Enlarged Board of Appeal  
European Patent Office  
For the attention of Mr Wiek Crasborn  
Richard-Reitzner-Allee 8  
85540 Haar

Subject: Amicus curiae brief by IPO CZ concerning Referral G 3/19

Dear Sir or Madam,

In accordance with Article 10 of the Rules of Procedure of the Enlarged Board of Appeal, please find attached an amicus curiae brief submitted by the Industrial Property Office of the Czech Republic with regard to Referral G 3/19.

Our Office is highly interested in the questions presented to the Enlarged Board of Appeal in the above mentioned Referral and looks forward to the Enlarged Board’s decision.

Yours sincerely,

[Signature]

Address: Industrial Property Office, A. Cermaka 2a, 160 68 Prague, Czech Republic  
Tel: +420 220 383 272, Fax: +420 224 313 249  
e-mail: jkratochvil@upv.cz
Amicus Curiae Brief by
the Industrial Property Office of the Czech Republic
concerning referral G 3/19

Background

Following the announcement of the referral of points of law concerning case G 3/19 by the EPO President to the Enlarged Board of Appeal (EBoA) under Article 112(1)(b) EPC, the Industrial Property Office of the Czech Republic (IPO CZ) wishes to submit the *amicus curiae* brief according to Article 10 of the Rules of Procedure of the EBoA.

The decision of the Technical Board of Appeal (TBoA) in case T 1063/18 of 5 December 2018 concerning the legal status of new Rule 28(2) EPC evoked a significant negative impact on the issue of patentability of inventions based on products emanating from the essentially biological processes. As a consequence it generated again legal uncertainty in terms of the applied European patent law in the field of biotechnology.

In order to ensure uniform application of the law, EPC provides for the opportunity for the President of the European Patent Office to refer a point of law to the EBoA where two Boards of Appeal (BoA) have given different decisions on that question. IPO CZ supported the idea of referral to the EBoA in the 150th meeting of the Administrative Council on 27 and 28 March 2019 as a reaction to decision in case T 1063/18. Therefore, IPO CZ welcomed the initiative of the President of EPO to submit two points of law to the EBoA according to Article 112(1)(b), which read as follows:

1. *Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal?*

2. *If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?*
IPO CZ is of the view that the points of law in referral G 3/19 are admissible. The referred points of law are of fundamental importance and the answers to them provided by the EBoA will bring the clarity in this issue and restore legal certainty in the interest of users of the European patent system and the general public in the field of biotechnology.

First question

*Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal?*

The issue of exclusion from patentability of products (plants/animals and plant/animal parts) produced by essentially biological processes were in great details discussed by representatives of the EPC Contracting States in the 47th and 48th meetings of the EPO Committee on Patent Law in November 2016 and in April 2017. In order to align the EPO’s law and practice with the interpretation of the Biotech Directive and to safeguard uniformity in harmonised European patent law, four possible options were closely analyzed. These options for action were a) to continue the examination practice based on the interpretation of Article 53(b) EPC established by decisions G 2/12 and G2/13; b) an amendment of the Convention; c) an amendment of the Implementing Regulations to the EPC; or d) a change of practice by the first instance based on modified administrative instructions (EPO notice, Guidelines) issued under Article 10(2) (a) EPC.

The Czech Republic attaches great importance to shedding light on patentability of products obtained by essentially biological processes in the harmonized manner. In the national capacity as a member of the EPO’s Committee on Patent Law and Administrative Council we duly consider all proposed options mentioned above form different legal angles and implications, with special attention to the compliance with Article 53(b) EPC and the hierarchy of norms principle pursuant to Article 164(2) EPC. Based on analysis of law and case law in terms of the implementation of the Biotech Directive into EPC we came to the conclusion that the adopted clarification of Article 53(b) EPC was fully compliant with the EPC.
The Czech Republic expressed its support of the amendment of the Implementing Regulations to the EPC in order to put it in line with the interpretation of the Biotech Directive as clarified in the Biotech Notice. In our view, the introduction of new Rule 28(2) EPC accompanied by the technically detailed clarification available at the Guidelines for Examination in the EPO was a legally straightforward, not time consuming and stakeholder oriented satisfactory way how to ensure the harmonization of European patent laws in terms of the application of exclusion from patentability plants/animals obtained by essentially biological processes by the EPO Contracting States.

To increase legal certainty in the biotech field in Europe and contribute to restoring an appropriate balance between patent-related rights and plant variety rights, the Czech Republic voted in favour of introducing the explicit exclusion of plants/animals exclusively obtained by an essentially biological process in the form of new Rule 28(2) EPC in the 152\textsuperscript{nd} meeting of the Administrative Council on 28 and 29 June 2017.

Article 164(2) EPC makes no mention of BoA decisions. Decisions (including interpretation) of the BoAs do not form an integral part of the EPC. Furthermore, it is not true that the only possible interpretation of the EPC is that by a BoA. Firstly, different BoAs may come to different interpretations (see Article 112(1)(b) EPC); secondly, national courts in the Member States may also have different interpretations, for example in proceedings for the revocation of a European patent. Thus, the interpretation by one of the BoAs is not something to be carved into stone. Clarification of the EPC Articles in Implementing Regulations cannot therefore be limited by the interpretation by one of the BoAs.

Finally, we wish to recall that according to Rule 33(1) EPC the Administrative Council is newly competent to amend the Articles of Convention without being limited by earlier decisions of the BoA or the EBoA. Thus, according to our belief, the Administrative Council has also the competence to clarify the meaning and scope of EPC's articles in order to bring them into line with EU legislation on patents regardless BoA decisions.

Based on the explanation as laid out above, the first question should be answered in the positive.
Second question

*If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?*

Article 53(b) EPC stipulates that “European patents shall not be granted in respect of plant and animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or products thereof”.

Rule 28(2) EPC further specifies that “under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process”.

Rule 26(5) EPC stipulates that “a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing and selection”.

The introduction of Rule 28(2) EPC had stemmed from the next steps of the Contracting Parties to the EPC following the publication of the Commission Notice\(^1\) on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (hereinafter referred to as ‘Biotech Directive’). The Notice provides a very useful reference and assistance in the application of the Biotech Directive.

IPO CZ strongly supported clarification and conclusions on exclusion of products obtained by essentially biological processes from patentability provided by the Commission in the Biotech Notice. Therefore, the Czech Republic supported adoption of Council Conclusions\(^2\) on the Commission Notice published on 1 March 2017. In line with the conclusions the Council of the EU urges Member States, in their capacity as members of the European Patent Organisation, to advocate that the practice of the European Patent Organisation is aligned with the conclusion that the EU legislator’s intention when adopting Directive 98/44/EC was to exclude from patentability products obtained through essentially biological processes.

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\(^1\) OJ C 411, 8.11.2016, p. 3.

\(^2\) OJ C 65, 1.3.2017, p. 2.
The Biotech Directive\(^3\) sets out principles regarding the patentability of biological material, such as the human body and its parts, animals and plants, namely across the patent acts of the EU Member States at the harmonised manner.

Based on a call of the European Parliament in December 2015 to look into the patentability of products derived from essentially biological processes, the issue of cross-licensing between patents and plant variety rights, and access to deposited biological material, possibly by means of interpretative guidelines, the Commission analyzed in details/ with high precision the intention of EU legislator in terms of the exclusion of products obtained by essentially biological processes from patentability, when adopting the Biotech Directive.

The Biotech Notice describes the evolution of negotiation of the proposed text in a very precise manner. Even if the final wording of the Biotech Directive does not contain a provision on the patentability of products (plants, animals or their parts) obtained through an essentially biological process, it can be inferred from the original wording of article 4 that the Commission’s intention was that such products were not regarded as patentable subject matter. Nevertheless, the adopted wording of the Biotech Directive provides with number of hints/orientations, mainly Articles 3(1) and (2), 4(1),(2) and (3) supported by recitals 32 and 33, to understand the scope of exclusion of products obtained by essentially biological processes, as demonstrated in the Commission Biotech Notice.

Despite of the fact that the European Patent Organization is a non-European institution, the relevant provisions of Biotech Directive were due transposed into the legal framework of the European Patent Organization, which had taken the liberty of amending the European Patent Convention’s implementing rules in this sense.

Thanks to the particular clarification provided in the Commission Biotech Notice, the interpretation and practice applied by the National Patent Offices of the EPC’s Contracting States and by the European Patent Office in terms of patentability assessment of plant/animal-related inventions, where a plant/animal was exclusively obtained by an essentially biological process, was reconciled. Therefore, IPO CZ highly welcomed that the

interpretation of respective EPC's provisions was put in accordance with the Biotech Directive provisions, leading to their uniform application.

Since Article 53(b) EPC does not contain a clear provision, it allows for a double interpretation. One way to eliminate this ambiguity is to clarify it in the Implementing Regulations. Rule 28(2) EPC is in line with one of the potential interpretations of the EPC, i.e. the one that corresponds to the interpretation applied in the EU. By its decision, AC EPO enabled Article 53(b) of the EPC to be interpreted in the same way as Article 4 of the Biotech Directive is interpreted in the EU. Indeed, it is obvious from Article 33(1)(b) EPC that the legislator considered it crucial for the EPC to be kept consistent with the EU law.

In case of patent application based on the products obtained by essentially biological processes, IPO CZ applies the interpretation and national patent practice which is fully in line with the text of the Biotech Directive as interpreted by the Commission Notice. Therefore, the plants/animals or their parts emanating from essentially biological processes are regarded as subject-matters excluded from the patentability.

**Conclusion**

The IPO CZ requests the Enlarged Board of Appeal to take into account the arguments why Rule 28(2) EPC constitutes a valid implementation of Article 53(b) EPC and bear the efforts to harmonise patent procedures between EPC and national law and practice of all EPC Contracting States in mind when deciding on this issue.