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EPO stay of proceedings for inventions concerning plants or animals obtained by means of essentially biological processes – Position paper

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Executive summary

The *ex officio* decision by the EPO to stay proceedings in which the decision depends entirely on the patentability of a plant or animal obtained by an essentially biological process is unjustified and has no legal basis.

Background - the EBA decision and EU Commission Notice

In Decision G2/13[1] dated 25.03.2015 the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) decided that the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC **did not prohibit** the allowability of product claims directed to plants resulting from such processes.

In a European Commission Notice published in the OJEU 8.11.2016[2], following a request from the European Parliament, the Commission also considered the question of the patentability of plants produced by essentially biological processes. The Commission Notice voices the view that the European Union (EU) legislator's intention when adopting Directive 98/44/EC (referred herein as the "Biotech Directive") was to **exclude** from patentability products such as plants that are obtained by means of essentially biological processes.

The EPO is not an EU institution, but a good example of co-operation between EU member and non-member states. The EPO is not required to implement EU laws, and is not subject to opinions of the European Commission nor decisions from Court of Justice of the EU (CJEU).

However, the intent and meaning of the Biotech Directive is relevant to the EPC because the EPO had previously decided (in 1999) to "implement" the Biotech Directive via the Implementing Regulations of the EPC[3]. Furthermore, Article 4(1)(b) of the Biotech Directive uses similar language to Article 53(b) EPC in relation to the non-patentability of *(inter alia*) essentially biological processes for the production of plants.[4] [5]

[1] http://www.epo.org/law-practice/case-law-appeals/recent/g130002ex1.html

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2016_411_R_0003&from=EN

[3] http://archive.epo.org/epo/pubs/oj99/8_99/8_5739.pdf

[4] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0044&from=EN

[5] http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html

EPO notice

In a Notice dated 24 November 2016[6] it is reported that the President of the EPO has decided that proceedings before EPO in which the decision depends entirely on the patentability of a plant or animal obtained by an essentially biological process will be stayed *ex officio.*

The Notice does not explicitly indicate when the stay will cease to apply. However a later news item on the EPO website[7] indicates that should the EPO member states follow the interpretation offered by the Commission Notice, the EPO will implement their decision.

The stay is unsatisfactory

In the present case the EBA have already concluded that Article 53(c) EPC does not exclude product claims for plants which are the direct product of essentially biological processes from patentability. It is clear from their Decision that such plants are in principle patentable subject matter under the EPC:

> "Article 52(1) EPC expresses the fundamental principle of a general entitlement to patent protection for any invention in all technical fields…
>
> …Any limitation to the general entitlement to patent protection is thus not a matter of administrative or judicial discretion, but must have a clear legal basis in the European Patent Convention"
>
> (G2/13, VII 2.(3)(b)).

In reaching this Decision, the EBA explicitly considered the effect of the Article 4(1)(b) of the Biotech Directive (G2/13, VII 4.(3)).

We note here that the Commission Notice does not point to any legal basis in the EPC for denying patent production for plants which are the direct product of essentially biological processes. Even ***if*** the Commission has correctly construed the intention of the Biotech Directive legislator, **that legislative intention does not equate to legal basis in the EPC to justify the EPO's stay.**

There is therefore no justification in the present wording of the EPC to deny such patentability.

It therefore seems that the stay is entirely predicated on a possible change in the EPC or its implementing regulations in the future.

With these points in mind:

Firstly, we do not consider that these circumstances warrant an *ex officio* stay in examination and opposition.

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[6] http://www.epo.org/law-practice/legal-texts/official-journal/information-epo/archive/20161212.html

[7] http://www.epo.org/news-issues/news/2016/20161212.html

A stay in these circumstances is not sanctioned by the EPC, implementing Regulations, or Guidelines for Examination. The EBA has already definitively answered the questions put to them[8]. The CJEU, which has jurisdiction concerning the interpretation of treaties[9], has apparently made no ruling relevant to this point. The Commission Notice concerns only their view on legislative intent, not on existing substantive law. The Commission Notice is not legally binding on the EPO or any EU institution.

In general terms, the EPO stay of proceedings under these circumstances can be seen as an executive decision which undermines a clear judiciary decision of the EBA. This is **constitutionally inappropriate**.

More specifically, users of the system having, or intending to file, patent applications relating to this particular subject matter, have had no opportunity to comment on the stay, and are clearly disadvantaged by the EPO deciding not to process such applications.

Furthermore, stays of this sort do nothing to remove uncertainty for 3rd parties, not least since the circumstances which are required to cease the stay are not clearly set down in the Notice from the EPO.

Secondly, pre-emptively, we question how an exception to patentability in this area could be implemented in the near future. Simply introducing a new exception to patentability solely via the Implementing Regulations would be contrary to Article 52(1) EPC, which would take precedence in any conflict[10]. Therefore, unless the EBA overturns its own Decision, it seems a Diplomatic Conference would be required to amend the Articles of the EPC to introduce a new exception to patentability.

Finally, even **if** the decision were to be made by EPC Member States to amend the EPC at some future date (and in this context it should be pointed out that the EPC Member States include countries outside the European Union), we suggest that until such time as that decision is made the law remains unchanged and for reasons of equity and natural justice, existing rights holders should not be adversely affected by any such future change in the law.

2 February 2017

[8] https://www.epo.org/law-practice/legal-texts/html/guidelines/e/e_vi_3.htm

[9] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E267:en:HTML

[10] http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar164.html