Dr Christoph Then
No patents on seeds!
Frohschammerstr. 14
80807 Munich
Germany
info@no-patents-on-seeds.org
Tel + 49 151 54638040

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The Chairman and the Deputy Chairman of the Administrative Council
Josef KRATOCHVÍL
Borghildur ERLINGSDÓTTIR

CC:
Members of the Board of the Administrative Council

Dear Ms Erlingsdottir and Mr Kratochvil

Further clarification is needed on the interpretation of Rule 28(2) in light of the G3/19 decision

Before the upcoming meeting of the Board of the Administrative Council on 28 May, we would like to inform you of our preliminary understanding of the current situation after the decision taken by the Enlarged Board of Appeal (G3 /19).

We very much appreciate the decision taken by the Enlarged Board of Appeal G3/19 and would like to congratulate the Administrative Council on their introduction of the new Rule 28(2) (see our media release: www.no-patents-on-seeds.org/en/node/638).

However, we are aware that some legal uncertainties and major problems remain. These arise from the vote of the Administrative Council in 2017 in reference to the G3/19, G1/08 and G2/07 decisions. The problems primarily concern the definition of what is regarded to be ‘essentially biological’. The definition of this term is crucial for all further decision-making regarding Article 53 (b) in connection with Rule 28(2).

The problem: According to the decisions of the Enlarged Board of Appeal (G2/07 and G1/08), a distinction has to be made between the profoundly different areas of ‘essentially biological’ processes (conventional breeding) and techniques used for genetic engineering. However, in the document drawn up by the former President of the EPO, which was used as preparatory document for the adoption of Rule 28 (2), no such differentiation is made. On the contrary, spontaneous mutations and random processes (non-targeted induced mutations) on the one hand, and targeted technical processes on the other hand, are interlinked with each other.

This blurring of technical differences and legal boundaries negatively impacts the intended effects of Rule 28(2) and allows the prohibitions in Art 53(b) to be easily, but unlawfully, avoided. In order to aid understanding of the legal problem, please find attached a short, condensed analysis. In addition, we attach a list of patents granted and issued on plants after the adoption of Rule 28(2). These patents on plants, which are derived from random processes, show how Rule 28 (2) is currently interpreted by the EPO. Furthermore, to exemplify the problem, *No Patents on Seeds!* recently published a report setting out possible scenarios in regard to pending patent applications in the context of current practice (www.no-patents-on-seeds.org/en/node/628).

In view of this analysis, we suggest the Contracting States of the EPO adopt a text as soon as possible which then will be binding for the correct interpretation of Rule 28(2), taking the G3/19 decision into consideration. Respective provisions should also be integrated into national laws. We propose the following wording:

“In light of the G3/19, G2/07 and G1/08 decisions, the Administrative Council adopts the following text which shall be used for the interpretation of Rule (28) and be integrated into the Implementing Regulations and the Guidelines for Examination:

- Spontaneous, random, non-targeted processes, such as physico-chemical mutagenesis, cannot escape Rule 28(2) and the prohibition in Article 53(b). Only targeted interventions, such as transgenesis and usage of targeted biotechnological mutagens, may give rise to patentable inventions.
- All products used in, or obtained by, ‘essentially biological processes’ are captured by Rule 28(2), including all breeding material, plant and animal parts, cells and genetic information.
- Patents on inventions derived from technical processes do not extend to plants, animals or other products that fall under Rule 28(2)."

Furthermore, we ask the Administrative Council to consider whether the G3/19 decision is in accordance with the general rules and provisions in patent law, especially in regard to its second part. The decision seems to exempt patents granted before July 2017 from the provisions of Rule 28(2). Our legal understanding is that EPO decisions on pending applications and oppositions are made in accordance with the current patent regulations; a transitional period should not be introduced. Otherwise, there will even be patents on plants and animals to be granted in the future, and pending oppositions and appeals will be decided without taking Rule 28(2) into account. Furthermore, provisions similar to those in Rule 28(2) have already been integrated into national patent laws in previous years. Consequently, new legal uncertainty might be created by this transitional period, as suggested in the G3/19 decision.

Finally, in the G3/19 decision, the Enlarged Board, under XXVI.1 and XXVI.2, refers to a list of documents which are relevant for the interpretation of Rule 28(2). We ask you to provide public access to these documents, which, as far as we know, have already been made available to industry representatives of BusinessEurope.

We also demand that *No Patents on Seeds!* is invited as an observer to the upcoming meetings of the Administrative Council - since BusinessEurope is already allowed to participate.

Please see attached our short legal analysis of G2/07 and G1/08 against the backdrop of the G3/19 decision, which shows why further clarification is urgently needed. Please let us know if you have any questions or comments. We would also very much appreciate an opportunity to explain our concerns in a meeting.

With kind regards



Dr Christoph Then for the coalition of *No Patents on Seeds!*
Tel + 49 (0) 151 54638040
info@no-patents-on-seeds.org

Annex 1:
Condensed legal analysis showing the need for further clarifications in light of the G3/19 decision.

Annex 2:
Examples of patents granted on plants derived from random mutagenesis after Rule 28(2) was adopted by the Administrative Council in June 2017

Annex 1:

Condensed legal analysis showing the need for further clarifications in light of the G3/19 decision.

Decision G3 /19 of the Enlarged Board of Appeal (EBoA) is intended to end the debate on whether products derived from 'essentially biological processes of breeding' are patentable or not. It states that "*the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC has a negative effect on the allowability of product claims and product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process."* (emphasis added)

A) Definition of essentially biological processes

In its decision, the EBoA refers to the definition of essentially biological processes given in earlier decisions (G2/07 and G1/08). The headnotes of these previous decisions read:

"*1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being 'essentially biological' within the meaning of Article 53(b) EPC.*

2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

4. In the context of examining whether such a process is excluded from patentability as being 'essentially biological' within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it." (emphasis added)

G2/07 and G1/08 decisions are not called into question by the G3/19 decision and, therefore, still have to be applied by the EPO in assessing patent applications on plant breeding. However, in regard to Rule 28 (2), there are substantial legal uncertainties which cannot simply be sorted out in future case law: the former President of the EPO, in preparing the decision of the Administrative Council in 2017, set out some explanations (paragraph 40-42) which clearly contradict the G2/07 and G1/08 decisions. Nevertheless, this text was accepted by the Administrative Council in preparation for its vote in June 2017.

The most problematic passage reads: *"Mutagenesis as such is considered to be a technical process which results in a modification of the genome of the plant or animal. This applies to "traditional"*

methods like irradiation or chemical mutagenesis, but even more so to molecular methods like Zinc Finger Nucleases, CRISPR, TALEN, ODM (oligonucleotide directed mutagenesis), etc. which require man-made molecules for targeted mutagenesis."

There is no doubt that this statement is in conflict with the G2/07 and G1/08 decisions. In order to assess whether a technical step can render the overall process eligible for patent protection, the Enlarged Board of Appeal, in its decisions G2/07 and G1/08, gives the following criteria: "*This is the case, for example, for genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process."* (emphasis added)

Accordingly, what is needed to overcome the prohibition of Article 53(b) and Rule 28(2), is a technical step within the process that directly and purposefully establishes a desired trait (defined phenotype) in the genome, and therefore has to be considered fundamentally different to methods of conventional breeding. In this regard, a clear technical distinction between 'essentially biological' processes (conventional breeding) and technical interventions (old and new methods of genetic engineering) can easily be made, as shown below:

(1) Essentially biological processes:

Conventional breeding starts from a broad range of genetic diversity, followed by further crossing and selection. If methods such as irradiation are used, this does not change the overall process in the meaning of Article 53 (b). In general, physico-chemical mutagenesis just triggers genomic changes in a non-targeted way to enhance genetic diversity in the plant material, which is needed for further steps of crossing and selection. To derive a desired trait (phenotype), for example, after irradiation, crossing and selection will always be needed to eliminate undesirable mutations (by segregation), and to introduce the desired mutations to a favorable genetic background. This genetic background typically should allow a high expression of the desired mutations in absence of genetic characteristics which negatively interfere with the biological characteristics of the intended phenotype. Therefore, to establish a desired trait after irradiation, the claims will always explicitly, or implicitly, include sexual crossing and selection processes. In conclusion, by introducing such a step, the overall process still cannot escape the prohibition in Article 53(b) and Rule 28(2). There is no doubt that, in light of the G2/07 and G1/08 decisions, such processes still have to be considered as 'essentially biological'.

(2) Technical processes:

On the other hand, technical methods of genetic engineering involve the insertion of additional DNA sequences or the usage of biotechnological mutagens, and therefore allow the direct and targeted change of specific genes in the genome. These techniques not only result in alterations of the genome, but enable direct introduction of defined biological characteristics (phenotypes), so-called 'traits', in existing varieties. To achieve its goal, genetic engineering typically uses genetic constructs consisting of promotors, start and stop codons and gene sequences optimized for the expression in the plant cells. Furthermore, genome engineering techniques can also introduce specific and targeted changes in the genome by using biotechnological mutagens, such as CRISPR/Cas. These techniques can typically overcome the steps of crossing and selection needed to establish a desired trait.

> Also in case of genetic engineering, crossing and selection might still be needed to establish the trait in specific varieties. However, this further breeding, typically, will not change the biological characteristics of the intended phenotype. Therefore, these genomic techniques can be considered as fulfilling the criteria established in the G2/07 and G1/08 decisions, while processes using steps like irradiation cannot escape the prohibitions in Art 53(b) and Rule 28(2).

To summarise, in view of the G2/07 and G1/08 decisions, the submission of the President is incorrect, because it mixes spontaneous mutations and physico-chemical methods on the one hand with more targeted techniques, such as Zinc Finger Nucleases, CRISPR, TALEN, ODM, on the other hand. Based on the G3/19 decision, this needs to be corrected to make sure that Rule 28(2) will be interpreted correctly in future. Therefore, further clarification is needed by the Administrative Council. We propose the necessary clarification to be decided by the Administrative Council in June 2020.

B) Patentability of cells

Further clarification is also needed for paragraph 51 of the submission by the former President which reads: *"In vitro plant and animal cells are regarded as patentable microbiological inventions"*.

Consequently, plant and animal cells cultured in vitro, which are used in or emanating from 'essentially biological processes', would remain patentable. There is not any justification for introducing such a specific exemption, which may render the effects of Rule 28(2) ineffective in many cases.

C) Scope of patents

The granting of European patents has to be restricted in a way that avoids any overlap between what can be patented and what is excluded from patentability under Article 53(b) of the European Patent Convention (and Article 4 of the European Patent Directive). The scope of patents granted on plants (or animals) derived from technical processes may encompass plants (or animals) sharing the same characteristics obtained by "essentially biological processes". Even though these are not deemed patentable, they still may fall under the scope of a patent.

We are aware of the possibility of the introduction of a disclaimer into the patent claims which might help in some cases. However, doubts remain if this will be the best solution for all future cases. Therefore, we request the Administrative Council to think about other solutions, considering the general difference between claims on the processes and claims on the products. In the context of Article 53(b) absolute product protection is highly problematic: If 'absolute product protection' is provided for plants and animals produced by methods of genetic engineering, then the scope of these patents can also cover plants and animals derived from "essentially biological processes" with the same or similar characteristics. Therefore, to make the exclusion in Article 53(b) effective, the scope of patents should be restricted to the technical process used to produce plants or animals. For further explanations see the report of *No Patents on Seeds!* (2018), https://www.no-patents-on-seeds.org/sites/default/files/2018-06/Report_No%20patents%20on%20broccoli,%20barley%20and%20beer_2018.pdf

Annex 2:

Examples of patents granted on plants derived from random mutagenensis after Rule 28(2) was adopted by the Administrative Council in June 2017

Patent number and Company *	Content	Date: grant intended announced	Date: grant of patent published
EP2547766 BASF	Herbicide resistance in Brassica	27.07.2017	27.12.2017
EP 2455475 Enza Zaden	Melon plants with disease resistance	23.10.2017	03.01.2018
EP 2966992 Rijk Zwaan	Lettuce with germination at higher temperature (opposed by NPoS)	22.12.2017	06.06.2018
EP 2882280 Green4health B.V.	Ripening-impaired mutant tomato	29.01.2018	18.07.2018
EP 2931902 SESVanderHave N.V.	Herbicide resistant sugar beets	23.03.2018	01.08.2018
EP 3016506 INRA	Mutation in the FIDG gene	16.04.2018	12.09.2018
EP 2992756 House Foods Group	Onion with reduced pungency	19.04.2018	26.09.2018
EP 2681234 Enza Zaden, Keygene	Powdery mildew resistance melon	25.04.2018	03.10.2018
EP 2681233 Enza Zaden, Keygene	Powdery mildew resistance cucumis	15.05.2018	24.10.2018
EP 2475243 Rijk Zwaan	Tomato with improved shelf life	30.05.2018	07.11.2018
EP 2700721 Cibus	Herbicide resistant plants	26.07.2018	02.01.2019
EP 2484200 Rijk Zwaan	Lettuce with tolerance to disorders	21.09.2018	13.03.2019

*** It appears that the EPO followed a policy of prioritsing the granting of patents to Dutch companies in this period of time. Possibly, the EPO adopted this policy to raise awareness that not only big international companies are interested in being granted of such patents. However, in same period of time, most patent applications in conventional plant breeding were filed by BAYER (Monsanto/ Seminis) see: www.no-patents-on-seeds.org/en/node/628.**