no patents on seeds

80807 München, Germany
info@no-patents-on-seeds.org
Tel + 49 151 54638040

29 May 2017

To the
President of the Administrative Council of the European Patent Office (EPO), Mr Jesper Kongstad,
Deputy Chairman of the Administrative Council, Mr Josef Kratochvil
Chair of the Committee on Patent Law of the EPO, Mr Sean Dennehey

Dear Mr Kongstad, Mr Kratochvil, and Mr Dennehey

Re: The need for further discussions and amendments before a vote is taken by the Administrative Council at the end of June 2017

We are writing to let you know that we are pleased with the initial results from the meeting of the Committee on Patent Law Committee at end of April. However, we do not believe that the proposal that has been presented is adequate for completely solving the problems involved. In our judgement, the following changes to the Implementing Regulations are key to ending the patenting of conventionally bred plants:

1. Definition of essentially biological processes

- Implementing Regulations must clarify that "essentially biologically processes" covers all conventional breeding processes, including exploitation of random mutations and all steps used in the process, such as selection and / or propagation.

Essentially biological processes are not limited to processes that exclusively consist of "crossing and selection", as suggested by current proposal. The selection and usage of genetic variants and random mutations, as well as processes for propagation, such as selfing, are all widely used in conventional breeding and cannot be regarded as methods of genetic engineering. Essentially, the proposal is not in accordance with the interpretation of patent law presented by the European Commission in November 2016. The EC interpretation stated that only methods of genetic engineering which directly intervene in the genome of plants and animals can be regarded as patentable. It is further not consistent with the European Parliament resolutions from 2012 and 2015, which called on the EPO "also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding."

The following point illustrates the importance of a comprehensive definition of "essentially biological processes": Random mutations, which according to the current proposal would still be patentable, accounted for 65% of all patents granted on conventionally bred plants and animals in 2016. Without a comprehensive definition of "essentially biological processes", the changes to the Implementing Regulations will fail to prevent future patents on conventionally bred plants and animals.

The patents granted to Carlsberg and Heineken (EP2384110, EP2373154 and EP2575433)

exemplify some of the relevant loopholes in your proposal. These patents are based on random mutations which supposedly improve the quality of barley. Obviously, the processes used to create the barley cannot be regarded as methods of genetic engineering in the sense of EU Directive 98/44. On the contrary, these methods have long been known to breeders, farmers and gardeners.

2. Definition of products

- Implementing Regulations must clarify that all "products" used in, or emanating from, essentially biological processes are captured by the exclusion, including all plant/animal parts and genetic information.

For the proposed exclusion to be effective, it must apply to plants and animals in *all* their forms and parts used in, or derived from, conventional breeding. The Commission's Notice clearly states that the exclusion from patentability applies to all "plants or plant materials (fruit, seeds, etc.) or animals/animal material". "Material" also includes genetic information. There is a growing trend in current patent applications to claim genetic information in the form of specific variants or random mutations. These applications attempt to avoid the provisions in Article 53 (b) of the Directive by referring to Article 3(2), which states that "biological material which is isolated from its natural environment" might be regarded as an invention. However, the Commission has now confirmed that this Article cannot be understood as a means of circumventing Article 53(b). This must now also be made clear in the Implementing Regulations of the EPC. Otherwise, it will still be possible to grant a patent on genetic information which extends to any use of that information, including in conventional breeding, and to any plants and animals containing the information.

3. Limiting the scope of protection

- Implementing Regulations must prevent any "absolute product protection" on plants which enables a patent on a plant or animal derived from a technical process to extend to all conventionally bred plants with the same traits

Restrictions on the scope of patents that may still be granted on inventions concerning plants or animals (such as patents on genetically modified plants) are necessary to prevent such patents from extending to conventionally bred plants and animals containing the same traits or breeding characteristics. This risk of this "overlap" is increasing especially in view of rapidly emerging methods of genome editing. A clarification on this issue is therefore essential to "future proof" the Implementing Regulations. For example, the patents granted to Carlsberg and Heineken are not restricted to specific processes, but provide absolute product protection for all plants with the characteristics as described in the patent. Clearly claims such as these raise some very general issues: If, for example, absolute product protection is extended to genetically engineered plants, the claims will cover all plants with the characteristics as described, even if these plants stem from native traits or are derived from essentially biological processes.

We were informed that a so-called 'disclaimer solution' is being discussed which would include a requirement to add disclaimers to each patent granted on plants or animals. We doubt this will bring about the necessary legal certainty and, therefore, see the need for further discussion on this issue. Our proposal is instead that patents on plants and animals should be restricted to process claims. Such a limitation would provide legal clarity and certainty for conventional breeders, comparable and complementary to the breeders' exemption established in the plant variety protection system: As long conventional breeders are not using methods of genetic engineering, gene editing, methods that enable a targeted introduction of a trait into plants or animals, or material derived thereof, they do not have to worry about the patent system and have sufficient freedom to carry on with their

breeding activities. Limiting the scope of product protection as stated in Article 53(b) is also in accordance with the European Parliament resolution of 17 December 2015 on patents and plant breeders' rights, which calls for the introduction of a full breeders' exemption into patent law. Further, it is in accordance with the decision of the Court of Justice of the EU C-428/08 on Monsanto, as well as national patent legislation on nucleic acid-related inventions in Germany, France, Luxembourg, Italy and Poland.[1] In order to ensure that the prohibitions in Article 53 (b) are not undermined, we conclude that inventions concerning plants and animals should not be afforded absolute product protection. Rather, only process claims should be granted to restrict the scope of the patent to the technical processes as described in the patent.

In conclusion, we believe the aims in our proposal to be indisputable: Bearing in mind the position of the EU institutions, it is apparent that legally binding rules for the interpretation of Article 53 (b) need to be established; these rules must exclude all methods and materials used in conventional breeding or produced by conventional breeding. We will only have sufficient legal certainty and clarity if this is achieved.

We would very much appreciate receiving your response to our comments, and would ask you to forward our proposal to the Members of the Administrative Council. Furthermore, we would be grateful for the opportunity to discuss our views directly with the representatives of the Administrative Council, and would once more like to ask for a meeting before any decision is taken. As yet, we have not received a response to our previous request for a meeting, which we sent at the end of February. This is particularly disappointing given the relevance of this debate to the interests of the broader public and the environmental concerns represented by the coalition "*No Patents on Seeds*".

In order to continue playing a constructive role in the future, we would herewith like to make a formal request to be a permitted observer in the meeting of the Administrative Council at end of June. We further request that we receive the relevant documents for this meeting. We are aware that other stakeholders (epi, Business Europe) will be present at the meeting, and that they will receive all relevant documents. Therefore, we do not believe that this can be denied to a civil society organisation.

We look forward to receiving your reply.

Yours sincerely

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

Attachment:
Updated technical briefing: How should the exclusions in Article 53(b) be interpreted to make them effective?

[1] See report of the Expert Group on "The development and implications of patent law in the field of biotechnology and genetic engineering", published by the EU Commission (E02973), http://ec.europa.eu/DocsRoom/documents/18604/attachments/1/translations/