

Principles and Recent Developments in Biotech, Nanotech and Pharmaceutical Patents

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I. Statutes

EPC 2000

<http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/contents.html>

Article 52 Patentable inventions

- (1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
- (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
 - (a) discoveries, scientific theories and mathematical methods;
 - (b) aesthetic creations;
 - (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
 - (d) presentations of information.
- (3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Article 53 Exceptions to patentability

European patents shall not be granted in respect of:

- (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
- (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 54 Novelty

- (1) An invention shall be considered to be new if it does not form part of the state of the art.
- (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.
- (3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.
- (4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.
- (5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

Article 56 Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.

Article 57 Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

Article 64 Rights conferred by a European patent

- (1) A European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State.
- (2) If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.
- (3) Any infringement of a European patent shall be dealt with by national law.

Rule 27 Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

- (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;
- (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

- (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Rule 28 Exceptions to patentability

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

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;
- (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.

Rule 29 The human body and its elements

- (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.
- (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.
- (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>

Recital 22

Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;

Recital 24

Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;

Article 2

- (1) For the purposes of this Directive,
 - a) 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
 - b) 'microbiological process' means any process involving or performed upon or resulting in microbiological material.
- (2) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.
- (3) The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.

Article 3

- (1) For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
- (2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4

- (1) The following shall not be patentable:
 - a) plant and animal varieties;
 - b) essentially biological processes for the production of plants or animals.
- (2) Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
- (3) Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5

- (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.

- (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.
- (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6

- (1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
- (2) On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
 - a) processes for cloning human beings;
 - b) processes for modifying the germ line genetic identity of human beings;
 - c) uses of human embryos for industrial or commercial purposes;
 - 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.

TFEU

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0047:0199:EN:PDF>

Article 267 (ex Article 234 TEC)

The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:

- (a) the interpretation of the Treaties;
- (b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union;

Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon.

Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court.

If such a question is raised in a case pending before a court or tribunal of a Member State with regard to a person in custody, the Court of Justice of the European Union shall act with the minimum of delay.

German Patent Act

(<http://bundesrecht.juris.de/patg/index.html>)

§ 1a (Non-official translation taken from *Kilger/Feldges/Jaenichen*, 87 J.P.T.O.S. 569, 573 [2005])

- (1) The human body, at the various stages of its formation and development, including germ cells and the simple discovery of one of its elements, including the sequence or partial sequence of a gene cannot constitute patentable inventions.
- (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.
- (3) The industrial application of a sequence or a partial sequence of a gene must be concretely disclosed in the application by indicating the function fulfilled by the sequence or partial sequence.
- (4) If the subject matter of the invention is a sequence or partial sequence of a gene the structure of which is concordant to the structure of a natural sequence or partial sequence of a human gene, then its use, for which the industrial application is concretely described in accordance with subsection 3, has to be included into the patent claim.

UK Patents Act 1977

(http://www.England-legislation.hmso.gov.uk/RevisedStatutes/Acts/ukpga/1977/cukpga_19770037_en_1)

Section 60. Meaning of infringement.

- (1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say—
 - (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
 - (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;
 - (c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

[...]

II. Cases

EPO

(<http://www.epo.org/patents/appeals.html>)

EBA (Enlarged Board of Appeal)

G 2/08 (not yet published in OJ EPO)
G 2/07 (not yet published in OJ EPO)
G 1/06 [2009] OJ EPO 306
G 1/92 [1993] OJ EPO 277
G 2/88 [1990] OJ EPO 93
G 6/83 [1985] OJ EPO 67
G 5/83 [1985] OJ EPO 64
G 1/83 [1985] OJ EPO 60

TBA (Technical Boards of Appeal)

T 20/94 (not published in OJ EPO)
T 939/92 [1996] OJ EPO 309
T 98/84 [1995] OJ EPO 209
T 49/83 [1984] OJ EPO 112
T 150/82 [1984] OJ EPO 304
T 128/82 [1984] OJ EPO 164

ECJ

(<http://curia.europa.eu>)

C-34/10
C-428/08

Germany

BGH (Federal Court of Justice)

BGH [1984] IIC 215
BGH [1970] IIC 136

BPatG (Federal Patent Court)

BPatG [1979] IIC 494

United Kingdom

HoL (House of Lords)

Kirin-Amgen, Inc. v Hoechst Marion Rous-
sel Ltd. [2004] UKHL 46

United States

U.S. (US Supreme Court)

Diamond v Chakrabarty, 447 U.S. 303
[1980]

III. Further Reading

Pharmaceutical Patents

Schneider, Dieter R.: Patenting of Pharmaceuticals – Still a Challenge?, in: 39 IIC 511-525 (2008)

Sterckx, Sigrid/Cockbain, Julian: Purpose-Limited Pharmaceutical Product Claims Under the Revised European Patent Convention: A Camouflaged Attack on Generic Substitution?, in: I.P.Q. 2010, S. 88-107

Ventose, Eddy D.: Patent Protection for Second and Further Medical Uses Under the European Patent Convention, in: 6 SCRIPTed 57-74 (2009)

Biotech Patents

Herdegen, Matthias: Patenting Human Genes and Other Parts of the Human Body Under EC Biotechnology Directive, in: 4 B.S.L.R. 102-107 (2000/2001)

Kock, Michael A.: Essentially Biological Processes: The Interpretation of the Exception Under Article 53(b) of the European Patent Convention, in: 2 J.I.P.L.P. 286-297 (2007)

Kilger, Christian/Feldges, Joachim/Jaenichen, Hans-Rainer: The Erosion of Compound Protection in Germany: Implementation of the EU Directive on the Legal Protection of Biotechnological Inventions – The German Way, in: 87 J.P.T.O.S. 569-600 (2005)

Leverve, Florian: Patent on Genes, Usefulness, and the Requirement of Industrial Application, in: 4 J.I.P.L.P. 289-295 (2009)

Nanotech Patents

Schellekens, Maurice: Patenting Nanotechnology in Europe: Making a Good Start? An Analysis of Issues in Law and Regulation, in: 13 J.W.I.P. 47-76 (2010)

Zech, Herbert: Nanotechnology – New Challenges for Patent Law?, in: 6 SCRIPTed 147-154 (2009)