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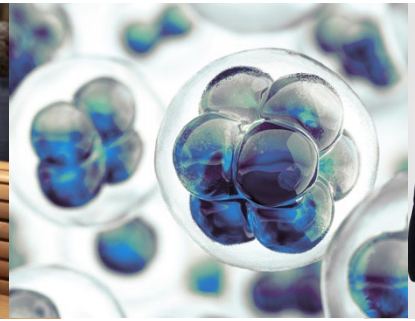
Guidelines2day

Biotechnology


Zoran Cilenšek
Scott Stanley, Marko Schauwecker

Examiner, Immunology
Lawyers, Patent Law

30 March 2022

Overview

Presenter

Marko Schauwecker

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

Technical modification of animals

Under Article 53(a) and Rule 28(1)(d) EPC no European patents for…

- …processes for the technical modification 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.

▶ Subject-matter claimed must comply with Rule 28(1)(d) EPC requirements **and** with Article 53(a) EPC

Background

T 315/03
T 19/90
T 1553/15
T 606/03
T 682/16 and T 789/16
T 186/18

→ **Article 53(a), Rule 28(1)(d) EPC**

Criteria to fulfil the requirements of R. 28(1)(d) EPC

Clarification

G-II, 5.3 item (iv)

All 4 criteria must be met:

- The subject-matter relates to a process to obtain genetically modified animals or animals resulting from said process
- Likelihood of animal suffering
- Likelihood of substantial medical benefit
- Correspondence between suffering and medical benefit

→ **Article 53(a), Rule 28(1)(d) EPC**

▶ The above must be applied to the whole scope of the claim (all animals embraced by the claims).

Criteria to fulfil the requirements of A. 53(a) EPC

Weighing up of…:

- …suffering of animals and…
- …possible risks to environment/evolution, against…
- …invention's usefulness to mankind, …
- …to the extent supported by evidence.

- Broader framework, e.g. including public attitudes and perception of genetic manipulation of animals in general.
- Assessment to be made as of filing/priority date.

Clarification

G-II, 5.3 item (iv)

→ **Article 53(a), Rule 28(1)(d) EPC**

Non-patentability of plants & plant material

Background

G 3/19

Under Article 53(b) and Rule 28(2) EPC no European patents for…

- …plants, including plant propagation material…
- …exclusively obtained by means of…
- …an essentially biological process.
- Filing/priority date on/after 1 July 2017.

→ Article 53(b), Rule 28(2) EPC

- Plants obtained by technical processes (e.g. transgenic and technical mutant plants) in principle patentable, with disclaimer.
- Offspring of transgenic/mutant plants not exclusively obtained by crossing if genetic change result of technical intervention.

Plant cells or tissues

Plant cells or tissues not patentable if…

- …able to regenerate the full plant (totipotent)…
- …plant from which the material originates has been exclusively obtained by “conventional” breeding.
- Irrespective of microbiological character.

- Does not affect plant cells or tissues from offspring of transgenic or mutant plants.
- Offspring not exclusively obtained by means of essentially biological process.

Clarification

G-II, 5.5.1

→ **Article 53(b), Rule 28(2) EPC**

Question

RAISE HAND

For an invention related to the genetic modification of animals, does it suffice for passing the patentability exception hurdle under the EPC if the requirements of Rule 28(1)(d) EPC have been fulfilled?

☐ yes

☐ no

= yes

Answer

The correct answer is **no.**

☐ yes

☒ **no**

Question

RAISE HAND

Are totipotent plant cells or tissues originating from the offspring of a transgenic or mutant plant (wherein the genetic change is the result of the technical process) excluded from patentability under Article 53(b) and Rule 28(2) EPC?

☐ yes

☐ no

= yes

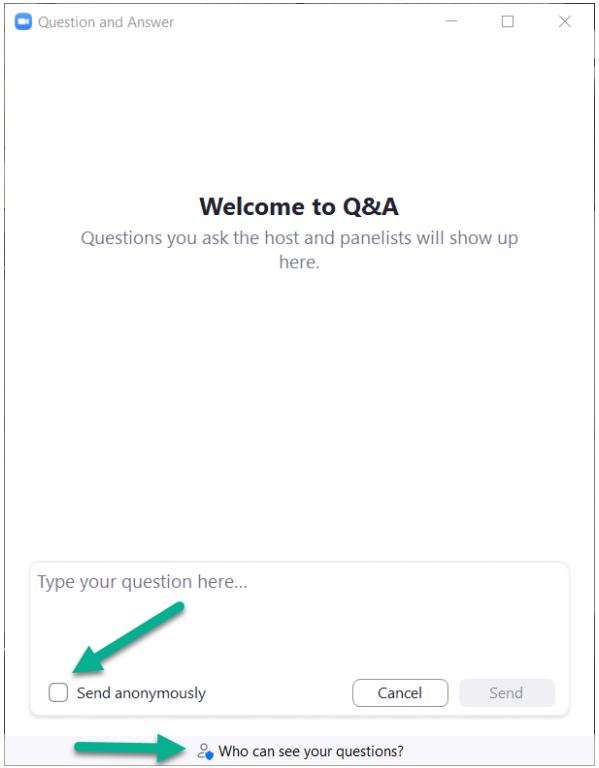
Answer

The correct answer is **no.**

☐ yes

☒ **no**

Your questions



Please write your questions in the Q&A (icon at the bottom of the Zoom window).

You may post questions anonymously, otherwise your name will be visible to all participants.

Overview

Presenter

Zoran Cilenšek

- Examiner
- Over 15 years of experience in search, examination and opposition in the field of immunology

Antibodies

- The section was first introduced in GL 2021

2 main parts:

- General remarks – technical aspects and clarity
- Inventive step assessment

GL 2022:

Definitions and requirements to comply with Art. 84 are refined

Inventive step assessment is clarified

Clarification

G-II, 5.6.1

G-II, 5.6.1.1

G-II, 5.6.2

Art. 84 and 56 EPC

Antibodies

Clarification

G-II, 5.6.1

General remarks - Definition of antibodies

- Various antibody formats
- IgG is the most common format
- “Zoo” of engineered (non-native) formats

Technical aspects

▶ Definition is refined to more accurately reflect dynamic technical field

Antibodies

Art. 84 EPC – essential technical features

- IgG comprises six CDRs – essential for antigen binding
- CDRs make direct contacts with antigen and provide necessary conformation
- Number of CDRs required for binding:

  All six CDRs, unless it is experimentally shown that some of the CDRs do not interact with antigen
- Disclaimer: antibody formats with < six CDRs

▶ Requirements to comply with Art. 84 are refined.

Clarification

G-II, 5.6.1.1

Art. 84 EPC

Antibodies

How common is the newly introduced scenario of fewer than six CDRs?

G-II, 5.6.1.1

Role of framework regions (FR):

- 20% of antibody residues making contacts with antigen are in framework regions, not in CDRs

- If surprising technical effect involves binding affinity – both CDRs and FR

Art. 84 EPC

- Examination practise evolves with antibody structure and function

Antibodies

Clarification

G-II, 5.6.2

Inventive step of antibodies

- Surprising technical effect
- Cross reference to G-VII, 13:
  no reasonable expectation of success of obtaining antibodies having the required properties

Art. 56 EPC

▶ Inventive step assessment is clarified, semantic improvements.

Antibodies

Perspective

- Evolution of technical field – technical aspects
- Antibody structure and function – Art. 84
- Development of technology – Art. 56
- Case Law

▶ Regular GL updates to keep pace

Clarification

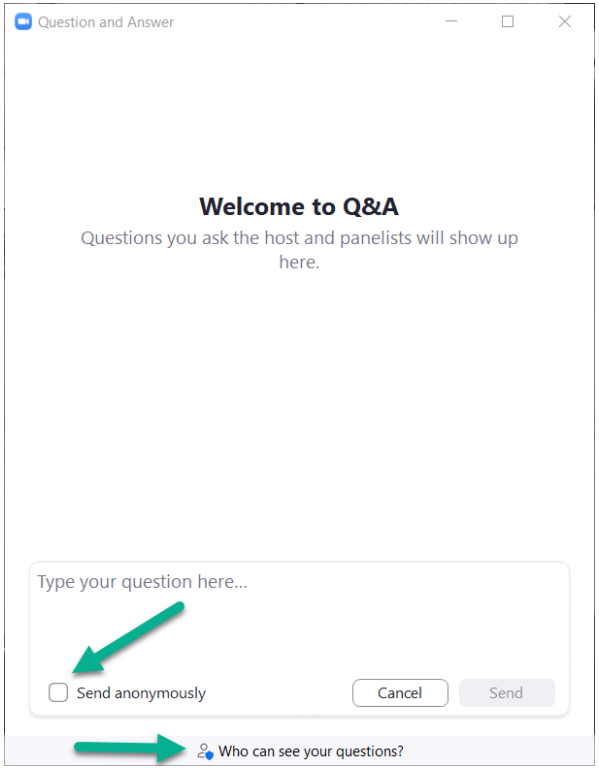
G-II, 5.6.1

G-II, 5.6.1.1

G-II, 5.6.2

Art. 84 and 56 EPC

Your questions



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Overview

Presenter

Scott Stanley

Lawyer in Directorate Patent Law

Nucleotide and amino acid sequences

Rule 30 EPC

Rule 30 EPC

- description shall contain a sequence listing
- conforming to the rules laid down by the President of the European Patent Office
- for the standardised representation of nucleotide and amino acid sequences

Current practice

Rule 30 EPC
Rule 163(3) EPC

- File on date of filing or upon invitation
- Late furnishing fee due if filed upon invitation
- If subsequently filed then not a part of the description
- Must comply with the decision of the President of the EPO
- If the required sequence listing is not filed when invited to do so, the application is refused.
- Remedy: further processing

▶ sequence listings need to be filed in WIPO ST.25 in TXT format

Current requirements and recommendations

- Recommended software
- Acceptable formats
- Which sequences must be in the sequence listing
- Which sequences may be identified by their database accession number instead
- Exception to the page fee
- Divisional applications
- Correction of errors
- Amendments of sequence listings
- Form of publication and file inspection

Background

OJ EPO 2011, 372
OJ EPO 2013, 542
GL A-IV, 5
GL F-II, 6
GL E-IX, 2.4.2
GL H-IV, 2.2.4

Drawbacks of ST.25

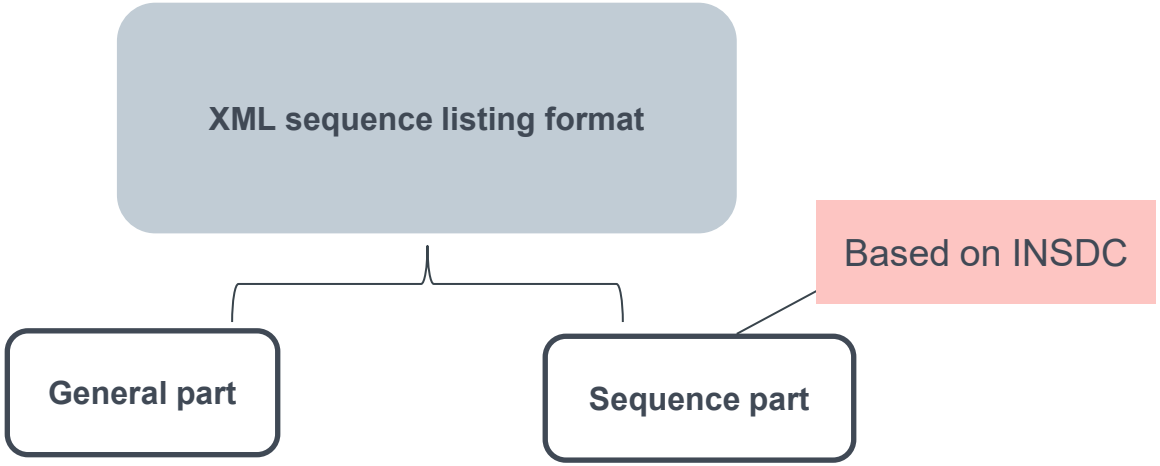
- **not aligned with the requirements of public databases**
  - obsolete feature keys and qualifiers
  - some standard abbreviations not supported
  - uncovered sequence types
- **Error-prone format as it is designed to be both human and computer readable:**
  - relative ease of creating a sequence listing with a non-dedicated software
  - mistakes difficult to detect
  - time and effort to correct the data
  - database providers otherwise drop the information

WIPO Standard ST. 26: advantages

- **Universality**
  - Common format for patent and non-patent communities
  - A single sequence listing acceptable in most cases for all patent filing procedures: PCT & national filings

- **Robustness and flexibility**
  - The syntax of WIPO Standard ST.26 provided by the DTD is more precise and easier to verify by means of automatic tools
  - Search is facilitated
  - Allows for easy exchange of data and incorporation of the sequences in electronic databases.

WIPO Standard ST.26 structure

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The INSDC databases

- INSDC: **I**nternational **N**ucleotide **S**equence **D**atabase **C**ollaboration:
  - DDBJ: DNA Databank of Japan
  - EMBL-EBI: The European Bioinformatics Institute
  - NCBI: National Center for Biotechnology Information (GenBank)

- The EPO, JPO, KIPO, USPTO submit published application sequence data to INSDC databases which are publicly searchable.

▶ **WIPO Standard ST.26 → wider dissemination, better standardisation, less errors and more accurate searches**

WIPO ST.26 at EPO

- Delay due to late implementation of revised PCT rules and entry into force of ST.26
- PCT – EPC alignment
- No changes to EPC Implementing Regulations
- New practice described in decision of the President and notice in the Official Journal

WIPO Standard ST.26 applies to applications filed from 1 July 2022

PCT General Assembly
PCT/A/53/3
WIPO General Assembly
WO/GA/54/14
PCT Administrative Instructions
PCT/AI/22 ADD.

WIPO ST.26 at EPO

- Application with filing date on or after 01.07.2022
- Divisional applications submitted on or after 01.07.2022
- Applications with a filing date before 01.07.2022 continue under ST.25
- Date of priority or entry into European phase is irrelevant

Basis

Committee on WIPO Standards CWS/5/22
OJ EPO 2021, A96
OJ EPO 2021, A97
Rule 30 EPC

▶ Reference to the new standard added in A-IV, 5

Editorial changes to be standard-neutral

WIPO ST.26 at EPO

- PDF, paper or TXT sequence listings are not ST.26 compliant
- Filing by reference is possible under Rule 40(1)(c) EPC
- If sequence listing available to EPO upon entry into European phase, no need to refile
- For divisionals, a separate sequence listing is needed unless only for search purposes and in ST.26 in the parent application
- Corrections and amendments in the same Standard

Basis

OJ EPO 2021, A96
OJ EPO 2021, A97
Rule 30 EPC

WIPO ST.26 at EPO: translations

- Need for translation is reduced – simplified approach
- Controlled vocabulary
- St.26 allows for two languages in the same file
- Requirement to repeat the free text in the main body of the description has been deleted from PCT (Rule 5(2)(b) PCT)
- Field to indicate the language which is considered to be the original version.

Basis

Rule 159(1)(a) EPC
OJ EPO 2021, A96
OJ EPO 2021, A97
PCT Administrative Instructions, Annex C, para 18-19

WIPO ST.26 at EPO: procedural improvements

- Sequence listings in original format made available for file inspection and publication
- No conversion to PDF for publication with application or specification
- Notification of communications containing sequence listings in the original format via the Mailbox

WIPO ST.26 at EPO: how to prepare

- WIPO has developed a software tool – WIPO Sequence
- Most recent version and user manual on WIPO's website
- WIPO and EPO presentations and webinars from 2021
- Send technical questions to EPO and WIPO

Question

RAISE HAND

If I file an application in June 2022 and a divisional application in July 2022, do I have to file a new sequence listing in ST. 26 upon filing the divisional?

☐ yes

☐ no

= yes

Answer

☒ **yes**

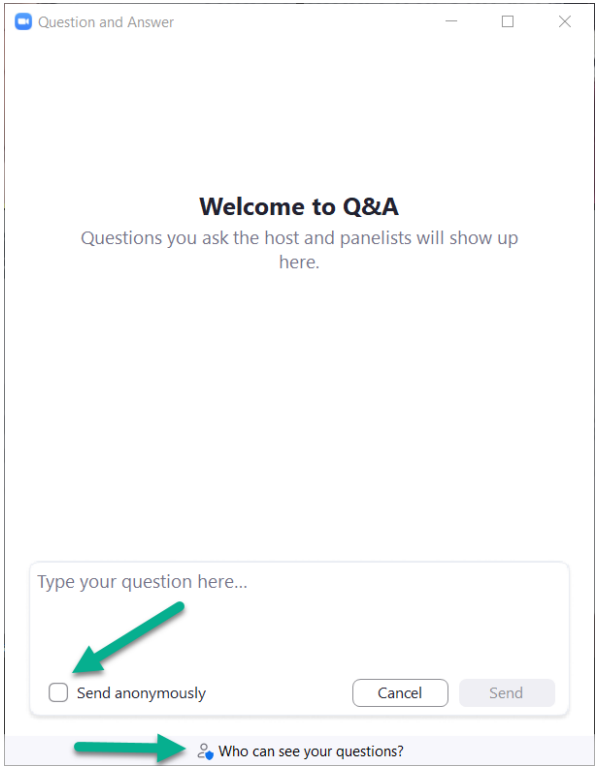
☐ no

The correct answer is **yes.**

A divisional application filed on or after 01.07.2022 must also contain a sequence listing in St. 26 format.

There is a possibility to copy the sequence listing from the parent application to the divisional application, but only for search purposes.

Your questions



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