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**Our reference**  
Min-BuZa.2019.4331-34

Date 26 September 2019  
Re Amicus curiae brief from the Kingdom of the Netherlands in case G 3/19

Dear Mr Crasborn,

I am pleased to provide you with written observations on behalf of the Kingdom of the Netherlands regarding the referral of a point of law to the Enlarged Board of Appeal (EBoA) by the President of the European Patent Office in case G 3/19.

The Netherlands is grateful for the opportunity offered to provide its opinion on the important legal questions that have arisen in this case. While being sensitive to the political and societal attention that this case has attracted, the Netherlands wishes, in this amicus curiae brief, to concentrate on the legal issues raised by this case.

The present amicus curiae brief only addresses substantive issues related to case G 3/19 and is without prejudice to procedural issues related to this case.

### **European patent system established by the EPC**

As a preliminary remark, the Netherlands wishes to note that the interpretation of article 53 (b) of the European Patent Convention (EPC), which is at the heart of the legal questions raised in this referral, should not be seen in isolation, but must be judged in the context of the patent system of the European countries concerned, consisting of different sources of law: the law of the European Patent Organisation, EU law and national patent law. These laws form a comprehensive system that can only be properly understood when all elements are viewed in conjunction with one another.

In accordance with article 164 (2) EPC, the Implementing Regulations form an integral part of the EPC. As laid down in article 33 of the EPC and confirmed in the case law of the Boards of Appeal and Enlarged Board of Appeal, the function of the Implementing Regulations is to determine in more detail how the provisions of the EPC should be applied. This function is not limited to matters of procedure, but also covers matters of substance (e.g. case G2/07; point 2.2 of the Reasons for the Decision, p. 29). Thus, Rule 26, paragraph 1 of the Implementing Regulations explicitly provides that '*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*' (emphasis added). In accordance with article 33, paragraph 1 (c) of the EPC, the Administrative Council, operating within its legislative competence, may amend

the Implementing Regulations. Under the EPC, the Administrative Council's law-making powers by means of the Implementing Regulations are limited by article 164 (2) EPC, which provides that, in case of a conflict between the provisions of the Convention and those of the Implementing Regulations, the provisions of the Convention prevail.

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The European patent system as established under the EPC acknowledges the importance of EU legislation for the interpretation and application of European law for the grant of patents. Thus, Rule 26, paragraph 1 of the Implementing Regulations explicitly requires that 'Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions *shall be used as a supplementary means of interpretation*' (emphasis added). Likewise, the EPC anticipates that future EU legislation may require amendment of certain provisions of the EPC and provides for a mechanism under article 33, paragraph 1 (b) for the Administrative Council to bring the provisions concerned *'into line with ... European Community legislation relating to patents'* (emphasis added).

In order to harmonise or reconcile potential inconsistencies between the European patent system under the EPC and obligations ensuing from European Union law, it is particularly pressing for those Contracting States to the EPC that are also Member States of the European Union that the European patent system as established under the EPC is able to maintain a mechanism that allows for subsequent developments in EU legislation to be taken into account in the interpretation and application of the EPC. In the absence of such a mechanism, a situation could arise where Contracting States to the EPC that are also Member States of the European Union would no longer be able to fulfil their obligations under the European Union treaties and such conflicts could threaten the coexistence of both legal orders.

### **Restrictive interpretation of article 53 EPC in cases G 2/12 and G 2/13**

In cases G 2/12 and G 2/13 of 25 March 2015 the Enlarged Board of Appeal (EBoA) concluded that it could not find a solid basis for a broad reading of the exception to patentability of 'essentially biological processes for the production of plants or animals' as contained in article 53 to encompass 'products (plants/animals and plant/animal parts) obtained by means of an essentially biological process'. In deciding on these cases, the EBoA applied Rule 26 (1) of the Implementing Regulations of the EPC, using Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions as a supplementary means of interpretation. Noting the identical wording of the exception to patentability according to article 53 (b) EPC and article 4, paragraph 1 (b) of the Biotech Directive, it could not infer a broad reading of the exception to patentability from the Directive either. Moreover, the EBoA noted that the national laws and practice of the Contracting States of the EPC were not uniform.

### **Subsequent developments following the decisions in cases G 2/12 and G 2/13**

The decisions of the EBoA in these cases aroused great concern among the EU Member States, the EU institutions (Council of the European Union, European Commission and European Parliament) and society at large. In the context of the EU, the decisions have been discussed on various occasions, including at several meetings of the EU Council, the symposium organised by the Netherlands during its EU Council Presidency and several meetings of the European Commission in May 2016. From these meetings the consensus emerged that a restrictive interpretation of the exception to patentability of 'essentially biological processes

for the production of plants or animals', to the exclusion of the products (plants/animals and plant/animal parts) obtained by means of such processes, was contrary to the intentions of the EU legislator.

**Commission Notice of 8 November 2016 and adoption of Rule 28, paragraph 2 of the Implementing Regulations**

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In its Notice of 8 November 2016 (OJ C 411/3) the Commission confirmed the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means of essentially biological processes. The views expressed by the Commission as to the EU legislator's intention when adopting Directive 98/44/EC were in line with the position adopted in the European Parliament in 2015 and were endorsed by the EU Council in February 2017.

As the Commission Notice makes clear, it was never an issue during the legislative process for the Biotech Directive that the products of essentially biological processes should not be patentable. Although the wording was amended throughout the legislative process, the rationale remained unchanged.

A restrictive interpretation of the provision would also eliminate its useful effect; it would make no sense to exclude certain processes from patentability, but not their resulting products. It would render the exclusion meaningless.

This has always been the position of the Dutch legislator. The Dutch Patent Act expressly excludes essentially biological processes and the products thereof from patentability.<sup>1</sup> When the Biotech Directive was implemented in Dutch patent law in 2004, this seemed the only appropriate way of implementing article 4, paragraph 1 (d) of the Biotech Directive, as that provision would be meaningless if it only excluded the process from patentability, and not the resulting product. The Dutch legislator considered it useful to explicitly state this in the text of the law. It is also the firm conviction of the Dutch legislator that this interpretation follows from the exact wording of article 4 of the Biotech Directive. This can also be inferred from the explanatory memorandum on the law approving the accession of the Kingdom of the Netherlands to the EPC from 1975, which states: '*No patent may be granted for plant and animal varieties as well as essentially biological processes for the production of plants and animals; therefore the products of these processes too will, in fact, not be patentable.*'<sup>2</sup>

The views set out in the Commission Notice were endorsed by the Contracting States of the EPC, including the 10 Contracting States of the EPC which are not members of the EU, when the Administrative Council voted in favour of the introduction of Rule 28, paragraph 2 of the Implementing Regulations of the EPC in June 2017.

Rule 28, paragraph 2 provides: '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.' By adopting this rule, the Administrative Council of the EPC acted in accordance with its competence under article 33, paragraph 1 (c) EPC to amend the Implementing Regulations of the EPC. As recognised in the case law of the Boards of Appeal (BoAs), the Administrative Council, as the legislator of the Organisation, may amend the Implementing Regulations in respect of matters

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<sup>1</sup> Section 3, subsection of the Dutch Patent Act 1995.

<sup>2</sup> Parliamentary Papers, House of Representatives, 1975-1976, 13 899 (R1013, no. 3, p. 18).

of both procedure and substance (e.g. case G2/12; point VII.2 of the Reasons for the Decision, p. 48; case G2/07; point 2.2 of the Reasons for the Decision, p. 29). This competence includes the possibility to implement the articles of the Convention by clarifying the intentions of the legislator (Contracting States) as regards their interpretation.

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As confirmed by the case law of the BoAs (case G2/07; point 2.2 of the Reasons for the Decision, p. 29), in exercising its legislative competence in accordance with article 33, paragraph 1 (c), the Administrative Council is limited only by the hierarchy of laws laid down in article 164, paragraph 2. It follows from this provision that a Rule clarifying the meaning and scope of a provision of the Convention adopted by the Administrative Council in accordance with article 33, paragraph 1 (c) is not a priori limited by earlier case law of the BoAs or the EBoA as long as the legislator remains within the ambit of that provision (cf. case G 2/06; point 31 of the Reasons for the Decision, p. 11).

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#### **Relevance of developments as a subsequent agreement and subsequent practice under the general rule of interpretation of treaties**

The Netherlands submits that the publication of the Commission's Notice of 8 November 2016 and its subsequent incorporation in the framework of the EPC as an Implementing Regulation, i.e. Rule 28, paragraph 2 in June 2017, as well as the alignment of the practices of the 38 Contracting States of the EPC, including the 10 EPC Contracting States which are not members of the European Union following the adoption of Rule 28, paragraph 2, are relevant elements to be taken into account as authentic means of interpretation of article 53 (b) EPC. These elements are to be considered as a 'subsequent agreement' and 'subsequent practice' under the rules of customary international law regarding the interpretation of treaties, as codified in article 31, paragraph 3 (a) and (b) of the Vienna Convention on the Law of Treaties. This means of interpretation has also been accepted in the case law of the EBoA (e.g. case G2/12; point VII.4 of the Reasons for the Decision, p. 49: 'Rule 26(5) EPC (formerly Rule 23b(5) EPC 1973) could be regarded as such subsequent agreement and practice.').

When the EBoA took its decisions in cases G 2/12 and G 2/13 in March 2015, it could not refer to a Rule establishing the agreement of the parties to the EPC regarding the interpretation of article 53 (b) EPC. Therefore, in applying the means of interpretation provided for under international law to the material available to it, the EBoA concluded that it could not find a solid basis for a broad reading of the exception to patentability. Nor could it find other considerations which would support such a broad reading. With the adoption of Rule 28, paragraph 2 of the Implementing Regulations, the Administrative Council has since provided a Rule 'clear enough to indicate to those applying it in what way the legislator intended the Article to be interpreted by means of that Rule' (cf. case G2/07; point 5 of the Reasons for the Decision, p. 50). This Rule must be considered as an authentic expression of the intention of the EPC legislator to be taken into account as an element relevant to the interpretation of article 53 (b) EPC.

Moreover, following the Commission's Notice of 8 November 2016 and the subsequent incorporation of the views expressed therein in Rule 28, paragraph 2 of the Implementing Regulations, the 28 EPC Contracting States which are members of the EU declared their national law and practice to be in line with the interpretation of article 53 (b) EPC excluding 'products (plants/animals and plant/animal parts) obtained by means of an essentially biological process' from

patentability under that provision. The 10 EPC Contracting States which are not members of the EU have likewise indicated that, under their national law and practice, plants and animals obtained by essentially biological processes are excluded from patentability. Thus, the convergence of the national laws and practice of the EPC Contracting States confirms the existing consensus, thereby establishing the agreement between the EPC Contracting States regarding the interpretation of article 53 (b) and corroborating the clarification contained in Rule 28, paragraph 2 of the Implementing Regulations.

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In the Netherlands' view, the assessment of the interpretation to be given to the terms of article 53 (b) should not be limited by earlier decisions of the EBoA, as was done in the T 1083/18 case, as this would lead to a static interpretation of the EPC which leaves no room to respond to relevant legal developments or clarifications. It is within the competence of the EBoA to establish the authentic interpretation of a provision, which should be done by taking into account all elements relevant to the interpretation of that provision, including developments qualifying as a subsequent agreement or subsequent practice in accordance with the established rules regarding the interpretation of treaties under international law.

I would like to thank you for the opportunity to express the views of the Kingdom of the Netherlands on this important matter. I am confident that you will give due attention to our considerations.

Please be informed that a copy of this letter will be sent to the Dutch Parliament, the European Commission and the members of the Administrative Council.

Yours sincerely,



Stef Blok

Minister of Foreign Affairs of the Kingdom of the Netherlands