Gouda, 30 September 2019

Subject: written statement Plantum in respect of case G 3/19

Dear Mr. Crasborn,

Plantum, the Dutch association for companies active in breeding, production and trade of seeds, tubers, bulbs, cuttings, tissue culture and young plants appreciates the opportunity to present our opinion on the questions submitted pursuant to Article 112 (1) (b) EPC by the President of the EPO to the Enlarged Board of Appeal on 5 April 2019, which relate to the patentability of plants exclusively obtained by essentially biological processes and to decision T 1063/18 of a Technical Board of Appeal of 5 December 2018. ¹.

Plantum strongly holds that the unrestricted access to all genetic resources for further breeding and the freedom to operate in crossing and selection must be safeguarded. In plant breeding, the physical use of the genetics of already existing plants is essential. The aim of a plant breeder is always to obtain the best possible combination of genetics responding to the determined breeding goals which are – to a large extent - driven by societal needs and environmental challenges. This work requires access to the widest possible genetic variability in order maximise options for such recombination.

Rule 28 (2) EPC adopted by the Administrative Council of the EPO in 2017 and the subsequent practice of the EPO to request a disclaimer in patent claims to restrict the scope of protection to the technical invention, are of key importance in safeguarding the abovementioned principles.

Plantum would like to express it’s support for the arguments put forward by the president of the EPO as described in part B sub 2 of his referral and in addition wishes to put forward the following considerations:

Admissibility of the President’s referral under article 112 (1) (b)

We fail to understand why the Technical Board in case T 1063/18 decided not to refer questions to the Enlarged Board of Appeal in regard to the validity of Rule 28 (2) EPC but to decide on this on its own. This in combination with the fact that the Technical Board in matters regarding biotechnology acts always in the same composition leads to the unacceptable conclusion that this Technical Board would be in the position to actually prevent any question regarding the validity of Rule 28 (2) EPC ever to reach the Enlarged Board

¹ Although positions within Plantum are decided upon by the majority, and the position expresses in this Amicus Curiae has the support of the large majority of our circa 350 members, we would like to clarify that some individual companies are not in agreement to this position.

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of Appeal. This is not in the spirit of article 112 EPC that means to enable a procedure before the Enlarged Board of Appeal in order to ensure uniform application of the law or if a point of law of fundamental importance arises. Both issues are at stake here.

The situation that has arisen since decision T 1063/18 is a very uncertain and undesirable one. Based on Rule 28 (2) EPC all patent applications relating to products of essentially biological processes will have to be declined by the EPO examination division. All these rejections can and probably will be opposed, after which the Technical Board of Appeal has to decide on a case by case basis on the validity of the rejection based on this Rule. To our knowledge, in the field of biotechnology, it is always the same Technical Board of Appeal that decides on these cases and therefore it is our expectation that the Technical Board of Appeal will in all cases come to the same conclusion as in decision T 1063/18 that Rule 28 (2) EPC is to be considered invalid and cannot be the basis for a rejection of the patent application. This means that for all currently pending patents based on products of essentially biological processes, which we believe to be a number of 250, an opposition procedure which is only ‘pro forma’ will have to be started by the applicant. This will cost unnecessary time and money and what is more it undermines the reliability of the legal framework of the EPC and its Implementing Regulations.

To make it even more complicated the situation could well arise that patents on products of essentially biological processes are to be granted by the EPO after such an opposition procedure that will not be enforceable before a national court in a number of EPC member states, since these countries have brought or are about to bring their national patent legislation in line with Rule 28 (2) EPC. This will at least be the case for those EPC member states that are a member of the European Union and therefore bound to implement the European Directive on Biotechnological Inventions 98/44/EC in their national patent law in line with the Commission Notice of 8 November 2016 on certain articles of this Directive.

At this moment all proceedings have been put on halt, but as soon as the Enlarged Board would decide this case inadmissible then there seems to be no longer any justification to continue this halt. In order to avoid this scenario it is deemed necessary that the Enlarged Board of Appeal takes a binding decision regarding the validity of Rule 28 (2) EPC in order to create legal certainty.

Ad question 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?

According to Plantum, this question should be answered positively.

According to Rule 26 (1) EPC the European Directive on Biotechnological Inventions 98/44/EC has to be taken into account for the interpretation of the EPC. The clarification issued by the European Commission in its Notice of 8 November 2016, and supported by the European Council\(^2\) and the European Parliament\(^3\), has to be taken into account when correctly interpreting the Directive.

The fact that the Commission Notice was issued just in 2016 does not reduce its relevance for the interpretation of the Directive and – in consequence – of the EPC. According to article 31 (3) Vienna


\(^3\) European Parliament resolution of 19 September 2019 on the patentability of plants and essentially biological processes
Convention any subsequent agreement between the parties regarding the interpretation of the treaty or its application, and any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation has to be taken into account. Rule 28 (2) must be seen as such a subsequent agreement and practice.

These circumstances lead to new factual findings which require a new legal analysis. Therefore earlier Boards of Appeal or the Enlarged Board of Appeal cannot preclude a clarification of Article 53 (b) EPC via the Implementing Regulation by the Administrative Council.

**Ad question 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?*

This question should as well be answered positively as we are convinced that Article 53 (b) EPC implicitly excludes plants and animals obtained by means of an essentially biological process. Rule 28 (2) EPC has now made this extension explicit.

We recognise that the Enlarged Board of Appeal in its decision of 25 March 2015 (G2/13) concludes on the basis of the absence of any indication for a broad reading of article 53 (b) EPC, that this article cannot be interpreted to the extent that the exclusion includes also the products resulting from essentially biological processes. At the same time also no indication was found by the Enlarged Board that necessitates a narrow reading. On the contrary, we are convinced that art. 53 (b) EPC, likewise to art. 4 (1) (b) of Directive 98/44/EC, was never written with the intention to facilitate the patenting of products of essentially biological processes such as natural crossing and selection. Only with the arrival of genetic engineering, the concept of patenting plant material, more specifically plant traits (created by technical processes) became an ambition.

In the Dutch explanatory memorandum regarding the approval of the European Patent Convention⁴ there is a clear explanation stating that the exclusion on essentially biological processes extends to the products of such processes. As the Netherlands has always been one of the countries in Europe with a well-developed plant breeding industry, and was involved in the writing of the Strasbourg Convention of 1963 as one of the six countries of the original EEC, it is typical that our legislators have drawn this conclusion directly after having been involved in the process of finalising the text of the European Patent Convention.

The Dutch text of the explanatory memorandum reads:

"Artikel 53. Terwijl het tweede lid van het vorige artikel materie noemt die niet als uitvinding mag gelden, omschrijft artikel 53 materie, die wel uitvinding kan zijn doch waarop nochtans nimmer octrooi mag worden verleend. Het betreft in de eerste plaats uitvindingen, waarvan openbaarmaking in strijd met de openbare orde of de goede zeden zou komen; in dit verband verdient Regel 34 de aandacht, bepalende dat onder meer materie, die in strijd met de openbare orde of de goede zeden komt, bij de publicatie van een octrooiaanvraag wordt weggelaten. Verder kan geen octrooi worden verkregen voor planten- en dierenrassen alsmede voor wezenlijk biologische werkwijzen voorde voortbrenging van planten en dieren; in feite zullen derhalve ook de

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⁴ Tweede Kamer, zitting 1975-1976, 13 899 (R1013), nr. 3 page 18
voortbrengselen van die werkwijzen niet octrooieerbaar zijn. Van de biologische werkwijzen zijn
weer uitgezonderd de microbiologische werkwijzen en de voortbrengselen daarvan, welke dus wel
voor octrooi verlening in aanmerking komen. De bepaling is vrijwel letterlijk ontleend aan het
meergenoemde Verdrag van Straatsburg. De beperking zondert dus van octrooi verlening niet uit
chemische en farmaceutische produkten, voedingsmiddelen en werkwijzen op het gebied van land-
en tuinbouw anders dan werkwijzen als hierboven bedoeld...."

We unofficially translate this as follows:

"Article 53. While the second paragraph of the previous article mentions matter that may not be
regarded as an invention, Article 53 defines matter that may be an invention but on which
nevertheless a patent may never be granted. These are, in the first place, inventions whose
disclosure would be contrary to public order or good morals; in this context, Rule 34 deserves
attention, stipulating that, among other things, matter which comes into conflict with public order or
morality, is omitted from the publication of a patent application. Furthermore, no patent can be
obtained for plant and animal varieties as well as for essentially biological processes for the
production of plants and animals; in fact, therefore, the products of those processes will also not be
patentable. From the biological methods, the microbiological methods and the products thereof, are
again excluded, which therefore do qualify for patenting. The provision is almost literally derived
from the aforementioned Strasbourg Convention. The limitation therefore does not exclude the
granting of patents from chemical and pharmaceutical products, foodstuffs and agricultural and
horticultural methods other than those referred to above...."

(note: our subscript)

Furthermore, this explanatory memorandum raises two other aspects that we would like to reflect on. The
first is the exclusion of microbiological processes and the products thereof and the second is the exclusion in
the Strasbourg Convention, from which the exclusion in the EPC is derived.

Microbiological processes and the products thereof
The Dutch legislator points to the fact that microbiological processes and the products thereof have been
excluded from the exclusion of article 53 (b) EPC. In this respect we would like to refer to our Amicus Curiae
in case G2/12 as submitted on 3-12-2012, and in particular to the following part thereof:

"The product claim should only be allowable if the plants or plant material are truly
"obtained" by the described method, under the condition that this method is falling
outside the exclusion of "essentially biological processes for the production of
plants".

This interpretation can in our view be derived from the wording of article 53 (b) EPC:
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; this provision shall not apply to microbiological processes or the products thereof;

The last part of this article specifies that the provision shall not apply to "microbiological processes
or the products thereof". The wording used here is "or" instead of "and", which implies that there is
a need to establish that the products of microbiological processes as such do not fall under the
exclusion of essentially biological processes. If the exclusion would only apply to processes and not
extend to the products resulting from these processes, then all products would have escaped the exclusion and there would be no need to clarify that the products of microbiological processes do escape this exclusion. In other words, where the products of microbiological processes escape the exclusion of patentability, the products of essentially biological processes clearly do fall under the scope of the exclusion....”

Strasbourg Convention
The Dutch legislator in its explanatory memorandum refers to the fact that article 53 (b) EPC is almost literally derived from article 2 (b) of the Strasbourg Convention. When wanting to understand the reasons for this exclusions it therefore makes sense to look at the travaux préparatoires of both the Strasbourg Convention and the European Patent Convention. We do not have access to these documents ourselves, but have been able to learn of some aspects through an interesting article written by Mrs. Justine Pila⁵, in which she explains that both Conventions were the result of extensive work undertaken over a 22-year period by two expert committees and two diplomatic conferences. What we take from the article is how the text of the exclusion has evolved throughout several drafts:

“Nevertheless, the contracting States shall not be bound to provide for the grant of patents, in respect of new plant or animal species or of processes directly employed to obtain such species.”

“Nevertheless, the contracting States shall not be bound to provide for the grant of patents, in respect of new plant or animal species or of purely biological, horticultural or agricultural (agronomic) processes.”

Originally the species and process exclusions were connected but during the processes they were decoupled. According to J. Pila this was done, so that the latter might be more expensively cast to cover any process of relevant type, regardless of the object which it produced. Later the text was redrafted as follows:

“essentially biological processes for the production of plants or animals”

Another observation is that the reference to production of plants or animals - rather than production of plant or animal [species or] varieties - was not understood as having a substantive effect. In other words, the difference between plant varieties and plants was not recognised at that time. This supports the reasoning that the drafters perhaps did not see the need to explicitly mention the exclusion of the products of essentially biological processes, as they were in the understanding that by excluding plant varieties they had already excluded the products of such processes. Not knowing of course that the exclusion on plant varieties would later be restricted in such a way that this exclusion is only applicable to one specific plant variety⁶.

Conclusion
Looking at the legislative history we may assume that at the time of drafting the Strasbourg Convention there was not yet a clear difference between the notions of plants, plant varieties or plant species. Given the way the exclusion was drafted in the Strasbourg Convention and the European Patent Convention, it was the clear intention of the drafters to exclude the products of essentially biological processes, whether

⁶ G1/98 Novartis / Transgenic plant systems, 20 December 1999
those are plants, plant varieties or plant species, from patentability. This is supported by the wording of article 53 (b) EPC that excludes from the exclusion microbiological processes and the products thereof and by the fact that the Dutch legislator in its explanatory memorandum of the text of the European Patent Convention so clearly states that the exclusion for essentially biological processes is also applicable to the products of these processes.

Plantum is thus still convinced that article 53(b) EPC was never meant to allow for the patenting of plants and animals obtained by means of an essentially biological process and as Rule 28(2) makes this explicit, Rule 28(2) EPC is in full conformity with article 53(b) EPC.

Yours sincerely,

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Director Plantum