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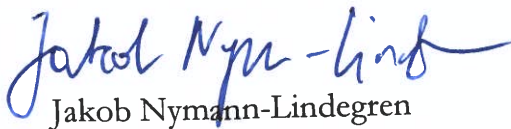
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Annexes	DK-Case ref.	Unit	Date
1	2019 - 34887	Department of EU-Law and International Litigation	30-09-2019

Amicus curiae brief in the Enlarged Board of Appeal Case G 3/19

Please find attached the amicus curiae submission of the Danish Government in case G 3/19, submitted pursuant to Article 10(1) of the Rules of Procedure of the Enlarged Board of Appeal of the European Patent Office.

Yours sincerely


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Ministry of Foreign Affairs of Denmark

Legal Service

Copenhagen, 30 September 2019

DK-Case ref.: 2019 - 34887

To

The European Patent Office

Registry of the Enlarged Board of Appeal

AMICUS CURIAE BRIEF

BY

THE DANISH GOVERNMENT

IN THE CASE G 3/19

REFERRAL OF A POINT OF LAW

TO THE ENLARGED BOARD OF APPEAL

BY THE PRESIDENT OF THE EUROPEAN PATENT OFFICE

1. Introduction

1. The Danish Government submits hereby and pursuant to Article 10 (1) of the Rules of Procedure of the Enlarged Board of Appeal the following statements:
2. The question of patenting of products obtained by an essentially biological process is an important matter for Denmark and for Danish companies. If the Enlarged Board of Appeal upholds that products exclusively obtained by means of an essentially biological process cannot be excluded from patentability, we will face two diverging legal frameworks on the matter in the European Patent Convention (EPC) and in EU law.
3. This discrepancy between the two legal frameworks will give rise to substantial legal uncertainty especially in the 28 EU-Member States, all being bound both by the EPC and EU legislation. The Danish Government notes that the processing of European patent applications in relation to Article 53(b) EPC has currently been put on hold pending the Enlarged Board of Appeal's decision in case G 3/19¹, which underlines the need for a clarifying decision.
4. Denmark has been a member of the European Patent Organization since 1990, and participates actively in the Administrative Council, including its sub-bodies such as the Patent Law Committee.

2. Factual background

5. As for the factual background of the current case, the government refers to the description hereof in case T-1063/18² and to the Referral of the President of the EPO³.

² Decision T 1063/18 ([Decision T 1063/18](#))

³ Referral of a point of law to the Enlarged Board of Appeal by the President of the European Patent Office (Article 112 (1)(b) EPC), of 5 April 2019

3. Admissibility

6. According to Article 112(1)(b) EPC, the President of the EPO can – in order to ensure uniform application of the law, or if a point of law of fundamental importance arises – refer a point of law to the Enlarged Board of Appeal when two boards of appeal have given different decisions on a certain question.
7. The purpose of this provision is thus to ensure *uniform* application of the Convention and to clarify legal matters of substantial importance. In his referral, the President of the EPO has argued extensively that not only is a referral to the Enlarged Board of Appeal necessary in this case, the conditions for such a referral are also met.
8. The Danish Government shares the assessment of the President of the EPO that the referral is admissible under Article 112(1) EPC, and that there is a substantial need for clarification of the potential impact of the subsequent legal developments for the interpretation of Article 53(b) EPC following Enlarged Board of Appeal's decisions in G 2/12⁴ and G 2/13⁵ in 2015.

4. Legal Assessment

4.1 The meaning and scope of Article 53 EPC can 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 (Question 1)

9. Article 53(b) EPC states that European patents shall not be granted in respect of:

“[...] (b) plant or animal varieties or essentially biological processes for the production of plants or animals: [...]”.

⁴ Decision G2/12 of 25 March 2015 also referred to as “Tomatoes II”, ([G 2/12](#))

⁵ Decision G3/13 of 25 March 2015 also referred to as “Broccoli II”, ([G 2/13](#))

10. It is undisputed that the wording of Article 53(b) does *not* specifically exclude nor allows the patentability of products, such as plants, obtained through an essentially biological process. Therefore, in order to clarify such substantive aspect of the EPC, the Administrative Council is **fully competent** to amend and introduce new Implementing Regulations regarding parts II to VIII of the EPC, which includes Article 53. This competence follows directly and explicitly from Article 33 (1)(b) and (c) EPC.
11. It is directly stated in Article 164(1) EPC that the Implementing Regulations form an *integral part* of the Convention, which supports the legally binding powers of these Rules when orderly adopted by the Administrative Council. The Administrative Council consists of all EPO Contracting States.
12. The amendment to the Implementing Regulation, Rule 28, was presented to EPO's Patent Law Committee; a sub-body set up by the Administrative Council, and subsequently adopted by the Administrative Council in 2017.
13. In the opinion of the Danish Government, there is no basis for arguing that such clarifying implementing provisions should be limited by earlier decisions by the Enlarged Board of Appeal. The Danish Government thus fully agrees with the assessment made by the President of EPO in the referral, points 45 to 69.
14. Article 164(2) EPC does not provide grounds for construing the former decisions made by the Enlarged Board of Appeal as binding on future implementing measures. Article 164(2) merely states that in case of conflict between the *provisions of the EPC* and the Implementing Regulations, the provision of the Convention shall prevail. Such conflict does not exist in the present case, since Rule 28 does not contradict the Convention provision itself, but merely clarifies it. It is therefore not correct, when the Technical Board of Appeal in their

decision stated that Rule 28 “*reverses the meaning of Article 53 (b) EPC*”⁶ or “*is in conflict with Article 53 (b) EPC*”⁷.

15. Instead, Rule 28 might “conflict” with the *former case law* in the cases of Tomatoes II⁸ and Broccoli II⁹, but Article 164(2) does not concern this situation, and there are no grounds for stating that former case law prevents the EPC legislator from adopting or amending Implementing Regulations.
16. This position is based on two main arguments:
17. **Firstly**, due to the wording of Article 164(2), the power of the EPC legislator is (only) limited to the extent that an administrative Rule will conflict with the provisions of the *Convention*. Thus, it follows from Article 164(2) read in conjunction with Article 33(1) that the competence of the EPC legislator is limited only by the Convention and thus not by case law.
18. **Secondly**, in a situation as the present, where there has been an important new development in law – European Community legislation as referred to in Article 33(1)(b) – it would not make sense, if the Administrative Council which, as a legislator has been assigned competence to amend, inter alia, Articles stated in parts II to VII of the Convention, was deprived of this Convention-protected right as a result of earlier case law (in the present situation the Tomatoes II and Broccoli II cases). It would de facto shift the balance between legislative and judicial power and per se preclude a development in the law or its interpretation.
19. **Moreover**, in the situation at hand, The Enlarged Board of Appeal found in the Tomatoes II¹⁰ and Broccoli II¹¹ cases that the EPC *in itself* did not contain general rules for interpreting Article 53(b). At this point in time, the *purpose* of the

⁶ Decision T 1063/18, par. 32

⁷ Decision T 1063/18, par. 25

⁸ Decision G 2/12

⁹ Decision G 2/13

¹⁰ Decision G 2/12, para. 29

¹¹ Decision G 2/13, par. 29

provision was not clear¹², and the Enlarged Board of Appeal therefore found no clear basis to deviate from a narrow construction of exceptions from patentability, which it applied to Article 53(b) EPC¹³.

20. These cases thus revealed that there was a need for clarification of the legislator's intention with the provision.

21. Within the European Union, this clarity was given by the European Commission in its Notice¹⁴ on the interpretation of the EU Biotechnology Directive¹⁵ in November 2016, which stated that the EU legislator's intention on the adoption of the Directive, was to exclude the patentability of products obtained by an essentially biological process.

22. As can be derived inter alia from Rule 26(1) EPC, according to which the EU Biotechnology Directive shall be used as a supplementary means of interpretation for the EPC, the Administrative Council and the EPC Contracting States attach utmost importance to the *uniform interpretation* and application of harmonized European patent law. This was also explicitly stated in relation to the EU Biotechnology Directive, at the time the Directive was adopted, cf. Notice dated 1 July 1999¹⁶, describing how several provisions in the Implementing Regulations were adjusted to comply with the Directive. It follows from this Notice, point 3, that even though EPO is not obliged to implement the Directive, "*European Patent law does need to be brought into line with the Directive, primarily in order to comply with the requirement for uniformity in harmonized European patent law.*"

¹² Decision G 2/12, p. 49 and decision G 2/13, p. 49

¹³ Decision G 2/12, p. 47 and decision G 2/13, p. 47

¹⁴ 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) of 8 November 2016

¹⁵ Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions

¹⁶ Notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, 573.

23. It was due to this requirement for uniformity that the Administrative Council decided to add a new paragraph 2 to Rule 28 of the Implementing Regulations¹⁷, stating 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*”, and thus clarify the intention of the EPC legislators. In this regard, the Danish Government stresses that the choice between amending Articles of the Convention and Implementing Regulations is one exclusively for the legislator, i.e. the Administrative Council¹⁸.

24. On that basis the Danish Government submits that this very much needed clarification was made in accordance with the Articles 33(1)(b) EPC, and does not contradict Article 53(b) EPC, and is therefore not limited by former case law of the Enlarged Board of Appeal having regard to Article 164(2) EPC.

25. In the light of the above mentioned the Danish Government suggests that Question 1 should be answered in the affirmative.

4.2. The exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC is in conformity with Article 53(b) EPC (Question 2)

26. The Danish Government submits that the adopted exclusion from patentability in Rule 28(2) is in conformity with Article 53(b) EPC.

27. As stated above, the **wording** of Article 53(b) EPC does not explicitly exclude or allow the patentability of products obtained by an essentially biological process, and thus leaves room for interpretation and clarification.

28. Such clarification is provided by the Implementing Regulations, Rule 28, which was duly adopted by the Administrative Council in full accordance with the EPC.

¹⁷ Amended by decision of the Administrative Council CA/D 6/17 of 29.06.2017 (OJ EPO 2017, A56) entered into force on 01.07.2017.

¹⁸ OJ EPO 2006, 15, point 5.8 of the Reasons for the Decision.

This regulation, which the EPC Contracting States voted in favor of, thus reflects and confirms the **intention** of the EPC legislator, and forms an integral part of the Convention, cf. Article 164(1) EPC.

29. This interpretation is also supported by Article 64(2) EPC, which lays down that the protection of the process is conferred to the product directly obtained by such processes. Using a parallel rationale, in case of allowing plants or animals exclusively obtained by means of an essentially biological process, the provision of Article 53(b) EPC would remain void.
30. Furthermore, such interpretation is also supported by **Article 31 in the Vienna Convention** on the law of Treaties¹⁹. As a general rule of interpretation, a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
31. It is further stated in Article 31(3)(a), that *“any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions”* shall be taken into account together with the context. This is also the case for any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation, and any relevant rules of international law applicable in the relations between the parties, Article 31 (3)(b-c).
32. The Danish Government submits that the amendment of Rule 28 shall be considered as an **agreement** between the parties in the meaning of the Vienna Convention, Article 31 (3)(a). The earlier decisions rendered by the Enlarged Board of Appeal cannot be considered a practice in the application of the Convention that establishes an agreement between the parties regarding its interpretation. On the contrary, most EPO Contracting States have either established national legislation or implemented a practice that corresponds with

¹⁹ The Vienna Convention on the law of treaties concluded in Vienna on 23 May 1969 (Vienna Convention).

the addition in Rule 28, thus excluding patents on plants or animals obtained by an essentially biological process.

33. Furthermore, it follows directly from the Implementing Regulations Rule 26(1) that the EU Biotechnology Directive shall be used as a **supplementary means of interpretation**. This provision clearly reflects the need for a uniform interpretation between harmonized EU patent law and the EPC, which was already explicitly stated when the EU Biotechnology was adopted, see also point 22 above.
34. In accordance with the abovementioned the Danish Government also considers this Rule 26(1) to be binding on the contracting parties due to Article 164 (1) EPC, and also considers this provision to be a **subsequent agreement** in the meaning of the Vienna Convention Article 31 (3)(a), which the contracting parties need to take into account when interpreting the EPC, including Article 53(b).
35. It is well established that Article 4 of The EU Biotechnology Directive contains a provision corresponding to Article 53(b) EPC, which states that “*plant and animal varieties*” and “*essentially biological processes for the production of plants or animals*” shall not be patentable. The wording of the Directive does not – as is the case for Article 53 EPC – explicitly exclude or allow the patentability of the products of an essentially biological process.
36. But as already mentioned, the European Commission clarified this in its Notice on certain articles of the EU Biotechnology Directive²⁰, by stating that in the view of the Commission, the EU legislator's intention when adopting the EU Biotechnology Directive was to exclude products (plants/animals and plant/animal parts) obtained by means of essentially biological processes from

²⁰ Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions ([link Directive](#))

patentability²¹. In this regard, the Commission refers to the relevant preparatory work relating to the adoption of the Directive.

37. It is true that the Notice is not legally binding in the same strict sense as EU-legislation or judgements rendered by the Court of Justice of the European Union. Nevertheless, the Notice states the view and intention of the EU-legislator, including the EU Council and Parliament. In the absence of relevant case law or provisions stating otherwise, such statements are an important mean of interpretation within the EU, and the EU Member States do commonly attach binding effects to such interpretations presented by the EU-legislator. This is also seen in the present case, where several EU Member States have already adapted their national legislation in accordance with the Notice. The Danish Government therefore submits that the Notice is indeed relevant for the interpretation and clarification of the intention and objective of the EU Biotechnology Directive, and should also be taken into account when interpreting the provisions of the EPC, due to the importance of a uniform approach.

38. In the view of the Danish Government, the interpretation laid down in the Notice corresponds with the aim of the Directive as reflected in Article 3 of the Biotechnology Directive, which provides that patentability should be directed towards new (technical) inventions, whereas biological material has to be isolated from its natural environment in order to be patentable.

5. Reflection on aim, function and consequences

39. In the view of the Danish Government, the EPC also has to be construed with regard to its aim, function and practical consequences for the European patent system as a whole.

²¹ 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) ([link Notice](#)).

40. Denmark – as for the other 27 EU-Member States – is in addition to being a Contracting State to the European Patent Office also a Member of the European Union and is thus bound by EU law. In this respect, Denmark, as an EU Member State, supported the Commission’s Notice on certain articles of the EU Biotechnology Directive.²²
41. Furthermore, Denmark voted in its capacity of representative in the Administrative Council in favor of the amendment of Rule 28.
42. Discrepancy between the EPO legal framework and the EU legal framework is not desirable for either EU Member States or companies in the European market. Should the Enlarged Board of Appeal uphold the decision of the Technical Appeal Board, the EU Member States would in an upcoming case on validation of a European patent have to decide whether to validate according to EPC or to refuse validation according to EU law. In the last instance, the EU Member States decision might have to wait for an opinion or a case brought before the European Court of Justice.
43. The Danish Government encourages the Enlarged Board of Appeal to take these considerations into account and would finally like to stress that a uniform interpretation of Article 53(b) EPC and the EU Biotechnology Directive is clearly intended by the EPC legislator and is of outmost importance, as is the question of legal certainty. It is noted that the Boards of Appeal, too, have recognized the significance of a uniform interpretation of harmonized European patent law²³.
44. In addition to the above mentioned, Denmark urges the Enlarged Board of Appeal to bear in mind the separate possibility to obtain intellectual protection within the plant-breeding sector.

²² Council conclusions on the 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
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017XG0301%2801%29>

²³ Established case law since decision G 5/83, OJ EPO 1985, 64; and G 2/06, OJ EPO 2009, 306, points 5 and 16 of the Reasons for the Decision.

45. The plant-breeders' rights system was established in 1961 with the UPOV-convention²⁴. The plant-breeders' rights system is a well-regulated and well-functioning system independent from the patent system.
46. One difference between the patent system and the plant breeders' rights system is the breeders' exemption. This exemption ensures that breeders have the necessary access to protected plant material to use for further breeding, without having to pay the license holder. The reason for the exemption is to ensure the continuous development of plants and plant varieties and hereby thus contribute to the development of sustainable and useable plant varieties.
47. Having two parallel systems upholds a balance, where respect for IP rights can coexist with the access to biological plant material for breeding.
48. Granting patents on plants obtained by an essentially biological process will shift in this important balance, which is obviously not the intention.

6. Conclusion

49. On those grounds, the Danish Government submits that the referred questions should be answered as follows:

“Question 1:

The meaning and scope of Article 53 EPC can 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.

²⁴ The International Convention for the Protection of New Varieties of Plants of December 2, 1961.

Question 2:

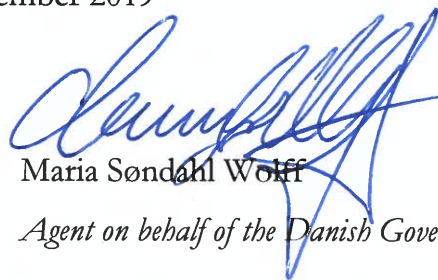
The exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC is in conformity with Article 53(b) EPC.”

Copenhagen, 30 September 2019



Jakob Nymann-Lindgren

Agent on behalf of the Danish Government



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