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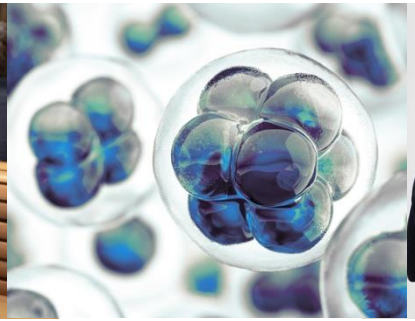
Guidelines2day

Biotechnology


René Wagner
Senior expert, Healthcare, Biotechnology and Chemistry
Marko Schauwecker
Lawyer, Patent Law

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Presenter

Marko Schauwecker

- Lawyer in the EPO’s patent law department since 2009
- Legal expert for questions related to patentability of biotechnology inventions

Overview

Background – Opinion G 3/19

Rule 28(2) EPC	T 1063/18	Referral G 3/19
1.7.2017: **No European patents for plants and animals exclusively obtained by means of an essentially biological process**	**December 2018:** **Rule 28(2) EPC is in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal (Art. 164(2) EPC)**	**April 2019:** **EPO President refers questions to the Enlarged Board in order to clarify the applicable legal framework**

Opinion G 3/19 (May 2020): Patentability exception confirmed as from 1.7.2017

Non-patentable plant/animal products

Essentially biological?	Exclusively obtained?	Plant/animal parts	Varieties
Crossing of whole genomes (and selection) G 2/07 - G 1/08 applies	Genetic change result of crossing Technical “assistance” steps not relevant G 2/07 - G 1/08	Propagation / reproductive material covered, too (ability to regenerate full organism) G 3/19	Clearly defined plant/ animal “groupings” Claim limited to varieties G 1/98 applies

Article 53(b) EPC

Rule 28(2) EPC

G 3/19

G 2/07 – G 1/08

G 1/98

Guidelines for Examination in the EPO, G-II, 5.4 and 5.5.1

Patentable plant/animal products

Technical production	Offspring	Plant/animal parts	Disclaimer
No crossing of whole genomes Genetic engineering Mutagenesis	Mutation / transgene result of technical process Not “exclusively obtained” by crossing	Products which are not propagation material (flour, sugars, fur…)	Whenever obtainable by technical or essentially biological process “with the proviso that the plant/animal is not obtained by an EBP”

Article 53(b) EPC

Rule 28(2) EPC

G 2/07 – G 1/08

T 1360/08; T 915/10 et al.

Guidelines for Examination in the EPO, G-II, 5.4

Implementation of non-retroactivity finding in G 3/19

Relevant date	No. of cases	Non-retroactivity	General patentability
Filing or valid priority date before 1 July 2017 European patents granted on the basis of such applications	Approx. 300+ in examination, ~ 10 in opposition	Rule 28(2) EPC cannot be applied No disclaimer to plants/ animals exclusively obtained by EBP required	Application/ patent and invention must comply with general patentability requirements, esp. - clarity - sufficiency - novelty - inventive step

G 3/19

Guidelines for Examination in the EPO, G-II, 5.4

Articles 83, 84, 54, 56 EPC

Revision of Guidelines in view of G 3/19 – summary overview

- Adaptation to Opinion G 3/19.
- Exclusion under Rule 28(2) does not apply to applications / patents with an effective filing/priority date before 1.7.2017.
- No disclaimer required if feature can unambiguously be only obtained by technical intervention, e.g. a transgene.

- Plant material which is able to propagate the full plant is excluded from patentability if the plant from which the material originates has been exclusively produced by an essentially biological process.
- Plant cells and tissues non-patentable for applications filed on/after 1.7.2017.

Clarification

Revised practice

Case law

G-II, 5.2 (ii)
G-II, 5.3
G-II, 5.4
G-II, 5.5

→ Article 53(b), Rule 28(2) EPC

Question 1

Has Opinion G 3/19 of the EPO’s Enlarged Board of Appeal triggered a revision of the practice of examining and opposition divisions in relation to plant- and animal-related inventions?

☑ yes ☒ no

Question 2

Are plants and animals exclusively obtained by means of an essentially biological process excluded from patentability under the EPC?

☑ yes ☒ no

Overview

Background – Stem cell patentability

EPC	EPO case law	CJEU decisions
Art. 53(a) together with Rule 28(1)(c) EPC No European patents for inventions which concern "uses of human embryos for industrial or commercial purposes"	**G 2/06 (2008)** Patentability exception also covers hESC taken from embryo (involving destruction) **T 2221/10 et al.** Also covered: hESC from stem cell lines obtained in the above-said manner	**Taken into account as persuasive by EPO** **C-34/10 (2010)** **C-364/13 (2014)** Parthenote not an "embryo"

EPO practice as reflected in the Guidelines

Patentability of hES cells – examination practice

Patentable

- hES cells from cell lines obtained without human embryo destruction (available as from January 2008) or obtained by parthenogenesis (as of June 2003)
- Culture media, supports and apparatuses "suitable for" use with hES cells
- Inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it

Non-patentable

Inventions which make use of hESC obtained by

- by de novo use of human embryos or
- of publicly available hES cell lines, which were initially derived by a process resulting in the destruction of the human embryos

Revision of the Guidelines re hESC - summary overview

- Insertion of relevant cut-off date for technical teaching concerning parthenotes.
- Patentability exception does not apply for applications with an effective filing date on/after 5.6.2003 and if the invention can be put in practice using human embryonic stem cells derived from parthenogenetically activated human oocytes.

- Foetal and post-natal human cells are in principle not excluded from patentability.
- Culture media, supports and apparatuses "suitable for" use with human embryonic cells, or even "specifically designed" for this purpose, are not per se excluded from patentability.

Clarification

Case law

G-II, 5.3 (iii)

→ Art. 53(a), Rule 28(1)(c) EPC

Question 1

?

Are judgments of the Court of Justice of the European Union regarding the patentability of hES cell-related inventions under EU Directive 98/44/EC taken into account in the EPO’s examination practice?

☑ yes ☒ no

Question 2

Does the patentability exception for uses of human embryos for industrial or commercial purposes under Article 53(a) and Rule 28(1)(c) EPC affect an application pertaining to hES cells filed in 2021?

☑ yes ☒ no

Overview

Presenter

René Wagner

- Examiner, senior expert
- Over 20 years experience in search, examination and opposition
  Immunology

Antibodies: G-II.5.6

- Clarification on the definition of antibodies by either structure, target antigen, functional features, production process, epitope binding, hybridoma and combinations thereof.
- No change of current practice - however first publication in the Guidelines.

- General remarks: What are antibodies?

Clarification

G-II, 5.6

Antibodies: 5.6.1.1 Definition by structure of the antibody

- Generally 6 CDRs are minimum requirement for defining binding specificity by sequence only
- If less than 6 CDRs - essential features missing
- Can be overcome by experimental data for the specific antibody of the invention
- Definition of CDRs by Kabat, Chothia, IMGT… if missing and not foreseen - objection under Article 83/84 EPC
- An antibody having the CDRs of the variable domains defined by SEQ ID NOs: 3 and 5.
- KABAT APHSIHALSA
- Chothia HALSAPRD

Antibodies: 5.6.1.2 Definition by reference to the target antigen

GL-G-II.5.6.1.2

- The antigen must be clearly defined
- Antigen must be defined by full sequence

! Novelty objection

Examples:

- Antibody binding to X
- Anti-X antibody
- Antibody reacting with X
- Antibody specific for antigen X
- Antibody binding to antigen X consisting of the sequence defined by SEQ ID NO: Y
- Antibody binding to X and not binding to Y

Antibodies: 5.6.1.3 Definition by target antigen and further functional features

GL-G-II.5.6.1.3

Antibody binding to antigen X and… for example

- Having an affinity of KD 1 to 10 nM
- Having an IC 50 of 5 nM
- Induction of apoptosis
- Inhibition of activation of receptor

Further functional features must be clear!

- Affinity by SPR – different methods give different results
- IC50 must have concentration of ligand

Antibodies: 5.6.1.3 Definition by target antigen and further functional features

- When defined by functional features:
  - Prior art antibodies obtained by the same methods are assumed to have identical properties – Novelty!
- Unusual parameters
  - Antibody competing with new antibody A as defined by full sequences is an unusual parameter
  - Unusual parameter: Consequence No Search
- Enabling disclosure over the entire scope (Article 83 EPC)
- Clearly defined the boundaries of the claim (Article 84 EPC), by having the essential details of the assay in the claim.

GL-F-IV.4.11.1

GL-B-VIII.3, example (iii)

Antibodies: 5.6.1.4 Definition by functional and structural features

GL-G-II.5.6.1.4

Combination of functional features and partial sequences of variable domains are possible

Antibodies: 5.6.1.5 Definition by production process

GL-G-II.5.6.1.5

- Immunisation protocol of a well-defined antigen
- Sequence of the antigen must be 100% defined

Antibodies: 5.6.1.6 Definition by the epitope

- Epitope = set of specific amino acids of the antigen with which the antibody interacts
  - functional definition: same issues as under G-II.5.6.1.3.
  - Linear epitopes vs non-linear epitopes
  - Non-linear epitopes often have a Clarity issue: different methods for determining an epitope give overlapping but different results!
- Clearly defined the boundaries of the claim (Article 84 EPC)
- Enabling disclosure over the entire scope (Article 83 EPC)

GL-G-VI.6

GL-F-IV.4.11.1

GL-F-III.6.3

Antibodies: 5.6.1.7 Definition by the hybridoma

- Hybridoma = cell producing antibody
  - Rule 31 EPC: deposit of biological material

Antibodies: 5.6.2 Inventive step of antibodies

- A new antibody against a known target is only inventive if the antibody has a surprising technical effect.
- It is not sufficient to have a further antibody because they can easily be obtained by routine methods.
- The fact that the sequence of the antibody is new and unpredictable is not sufficient.
  - NO structural non-obviousness.
- Surprising effects e.g. improved activities, reduced toxicity, reduced immunogenicity, cross-reactivity, improved stability, improved manufacturing, new format…
- Higher affinity: requires full sequence of the variable domains

Question 1

?

Does the following claim comply with Article 84 EPC?

A human antibody that binds to a peptide of amino acids sequence Asp-Tyr-His-Ala-Val within **antigen X**

☑ yes ☒ no

Question 2

?

Does the following claim comply with Article 84 EPC?

A monoclonal antibody wherein the antibody comprises at least **one variable domain** having at least **one CDR** having SEQ ID NO: 3.

☑ yes ☒ no

Further questions

now via chat to "All Panelists"