

Enlarged Board of Appeal
European Patent Office
80298 Munich
Germany

Rotterdam, 24 September 2019

Re: Amicus Curiae brief regarding G 3/19, plants and animals exclusively obtained by means of an essentially biological process

Dear Sirs,

The EPO President has referred the following points of law to the Enlarged Board of Appeal:

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?

Regarding this case, I respectfully observe as follows:

Background

Article 52(1) EPC reads as follows:

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.

Article 53 EPC reads as follows:

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 164 EPC reads as follows:

Article 164 Implementing Regulations and Protocols

(1) The Implementing Regulations, the Protocol on Recognition, the Protocol on Privileges and Immunities, the Protocol on Centralisation, the Protocol on the Interpretation of Article 69 and the Protocol on Staff Complement shall be integral parts of this Convention.

(2) In case of conflict between the provisions of this Convention and those of the Implementing Regulations, the provisions of this Convention shall prevail.

Rule 26(1) EPC reads as follows:

Rule 26 General and definitions

(1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.

Rule 28 EPC reads as follows:

Rule 28 Exceptions to patentability

(1) 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.

(2) 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 29(1) EPC reads as follows:

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.

EU Directive 98/44/EC on the legal protection of biotechnological inventions (hereinafter: the EU biotech directive) contains the following clauses corresponding to Articles 52(1) and 53 EPC, and Rules 28(1) and 29(1) EPC:

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.

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.

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.

In decision T 1063/18, the Technical Board of Appeal has decided that Rule 28(2) EPC is in conflict with Article 53(b) EPC, as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13. In accordance with Article 164(2) EPC, the provisions of the Convention prevail. As a result, the appealed decision of the Examining Division that was based on Rule 28(2) EPC was set aside, and the case was referred back to the Examining Division for further prosecution.

This caused some anxiety at the administrative branch of the EPO as Rule 28(2) EPC was inserted into the EPC Implementing Regulations to overrule Enlarged Board of Appeal decisions G 2/12 and G 2/13. This insertion was triggered by a non-binding notice¹ from the European Commission, supported by the Council of the European Union, which held that the EU biotech directive should be interpreted in such a way that also plants or animals exclusively obtained by means of an essentially biological process are excluded from patentability.

Analysis

The law

It is the task of the judiciary², and thus of the Enlarged Board of Appeal, to apply the law as it is. It is the task of the legislator to align the law with what is politically desirable.

¹ Commission Notice on certain articles of Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (2016/C 411/03), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016XC1108%2801%29>.

This Notice contains the following statements: "The Notice is intended to assist in the application of the Directive, and does not prejudice any future position of the Commission on the matter. Only the Court of Justice of the European Union is competent to interpret Union law."

² Les juges de la nation ne sont que la bouche qui prononce les paroles de la loi, des êtres inanimés, qui n'en peuvent modérer ni la force ni la rigueur. (Montesquieu, Esprit des Lois 1777)

The mere fact that certain EU Institutions and certain parts of the European Patent Organisation believe it to be politically desirable to exclude from patentability plants or animals exclusively obtained by means of an essentially biological process, does not result in that the law has changed.

The view of the European Parliament that Article 4 of the EU biotech directive states that products obtained from essentially biological processes shall not be patentable, is simply not based on the text of the EU biotech directive. If EU Institutions are no longer happy with the text of the EU biotech directive, they should change it in accordance with the applicable TFEU provisions; merely adopting resolutions, non-binding reports, and Council statements supporting such non-binding reports, does not result in a change of EU law.

To change the law as laid down in the EPC, the EPC legislator has several options:

- A diplomatic conference under Article 172 EPC, followed by tedious and lengthy national ratification procedures that involve national parliaments.
- An Administrative Council decision under Article 33(1)(b) to amend the EPC Articles. As in this way, the national parliaments are not involved, this possibility is subject to certain restrictions, including that the EPC amendment must serve alignment with an international treaty relating to patents or European Community legislation relating to patents that has already entered into force. Further restrictions are given in Article 33(5) and 35(3) EPC. In those cases, democracy is still served as such a treaty or EU law will already have been subject to parliamentary scrutiny.
- An Administrative Council decision under Article 33(1)(a) to amend certain time limits in the EPC Articles. As this is a relatively minor matter, no parliamentary scrutiny is needed.
- An Administrative Council decision under Article 33(1)(c) to amend the EPC Implementing Regulations. As under Article 164(2) EPC, the EPC Implementing Regulations may not conflict with the EPC Articles, and thus must remain within the boundaries that have been subject to parliamentary scrutiny, no parliamentary scrutiny is needed for amending the EPC Implementing Regulations.

Rule 28 EPC has 2 paragraphs. Just like Rule 29(1), Rule 28(1) can indeed be seen as genuine examples of the not precisely defined concept “*ordre public*” of Article 53(a) EPC, just like Articles 5(1) and 6(2) of the EU biotech directive can be seen as genuine examples of the concept “*ordre public*” of Article 6(1) of that directive. So, there is no conflict between Article 53(a) EPC on the one hand, and Rules 28(1) and 29(1) EPC on the other hand.

In contrast, Article 53(b) EPC does not contain a similar not precisely defined concept that can be interpreted. Article 53(b) EPC simply lists 3 distinct items that are excepted from patentability, viz.

- plant or
- animal varieties or
- essentially biological *processes* for the production of plants or animals.

This means that whatever is not listed as an exception in Article 53(b) EPC, must be patent-eligible as soon as the conditions for patentability of Article 52(1) EPC have been met.

From a clarification in Article 53(b) EPC itself, viz. “this provision shall not apply to microbiological *processes* or the *products* thereof”, it is clear that the EPC legislator was well aware of the difference between methods and products of such methods, so that if the EPC legislator had desired to also exclude the *products* of essentially biological *processes* for the production of plants or animals from patentability, the legislator would have said so.

If it were allowed to “interpret” an exclusion of methods as also covering an exclusion of devices if politicians and the administrative branch believe this to be politically convenient, then Article 53(c) EPC could be “interpreted” as also covering an exclusion of medical diagnostic devices, including “interpreting” the safeguard for “products, in particular substances or compositions” as being limited to substances or compositions. This is clearly an “interpretation” against the legislator’s intent.

It is thus not possible for Rule 28(2) EPC to add the *products* of essentially biological *processes* for the production of plants or animals as an additional exception to patentability, because doing so with immediately conflict with Article 52(1) EPC as whatever has not been explicitly excluded from patentability, must be patent-eligible if the conditions of Article 52(1) EPC are met.

As Rule 28 EPC is presented as being a mere implementation of the EU biotech directive, it is important to stress that exactly the same reasoning can be held under the EU biotech directive.

Like Article 52(1) EPC, Article 3(1) of the EU biotech directive provides that “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.”

Like Article 53(b) EPC, Article 4(1)(b) of the EU biotech directive merely excludes from patentability “essentially biological *processes* for the production of plants or animals”.

Again like the clarification in Article 53(b) EPC, in Article 4(3) of the EU biotech directive also the EU legislator has shown to be well aware of the difference between *processes* and *products* of such processes by providing “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.”

So, Rule 28(2) EPC not only conflicts with Article 52(1) EPC, but also with Article 3(1) of the EU biotech directive, so that the EPC legislator cannot re-legislate the content of Rule 28(2) EPC by using the procedure of Article 33(1)(b) EPC. And if the Administrative Council nevertheless adopted such a change of the EPC Articles, that change would be null and void, i.e. of no effect whatsoever.

Also a diplomatic conference cannot be used to re-legislate the content of Rule 28(2) EPC, as the 28 (or 27) EU Member States among the 38 EPC Contracting States cannot support an EPC amendment that would conflict with EU law, as doing so would be a direct violation of their Union loyalty obligations under Article 4(3) EU Treaty. The 75% majority of Article 172(2) EPC thus cannot be lawfully met.

President’s referral

It is respectfully submitted that the President’s questions are ill-formulated.

As to Question 1, for determining the lawfulness of an EPC Rule, it is not at all relevant whether an EPO Board of Appeal, or the EPO Enlarged Board of Appeal, has already interpreted an EPC Article. What matters is whether the EPC Article is susceptible of refinement / interpretation by means of an EPC Rule.

As mentioned above, Articles 5(1) and 6(2) of the EU biotech directive are a *bona fide* refinement / interpretation of the not precisely defined concept “*ordre public*” in Article 6(1) of the EU biotech directive, and likewise, Rules 28(1) and 29(1) EPC are a *bona fide* refinement / interpretation of the same not precisely defined concept in Article 53(a) EPC.

In contrast, Article 53(b) clearly only excludes 3 distinct items from patentability, so that it is simply impossible for an EPC Rule like Rule 28(2) EPC to refine or interpret these 3 distinct items by adding a 4th item.

In T 1063/18, the relevance of mentioning the Enlarged Board of Appeal decisions G 2/12 and G 2/13 is just that as a result of these Enlarged Board of Appeal decisions, the matter is already an *acte éclairé*, so that it was not necessary anymore for the Technical Board of Appeal to refer a question to the Enlarged Board of Appeal.

Only in case the Technical Board of Appeal had considered it necessary to deviate from the Enlarged Board of Appeal decisions G 2/12 and G 2/13, it should³ first have referred the matter to the Enlarged Board of Appeal.

Even in the absence of Enlarged Board of Appeal decisions G 2/12 and G 2/13, it would not have been legally possible to adopt Rule 28(2) EPC.

Also Question 2 is ill-formulated because of its misleading suggestion that Article 53(b) EPC neither explicitly excludes nor explicitly allows patentability of plants and animals exclusively obtained by means of an essentially biological process.

As explained above, Article 53(b) EPC only excludes the essentially biological *processes* themselves for the production of plants or animals from patentability, not the plants and animals exclusively obtained thereby. So, there is nothing left for interpretation by means of Rule 28(2) EPC.

I hope that the above is helpful.

Yours faithfully,



L.J. Steenbeek.

³ Article 21 of the Rules of Procedure of the Boards of Appeal.