Report of the Committee on Biotechnological Inventions

A. De Clercq (BE), Chair

Newly elected Committee members

The Biotech Committee members for term 2020-2023 were elected ad the last Council meeting: https://patentepi.org/r/info-2004-02. We also have many associate members who actively help us with biotech **epi** advice.

Patentability of plants and animals – G 3/19

Opinion **G3/19** dated 14 May 2020[1] has a high impact and is being commented on by many **epi** members and legal practitioners in the life sciences area.

Ann De Clercq

epi Biotech Committee discussed the impact of this opinion in its last digital committee meeting of 26 August 2020 as well as that of 12 October 2020 and will continue to do so.

The CPL52 (Committee on Patent Law) meeting on 10-11 November 2020 was attended by Ann De Clercq as well as the **epi** President Francis Leyder and Vice-President Heike Vogelsang-Wenke.

The EPO explained that **G3/19** was held to:

- Confirm the law and practice followed by the EPO
- Safeguard the uniform application of harmonised European patent law
- Reaffirm the power of the AC of the EPO to clarify questions of patentability

The EPO has implemented Opinion G 3/19 in its examination and opposition practice. Stays have been lifted. A revised draft of the relevant parts of the GLs for Examination has been prepared.

Exclusions according to R. 28(2)

The EPO confirmed that no EP patents can be granted for conventional plants/animals for applications filed on or after July 2017 and claiming no valid earlier priority date. The exclusion covers plants, plants reproductive material (incl. cells) and animals.

Technically-induced mutated plants

The EPO confirmed that technically-induced mutant plants (both via targeted and random mutagenesis causing modifications in the genome of a plant) are patentable. Patents related to such plants need a disclaimer to exclude the scope of the same plant obtained by a non-technical process

Mandatory disclaimers

The EPO clarified their position on disclaimers: they are required in all cases in which a feature of a claimed plant can be the result of both a technical intervention and an essentially biological process (EBP). The disclaimer requirement is set out in the Guidelines for Examination and is strictly enforced in the EPO's practice since implementation of Rule 28(2) EPC in 2017 (about 20 grants and 30 refusals).

Non-retroactivity of R. 28(2) – status of affected cases

According to Opinion G 3/19, Rule 28(2) EPC cannot be applied to applications filed or claiming priority before 1 July 2017 as well as European patents granted before that date.

About 310 examination and 10 opposition cases are affected. Proceedings are gradually being resumed. Application or patent at issue to be examined for compliance with all EPC requirements.

About 18 cases are pending before the Boards of Appeal. 2 cases already remitted to the examining division; in a number of further cases Board has expressed intention to remit the case.

Impact of G3/19 for granted EP patents

The EPO confirmed that a European patent confers on its proprietor the same rights as a national patent, subject only to formal validation (payment of national renewal fees and translation of the full or of the claims of the European patent if required). A European patent may be

1 https://patentepi.org/r/info-2004-03

revoked with effect for a Contracting State only on the grounds stipulated in the EPC.

The EPO also conveyed that the effect of a decision or opinion of the Enlarged Board of Appeal on the interpretation of the EPC by the authority or court of a Contracting State is subject to the law and practice of that State.

What is next?

The EPO submits that G 3/19 brings legal certainty and provides a sound basis for the EPO's practice concerning plant-and animal-related inventions. The Contracting States will be regularly informed by the EPO about the implementation of Opinion G 3/19 and the EPO's practice in this field.

The EPO is mindful of the ethical and economical implications of the issue and is continuing discussions with stakeholders, incl. NGOs.

In the following discussion at the CPL52 meeting national delegations and observers (such as **epi** and Business Europe) took the floor, all announced that they thanked the EPO for all their work. Discussion items were mainly related to random mutagenesis, mandatory disclaimers, ethical debates on plant patentability and potentially upcoming national courts or other decisions.

The **epi** Biotech Committee agrees in general with the overview given by the EPO but does have concerns and comments and a further discussion within the **epi** Biotech Committee on these points will take place.

Future discussions in other circles with respect to disclaimers, random mutagenesis, propagation material and animal patentability will also be followed by the **epi** Biotech Committee and commented on where needed. It is clear that the discussion on these topics will continue for a while.

These disclaimers might be the subject of future EBA or CJEU referrals and the Biotech Committee will follow up and discuss these developments closely.

Updated Guidelines for Examination Biotech 2021

Extensive amendments to parts F and G of the GLs relating to biotech inventions were proposed by the EPO to **epi** for discussion in several rounds. The topics mainly relate to:

- Plant biotech: G3/19 and disclaimers (amendments in existing parts and new paragraphs)
- Antibodies (NEW)
- Exclusions (stem cells) (amendments in existing parts)
- Homology, similarity, identity of genes and protein sequences (NEW)

We will keep on providing comments and information as the biotech parts are largely in review and new parts are being introduced in the new Guidelines that will come out in 2021.

These amendments to the Guidelines will imply also educating practitioners all over the world to learn what the norms of the EPO will include so that applications can be drafted to take account of these new Guidelines. We welcome that biotech examination practices of the EPO are clarified in the Guidelines for Examination.

Updating national biotech law overviews

epi Biotech Committee is updating its overviews on plant patentability, patentability of gene sequences and other matters and will provide them in one of the next **epi** Information editions.

Other points discussed

The Biotech Committee discussed the EC roadmap document and provided suggestions to Presidium.

A contribution to the **epi** strategic plan was forwarded to the **epi** Council and Presidium.

epi Biotech Committee will also look into patent disclosure requirements for Genetic Resources and Traditional Knowledge and will look into WIPO Standard ST.26 for Sequence Listings.

Meetings attended and to be scheduled

Topics were passed to EPPC for a new meeting with DG1 concerning biotech and other life sciences topics. Dates are being planned for beginning 2021 with EPO and with the EPPC thematic groups and Biotech Committee. These meeting are very informative and constructive for both sides.

The **epi** inaugural Biotech Committee meeting will take place on 7 December 2020 and other (ad hoc) digital meetings will be planned to meet with our new members and all our associate members in function of other upcoming meetings and additional topic discussions within the Biotech Committee.