clear provision under Rule 23c(b). Besides this remaining unclarity, the new Rules might, however, help to safeguard a common standard regarding the patenting of biotechnological inventions throughout Europe.