



To the Enlarged Board of Appeal

Amicus Curiae letter regarding G3/19

(1) Introductory remark

In March 2019, the President of the EPO forwarded two questions to the Enlarged Board of Appeal on the patentability of plants and animals derived from ‘essentially biological processes’. These questions arose from a decision taken by the Technical Board of Appeal in December 2018. In the decision (T1063/18) it is stated that while ‘essentially biological processes’ for the production of plants and animals are non-patentable, this prohibition would not apply to plants and animals derived from these processes. In its decision, the Technical Board referred to decisions taken by the Enlarged Board of Appeal in 2015 known as the ‘broccoli and tomato’ decisions II (G2/12 and G2/13).

In this decision, the Technical Board declared the new Rule 28 (2) of the Implementing Regulations of the European Patent Convention (EPC) to be non-binding for further EPO decision-making. Rule 28 (2) declares patents on plants and animals to be prohibited. The Rule was introduced by a decision of the Administrative Council in 2017. The decision was supported by all 38 contracting states (with Austria asking for even stricter rules) and backed by EU institutions, including the EU Parliament, the EU Members States and the EU Commission.

Now, in essence, the President of the EPO is asking whether the Administrative Council had the power to take the decision on the interpretation of the EPC. Secondly, the President is asking whether the Administrative Council and Rule 28 (2) decision are in accordance with the EPC.

(2) The Position of *No Patents on Seeds!*

No Patents on Seeds! has concluded that both questions should be answered with ‘Yes’. Based on the EPC and the EU Directive 98/44/EC, which became part of the Implementing Regulations 20 years ago, patents on breeding of plants and animals can only be granted if methods of genetic engineering are applied. All other processes for breeding as well as resulting plants and animals are excluded from patentability.

At the same time, *No Patents on Seeds!* is aware of larger loopholes in regard to the decision taken by the Administrative Council. These loopholes should be closed as soon as possible to bring the EPC fully in line with the intention of the legislator to exclude conventional breeding from patentability. However, the necessity for further decision-making by the Administrative Council, does not call the legitimacy of the Council into question. On the contrary, as the text of the EPC shows, the Administrative Council has the power to take decisions concerning Rule 28 (2) and to provide clarification on the interpretation of Article 53 (b).

The EPC defines the role of the Council and therefore it has the responsibility to act as a political control on behalf of the democratically legitimated institutions of the contracting states of the EPO. There is no doubt that the Enlarged Board of Appeal and the Technical Board of Appeal as well as the examination and opposition division are bound by the decision of the Council in future decision-making. If the role of the Council is weakened, the EPO will lose public credibility and might be called into question more generally in its role as an international institution.

Therefore, the democratically legitimized control on the correct interpretation of European patent law should not be undermined by EPO decision-making. In this case, the power of the Administrative Council, based on the support from all 38 Contracting States, cannot be overruled by decisions of a technical body of the EPO. As shown below, there is no contradiction between Rule 28 (2) and Article 53 (b). Therefore, the Boards of Appeal of the EPO are bound by this change in the Implementing Regulations of the EPC.

In the following section, we provide explanations and evidence showing that Rule 28 (2) is indeed not in contradiction with the EPC but just requires further adjustment by the Administrative Council to provide sufficient legal certainty and clarity.

(3) Technical background: How to delineate biological processes from genetic engineering in the context of patent law

Conventional breeding can be understood as non-technical traditional methods of producing plants and animals based on crossing and selection, without using technologies to bypass natural biological mechanisms governing gene regulation, reproduction and inheritance. Based on this understanding of conventional breeding as ‘essentially biological’, there are some fundamental differences in comparison to genetic engineering that are highly relevant for the interpretation of Article 53 (b) EPC:

Essentially, conventional breeding is always based on a wide range of genetic and biological diversity found in natural populations, as well as in previously bred plant and animal varieties and breeds. In addition, new mutations happen continually and can, for example, be triggered in plants by exposure to sunlight. Not all of these mutations are beneficial. Crossing and selection are, therefore, crucial to breeding plants with desirable traits with optimal combinations of genetic information.

Other additional techniques can be used to increase genetic diversity, e.g. by exposing the seeds to specific chemicals to increase the natural rate of mutation. This process is known as mutagenesis, which, in a first step, enhances genetic diversity through known biological mechanisms. So-called ‘random’ mutagenesis does not escape the biological mechanisms as evolved over billions of years. The plants and their cells just react to unspecific stress factors and the desired traits are established in the following steps of crossing and selection. Thus, breeding through mutagenesis can generate greater genetic diversity, but the desired traits are not brought about by direct technical intervention.

In consequence, plants and animals produced by methods of conventional breeding are the result of cross breeding and selection of particular plants or animals that are chosen from a whole range of biodiversity, no matter if ‘random’ mutagenesis was used or not. This process is always time-consuming and requires careful choice by breeders.

This process of conventional mutagenesis has been used in plant breeding for many decades and is still widely applied. Experts estimate that there are already thousands of varieties grown based on random mutation. Until now, all these varieties could be used freely to produce the next generations of plants and varieties. However, patents can severely hamper or block access to these plants for other breeders. In many varieties, patents might well accumulate with every further step in crossing. This could seriously disadvantage small to medium size breeders, as well as damage overall innovation and diversity in plant breeding.

Genetic engineering, on the other hand, uses direct technical and targeted intervention to establish new traits. These technical interventions bypass natural biological mechanisms governed by evolution, inheritance and gene regulation, and are much faster than conventional breeding. For example, additional gene sequences can be directly inserted into the genome. Other applications enable the direct deletion of all copies of a gene by nucleases like CRISPR/Cas. Genetic engineering intervenes directly in the genome, and therefore the resulting plants and animals can be very different to those from conventional breeding. This is a fundamental difference between genetic engineering and ‘essentially biological processes’ for breeding.

In the context of the EPC, methods used in conventional mutagenesis can be clearly distinguished from technology used in genetic engineering: genetic engineering can be used to directly establish new traits in plants. Mutagenesis, on the other hand, is a first step in the selection and crossing process that simply increases genetic diversity. As is the case with all conventional breeding processes, crossing and selection play an essential and central part in the subsequent choice of the desired traits.

According to the decisions of the Enlarged Board of Appeal G2/07 and G1/08, the application of simple technical tools, does not turn an ‘essentially biological process’ into a technical, patentable invention:

„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.”

Only a technical intervention which directly introduces a new trait would be eligible for patent protection:

„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.”

This reasoning is also in accordance with the current Guidelines for Examination (part G, Chapter II, point 5.4):

"Thus transgenic plants and technically induced mutants are patentable, while the products of conventional breeding are not."

"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, are patentable."

Moreover, the EU Commission in its Notice¹ on corresponding articles in Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions of 6 November 2016 follows the same reasoning:

“The trigger point for ensuring the patentability of either a plant or an animal is the technical process, such as for instance the insertion of a gene into a genome. Essentially biological processes are not of a technical nature and therefore, according to the position taken by the legislator, they cannot be covered by a patent.”

Indeed, EU Directive 98/44/EC, in recitals 1, 2, 52 and 53, as well as in Article 16, explicitly refers to the term ‘genetic engineering’. In addition, recitals 9 and 10 refer to ‘biotechnology’. This wording – as well as the negotiating history of the Directive – clearly shows that patents should only be granted on modern biotechnology and genetic engineering processes and products, and should not be extended to conventional breeding by any backdoor decision making.

(4) Rule 28 (2) is not in contradiction with Article 53 (b) EPC

According to the Notice of the EU Commission, products derived from ‘essentially biological processes’ are not patentable:

“the Commission takes 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.”

1 [http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478769496064&uri=CELEX:52016XC1108\(01\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478769496064&uri=CELEX:52016XC1108(01))

This interpretation of current patent law in regard to the prohibition of patents on plants and animals derived from conventional breeding was also adopted by all the governments of the EU member states in a decision taken in February 2017.² Corresponding prohibitions are also part of national legislation in several of the contracting states of the EPO such as Germany, the Netherlands, France, Austria and Portugal. Finally, in June 2017, the Administrative Council of the EPO, made a decision on amending the Implementing Regulations of the EPC with the new Rule 28 (2).

Further, according to the text of the resolution from 2012, the EU Parliament

*“Calls 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;(…)”*³

However, in December 2018, the Technical Board of Appeal of the EPO came to the conclusion that Rule 28 (2) is in conflict with the EPC and could therefore not be applied in subsequent decision making. In this decision, the Technical Board of Appeal overlooked the fact that even without the new Rule 28 (2), the prohibitions set out in Article 53 (b) are binding for plants and animals derived from ‘essentially biological processes’. There are several reasons for this, one of which is the legal logic of the patent system: if the patentability of processes alone is prohibited, but patents on plants and animals are allowed, then prohibitions on the patenting of processes would be ineffective. This point of view is expressed in another decision of the Technical Board of Appeal of the EPO. In its decision T1242/06⁴ from 31 of May 2012 it states:

„The board still has to address the further argument that, (...) it would be wrong to the claimed subject-matter to be patented, since this would render the exclusion of essentially biological processes for the production of plants completely ineffective, thereby frustrating the legislative purpose behind the process exclusion in Article 53(b) EPC. (Nr. 40)

Disregarding the process exclusion in the examination of product claims altogether would have the general consequence that for many plant breeding inventions patent applicants and proprietors could easily overcome the process exclusion of Article 53(b) EPC by relying on product claims providing a broad protection which encompasses that which would have been provided by an excluded process claim (...). (Nr. 47)“

Especially relevant in this context is the systematic legal interpretation of the prohibition of patents on ‘essentially biological processes’: Article 53 (b) EPC for the most part excludes 'essentially biological processes' for the production of plants and animals from patentability. However, an exception set out in the second sentence of Article 53 (b) EPC states that “microbiological processes or the products thereof” are patentable.

The EPC accepts thereby that a process for breeding plants or animals should be excluded from patentability. A patent covering a process provides the patent holder with protection for process. Furthermore, a patented process covers all products manufactured with the process. Conversely, a patent covering a product only affords the patent holder protection for the product.

From this it follows that if Article 53 (b) EPC excludes a process for the breeding of plants and animals from patentability, then this encompasses product protection for products manufactured with this process. To then grant a patent on a product which was derived from the process and which is excluded from patentability according Article 53 (b) EPC, undermines the intention of the legislator and provides protection for something that would have been already within the scope of the (excluded) patent on the process, which, according to Article 53 (b) EPC, cannot be granted.

2 <https://www.consilium.europa.eu/en/meetings/compet/2017/02/20/>

3 www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0202+0+DOC+XML+V0//EN

4 <https://www.epo.org/law-practice/case-law-appeals/pdf/t061242ex2.pdf>

The legislator was aware of this and framed the following legal provisions accordingly: the exception explicitly allows that, on the one hand, microbiological processes themselves, and, on the other hand, the products obtained with the help of these processes are patentable. If the legislator had been of the opinion that the products were invariably not encompassed by Article 53 (b), then it would not have been necessary to add the products in Sentence 2 of Article 53 (b). However, this precise exception shows that, according to the intention of the legislator, the (wider) process claim, as opposed to simply the product claim, encompasses the product that has been (excluded from patentability) manufactured using the process.

Therefore, a claim on plants and animals directed at a plant or animal derived from ‘essentially biological processes’, cannot be granted due to the already effective prohibition in Article 53 (b) EPC. This would in effect mean placing something under protection that was already contained in the prohibited process claim set out in Article 53 (b) EPC - and if this product was clearly within the scope of the (excluded) process claim, it cannot be re-protected by a patent granted solely on the product.

It is widely known that the Enlarged Board of Appeal came to other conclusions in its decisions G2/12 and G2/13. However, there is a legal error in the systematic interpretation of patent law: the Enlarged Board of Appeal solely and separately dealt with the ‘systematic interpretation’ (G2/12 grounds for decision VII No. 2) of Sentence 1 in Article 53 (b) EPC thereby taking Article 53 (a) and 53 (c) EPC into account. However, the Enlarged Board ignored the direct context of Sentence 2 in Article 53 (b) EPC and does not answer the question of how this sentence is to be interpreted within the legal context as an exception to Sentence 1, Article 53 (b), EPC. It should also be noted that Article 53 (c) EPC was only adopted after Article 52 (4) EPC 1973 was adopted in Article 53 in which exceptions were defined as ‘non-commercial’ and therefore only to a limited extent useful for systematic interpretation.

Thus, if Sentence 2 of Article 53 (b) EPC is taken into account for the interpretation of Sentence 1 in Article 53 (b), the decisions G2/12 and G2/13 are not sustainable and cannot be applied in future decisions.

(5) Conclusions

Being aware of the previous decisions of the Technical Boards (such as T1242/06) and the Enlarged Board of Appeal (G2/07 and G1/08) as well as the position of the EU and the wording of national patent laws, the current legal uncertainty emerged from the decisions G2/12 and G2/13. This uncertainty was eliminated by the new Rule 28 (2), which now has to be confirmed in the upcoming decision of G3/19.

In addition, there is a need for further clarification regarding the definition of ‘essentially biological processes’ to bring this definition in line with the intention of the legislator, and to exclude conventional breeding from patent law. This urgently warrants further prompt action on the part of the Administrative Council in regard to G3/19.

In regard to the question raised by the President of the EPO, *No Patents on Seeds!* concludes that both questions should be answered with ‘Yes’.