



COMMENTARY
JULY 2017

Clarifying or Conforming? The EPO Bows to the European Commission

IN SHORT

The Situation: In late 2016, an Interpretive Notice by the European Commission stated that products produced by essentially biological processes should not be patentable.

The Development: The European Patent Office has concurred with the Commission, deciding to formally ban the patenting of products (animals and plants) obtained exclusively from essentially biological processes.

Looking Ahead: The decision applies to European patent applications filed on or after July 1, 2017, as well as to European patent applications and European patents pending at that time.

In December, we reported that the European Commission ("Commission") had issued an Interpretive Notice (2016/C 411/03) stating products produced by essentially biological processes should not be patentable (see our [Alert](#) on the Commission view). The notice came as a surprise to many, particularly because the position expressed by the Commission was at odds with a recent ruling of the Enlarged Boards of Appeal ("EBA") of the European Patent Office ("EPO") (see our [Commentary](#) on this decision), which confirmed the established practice of the EPO to grant patents for such products. We now report that the EPO has fallen in line with the Commission and has amended the rules of the European Patent Convention ("EPC") accordingly (see [Decision of the Administrative Council of 29 June 2017](#)).

In 2015, the EBA decided on joint referrals G 2/12 and G 2/13 (Tomatoes II and Broccoli II). Essentially, the decisions turned on the argument that if the legislature had intended to prohibit the patenting of plants or plant parts obtained by essentially biological processes the legislation would have explicitly reflected this intention. Following the EBA decisions, plant technology innovators breathed a sigh of relief believing they could obtain patents to protect the fruits of their research. Their relief was short-lived however, as the Commission's notice had an immediate impact at the EPO, which responded by staying proceedings before the Examination and Opposition Divisions in all cases dealing with plants or animals obtained by essentially biological processes.

Current Situation

On June 29, 2017, the Administrative Council of the EPO decided to formally ban the patenting of animals and plants obtained exclusively from essentially biological processes. Consequently Rules 27 and 28 EPC were amended to reflect the policy. With effect from July 1, 2017, Rule 27—setting out which biotechnological inventions are patentable—has been amended as italicized:

"(b) without prejudice to Rule 28, paragraph 2, plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety";

and accordingly paragraph (2) has been added to Rule 28:

"(2) 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 using the word "exclusively" before "obtained by means of an essentially biological processes," new paragraph (2) appears to create a rather narrow exclusion to the kinds of plants and animals that are deemed patentable. An "essentially biological process" is defined in the EPC as one that consists "entirely of natural phenomena such as crossing and selection" (Rule 26(5) EPC). Specifically, the EBA ruled that it refers to processes consisting only of sexually crossing *whole* genomes of plants or animals and subsequent selection. A process is not considered *essentially* biological if it involves additional or alternative technical means that contribute to producing the plant or animal beyond a trivial level. The additional or alternative means must introduce or modify a trait in the genome of the plant or animal: it is not sufficient that it merely assists in performing the steps of sexual crossing or selection.

Thus, the word "exclusively" seems to imply that a plant or an animal that is obtained by an essentially biological process is patentable if it is also obtainable by additional or alternative technical means.

The decision of the Administrative Council amending Rules 27 and 28 of the Implementing Regulations, applies to European patent applications filed on or after July 1, 2017, as well as to European patent applications and European patents pending at that time. This raises the possibility that even granted patents, if subject to EPO opposition or limitation proceedings or national revocation proceedings will be subject to the new rules upon reevaluation. Moreover, it implies that the standing and binding case law established by the Enlarged Board in G 2/12 and G 2/13 is now in conflict with the EPC.

Despite the ambiguity created by the rule change, the stay of proceedings has now been lifted; and examination and opposition proceedings have gradually resumed as of July 1, 2017 (see [Notice from the European Patent Office dated 3 July 2017](#)).

From now on, when drafting patent applications destined for European prosecution, the description and the claims should not be limited to the essentially biological processes that produce plants or animals, but if possible should also include alternative ways of producing such plants or animals, preferably supported by examples. It may also be valuable to contemplate patenting downstream products and uses for the plants and animals.

In the case of pending applications falling under this exclusion, applicants may consider filing divisional applications directed to the downstream products derived from such plants or animals, or to technical uses of the plants or animals derived from an essentially biological process.

THREE KEY TAKEAWAYS

1. The term "exclusively" seems to create a narrow exclusion to the plants and animals that are deemed patentable.
2. The descriptions and claims of patent applications destined for European prosecution should not be limited to plants or animals produced only by essentially biological processes.
3. Consideration should also be given to patenting downstream products and uses for the plants and animals.

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