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Patentability of conventionally bred plants at the EPO – Rule change, but no end of legal uncertainty in sight

With effect of July 1, 2017, the Implementing Regulations of the EPC were changed and new Rule 28(2) EPC was introduced reading:

> (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.

The new Guidelines for Examination (valid from November 1, 2017) have been updated accordingly (see section G-II, 5.4).

According to the Administrative Council (AC) of the EPO, this amendment of law was made "in order to ensure very swiftly as much harmonisation and legal certainty as possible" (OJ EPO 2017, A54). However, whether this goal will be reached is questionable. The wording of new Rule 28(2) EPC is not in line with the Enlarged Board of Appeal (EBA)'s decisions G 2/12 (Tomatoes II) and G 2/13 (Broccoli II) of March 25, 2015. Therein, the EBA very thoroughly analyzed the relevant provisions, in particular Article 53(b) EPC and the EU Biotech Directive 98/44/ EC, and concluded that the exclusion clause of Article 53(b) EPC relating to "essentially biological processes for the production of plants" does not extend to plants obtained thereby. Thus, new Rule 28(2) EPC directly contradicts the EBA's interpretation of Article 53(b) EPC. The ensuing legal uncertainty runs counter the intentions voiced by the AC.

The situation caused by the law change is reminiscent of the tension between Article 53(b) EPC (excluding "essentially biological processes") and Rule 26(5) EPC (defining the excluded processes as "consisting entirely of natural phenomena such as crossing and selection") that led to the first Broccoli referral some ten years ago (T 83/05 of May 22, 2007 that triggered EBA decision G 2/07). In that case, the EBA resolved the conflict between Article and Rule by completely ignoring the Rule due to its "self-contradictory wording." New Rule 28(2) EPC could suffer the same fate should it once be scrutinized by the EBA.

The essential logic behind the new Rule was, according to the law makers, that Article 4 of the Biotech Directive has to be interpreted as foreseeing that its process exclusion (corresponding to that of Article 53(b) EPC) is to be extended to plants obtained thereby. Thus, the Rule change was called a mere "clarification." Whether this is a sound interpretation of Article 4, however, has to be doubted since its sub-sections (1) and (2) are very clear in that they leave no loophole for such a "clarification", i.e. excluding anything else in terms of plant-related products but plant varieties; see:

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1. The following shall not be patentable:

   (a) plant and animal varieties;

   (b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

Interestingly, the first time that this provision was interpreted as providing for an exclusion of plants obtained by essentially biological processes was done in 2013 (during pendency of the G 2/12 and G 2/13 proceedings!). Then the German legislator introduced into Section 2a of the German Patent Act the exclusion of "plants and animals exclusively obtained by such processes." This interpretation of Article 4 was later picked up by a Resolution of the European Parliament of December 2015, a Notice of the EU Commission issued on November 3, 2016 and, finally, the EPO President's opinion CA/PL 4/17 based on which the AC adopted new Rule 28(2) EPC. Given its thorough analysis of the pertinent law, in particular of Article 4 of the Biotech Directive, in G 2/12 and G 2/13, it is difficult to see how the EBA could depart therefrom and accept the "clarification" should they now be asked to again judge the patentability of conventionally produced plants. Actually, in the pending appeal case T 1957/14, the Appellant has already requested referral of questions of law to the EBA to clarify the legal situation. We have to wait and see what will happen next.

As a further point, it needs to be considered that the new Rule's exclusion of plants produced by essentially biological processes additionally creates legal uncertainty because such plants may nowadays no longer be clearly distinguishable from plants produced by new technologies of homologous recombination ("gene-editing", such as CRISPR-Cas). An Expert Group specifically established by the EU Commission to evaluate the patentability of conventionally produced plants pointed to this potential problem in their Report[1]. However, this voice remained unheard.

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[1] EU Commission: Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (http://ec.europa.eu/DocsRoom/documents/18604/attachments/1/translations/), pages 37 and 38